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4-21-83
Vol. 48 No. 78
Pages 17055-17328

# federal register

Thursday
April 21, 1983

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**Administrative Practice and Procedure**
Federal Energy Regulatory Commission
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Pension Benefit Guaranty Corporation

**Air Pollution Control**
Environmental Protection Agency

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**Marketing Agreements and Orders**
Agricultural Marketing Service

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# Presidential Documents

Title 3—

## The President

**Proclamation 5053 of April 19, 1983**

## Jewish Heritage Week, 1983

**By the President of the United States of America**

**A Proclamation**

American Jews have made significant contributions to every phase of American life. They have served this Nation by fighting for her freedom, building her industry, working for her goals, and nurturing her dreams. They have brought distinction to every field of American endeavor and have participated in the cultural development, economic growth, and spiritual progress of America.

The Jewish people remain dedicated to ancient and revered traditions which have been severely tested over the centuries. From the observance of Passover, which tells the story of the passage from bondage to freedom and rekindles the hope for all who are oppressed, through the participation in the National Days of Remembrance honoring the victims and survivors of the Holocaust and the anniversary of the Warsaw Ghetto Uprising, Jews pay tribute to their past.

Each spring, the American Jewish community remembers its struggles, celebrates its achievements, and renews its commitment to a future of continued advancement. It is during this time that American Jews renew their common heritage with Jews throughout the world by celebrating such occasions as Israel's Independence Day and Solidarity Day for Soviet Jews. In particular, these Jewish traditions have been honored in 1983 by the American Gathering of Holocaust Survivors.

In recognition of the special significance of this time of year to American Jews, in tribute to the important contributions they have made to American life, and in tribute to the cultural diversity of the American people, the Congress of the United States, by House Joint Resolution 80, has authorized and requested the President to proclaim April 17 through April 24, 1983, as Jewish Heritage Week.

NOW, THEREFORE, I, RONALD REAGAN, President of the United States of America, do hereby proclaim the week beginning April 17, 1983, as Jewish Heritage Week. I call upon the people of the United States, Federal, State and local government officials, and interested organizations to observe that week with appropriate ceremonies, activities, and reflection.

IN WITNESS WHEREOF, I have hereunto set my hand this 19th day of April, in the year of our Lord nineteen hundred and eighty-three, and of the Independence of the United States of America the two hundred and seventh.

Ronald Reagan

[FR Doc. 83-10625
Filed 4-20-83; 10:53 am]
Billing code 3195-01-M

# Presidential Documents

**Proclamation 5054 of April 20, 1983**

## Death of Federal Diplomatic and Military Personnel in Beirut, Lebanon

**By the President of the United States of America**

**A Proclamation**

As a mark of respect for the American diplomats, military personnel and loyal staff members who died violently in the performance of their duty on April 18, 1983, in the tragic bombing of the United States Embassy in Beirut, Lebanon, I hereby order, by virtue of the authority vested in me as President of the United States of America by Section 175 of Title 36 of the United States Code, that the flag of the United States shall be flown at half-staff upon all public buildings and grounds, at all military posts and naval stations, and on all naval vessels of the Federal government in the District of Columbia and throughout the United States and its Territories and possessions through Tuesday, April 26, 1983. I also direct that the flag shall be flown at half-staff for the same length of time at all United States embassies, legations, consular offices, and other facilities abroad, including all military facilities and naval vessels and stations.

IN WITNESS WHEREOF, I have hereunto set my hand this 20th day of April, in the year of our Lord nineteen hundred and eighty-three, and of the Independence of the United States of America the two hundred and seventh.

Ronald Reagan

[FR Doc. 83-10826
Filed 4-20-83; 10:54 am]
Billing code 3195-01-M

# Rules and Regulations

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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 905

[Orange, Grapefruit, Tangerine, and Tangelo Reg. 6, Amdt. 22 ]

## Oranges, Grapefruit, Tangerines, and Tangelos Grown in Florida; Amendment of Grade Requirements

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

**ACTION:** Final rule.

**SUMMARY:** This final rule relaxes grade requirements currently in effect for fresh domestic and export shipments of pink seedless grapefruit and Honey tangerines to U.S. No. 2 Russet for the period April 25–August 21, 1983. This action is designed to increase the supply of such grapefruit and tangerines in recognition of demand conditions and the available remaining supplies in the interest of growers and consumers.

**EFFECTIVE DATE:** April 25, 1983.

**FOR FURTHER INFORMATION CONTACT:** William J. Doyle, Chief, Fruit Branch, F&V, AMS, USDA, Washington, D.C. 20250, telephone (202) 447–5975.

**SUPPLEMENTARY INFORMATION:** This final action has been reviewed under USDA procedures and Executive Order 12291 and has been designated a "non-major" rule. William T. Manley, Deputy Administrator, Agricultural Marketing Service, has certified that this action will not have a significant economic impact on a substantial number of small entities. This action is designed to promote orderly marketing of the Florida pink seedless grapefruit and Honey tangerine crops for the benefit of producers, and will not substantially affect costs for the directly regulated handlers.

This final rule is issued under the marketing agreement and Order No. 905 (7 CFR Part 905), regulating the handling of oranges, grapefruit, tangerines, and tangelos grown in Florida. The agreement and order are effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674). This action is based upon recommendations and information submitted by the Citrus Administrative Committee, and upon other available information. It is hereby found that amendment of the regulation currently in effect for pink seedless grapefruit and Honey tangerines, as hereinafter provided, will tend to effectuate the declared policy of the Act.

The minimum grade requirements, specified herein, reflect the Committee's and Department's appraisal of the need to revise the grade requirements applicable to pink seedless grapefruit and Honey tangerines. Such revision will augment the total available supply of pink seedless grapefruit and Honey tangerines, available for shipment to market by handlers.

Under section 8e of the Act (7 U.S.C. 608e–1), whenever specified commodities, including grapefruit, are regulated under a Federal marketing order, imports of that commodity must meet the same or comparable grade, size, quality or maturity requirements as those in effect for the domestically produced commodity. Thus, grade requirements for imported pink seedless grapefruit will also change to conform to the grade requirements for domestic shipments of Florida pink seedless grapefruit.

It is further found that it is impracticable and contrary to the public interest to give preliminary notice, engage in public rulemaking, and postpone the effective date until 30 days after publication in the **Federal Register** (5 U.S.C. 553), because of insufficient time between the date when information became available upon which this final rule is based and the effective date necessary to effectuate the declared purposes of the Act.

Interested persons were given an opportunity to submit information and views on the revisions of the grade requirements at an open meeting. This final rule relieves restrictions on the handling of pink seedless grapefruit and Honey tangerines. Handlers have been apprised of such provisions and the effective date.

### List of Subjects in 7 CFR Part 905

Marketing agreements and orders, Florida, Grapefruit, Oranges, Tangelos, Tangerines.

Accordingly, the provisions of § 905.306 are amended by revising the following entries in Table I, paragraph (a) applicable to domestic shipments, and Table II, paragraph (b), applicable to export shipments, to read as follows.

**§ 905.306 Orange, Grapefruit, Tangerine and Tangelo Regulation 6.**

(a) * * *

TABLE I

| Variety | Regulation period | Minimum grade | Minimum diameter (in.) |
|---|---|---|---|
| (1) | (2) | (3) | (4) |
| * * * * * | | | |
| Grapefruit: | | | |
| Seedless, pink | 4/25/83–8/21/83. | U.S. No. 2 Russet. | 3/5/16 |
| | On and after 8/22/83. | Improved No. 2 (External) U.S. No.1 (Internal). | 3-9/16 |
| Tangerines: | | | |
| Honey | 4/25/83–8/21/83. | U.S. No. 2 Russet. | 2-4/16 |
| | On and after 8/22/83. | Florida No. 1 | 2-6/16 |
| * * * * * | | | |

(b) * * *

TABLE II

| Variety | Regulation period | Minimum grade | Minimum diameter (inches) |
|---|---|---|---|
| (1) | (2) | (3) | (4) |
| * * * * * | | | |
| Grapefruit: | | | |
| Seedless, pink | 4/25/83–8/21/83. | U.S. No. 2 Russet. | 3-5/16 |
| | On and after 8/22/83. | Improved No. 2 (External) U.S. No. 1 (Internal). | 3-5/16 |
| Tangerines: | | | |
| Honey | 4/25/83–8/21/83. | U.S. No. 2 Russet. | 2-4/16 |
| | On and after 8/22/83. | Florida No. 1 | 2-6/16 |
| * * * * * | | | |

* * * * *

(Secs. 1–19, 48 Stat. 31, as amended; 7 U.S.C. 601–674)

Dated: April 15, 1983.

D. S. Kuryloski,

*Acting Director, Fruit and Vegetable Division, Agricultural Marketing Service.*

[FR Doc. 83-10633 Filed 4-20-83; 8:45 am]

BILLING CODE 3410-02-M

## 7 CFR Part 907

**[Navel Orange Regs. 575 and 574, Amdt.]**

## Navel Oranges Grown in Arizona and Designated Part of California; Limitation of Handling

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes the quantity of fresh California-Arizona navel oranges that may be shipped to market during the period April 22–28, 1983, and increases the quantity of such oranges that may be so shipped during the period April 15–21, 1983. Such action is needed to provide for orderly marketing of fresh navel oranges for the period specified due to the marketing situation confronting the orange industry.

**DATES:** This regulation becomes effective April 22, 1983, and the amendment is effective for the period April 15–21, 1983.

**FOR FURTHER INFORMATION CONTACT:** William J. Doyle, 202–447–5975.

**SUPPLEMENTARY INFORMATION:**

### Findings

This rule has been reviewed under USDA procedures and Executive Order 12291 and has been designated a "non-major" rule. William T. Manley, Deputy Administrator, Agricultural Marketing Service, has certified that this action will not have a significant economic impact on a substantial number of small entities. This action is designed to promote orderly marketing of the California-Arizona navel orange crop for the benefit of producers and will not substantially affect costs for the directly regulated handlers.

This regulation and amendment are issued under the marketing agreement, as amended, and Order No. 907, as amended (7 CFR Part 907), regulating the handling of navel oranges grown in Arizona and designated part of California. The agreement and order are effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674). The action is based upon the recommendation and information submitted by the Navel Orange Administrative Committee and upon other available information. It is hereby found that this action will tend to effectuate the declared policy of the Act.

This action is consistent with the marketing policy for 1982–83. The marketing policy was recommended by the committee following discussion at a public meeting on September 21, 1982. The committee met again publicly on April 19, 1983 at Los Angeles, California, to consider the current and prospective conditions of supply and demand and recommended a quantity of navel oranges deemed advisable to be handled during the specified weeks. The committee reports the demand for navel oranges is continuing a little slow.

It is further found that it is impracticable and contrary to the public interest to give preliminary notice, engage in public rulemaking, and postpone the effective date until 30 days after publication in the **Federal Register** (5 U.S.C. 553), because of insufficient time between the date when information became available upon which this regulation and amendment are based and the effective date necessary to effectuate the declared policy of the Act. Interested persons were given an opportunity to submit information and views on the regulation at an open meeting, and the amendment relieves restrictions on the handling of navel oranges. It is necessary to effectuate the declared purposes of the Act to make these regulatory provisions effective as specified, and handlers have been apprised of such provisions and the effective time.

### List of Subjects in 7 CFR Part 907

Marketing agreements and orders, California, Arizona, Oranges (navel).

1. Section 907.875 is added as follows:

**§ 907.875 Navel orange regulation 575.**

The quantities of navel oranges grown in California and Arizona which may be handled during the period April 22, 1983 through April 28, 1983, are established as follows:

(1) District 1: 1,600,000 cartons;
(2) District 2: Unlimited cartons;
(3) District 3: Unlimited cartons;
(4) District 4: Unlimited cartons.

2. Section 907.874, Navel Orange Regulation 574 (48 FR 16025), is hereby amended to read:

**§ 907.874 Navel orange regulation 574.**

* * * * *

(1) District 1: 1,700,000 cartons;
(2) District 2: Unlimited cartons;
(3) District 3: Unlimited cartons;
(4) District 4: Unlimited carton.

(Secs. 1–19, 48 Stat. 31, as amended; 7 U.S.C. 601–674)

Dated: April 20, 1983.

D. S. Kuryloski,

*Deputy Director, Fruit and Vegetable Division, Agricultural Marketing Service.*

[FR Doc. 83-10844 Filed 4-20-83; 11:34]

BILLING CODE 3410-02-M

## DEPARTMENT OF JUSTICE

### Immigration and Naturalization Service

### 8 CFR Part 100

### Statement of Organization; Powers and Duties of Service Officers

*Correction*

In FR Doc. 83–8066 beginning on page 13146 in the issue of Wednesday, March 30, 1983 make the following correction.

On page 13147, column two, §100.2(b)(2), line six, "and" should appear after "activities".

BILLING CODE 1505-01-M

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

### 14 CFR Part 71

**[Airspace Docket No. 82-AGL-31]**

### Alteration of Control Zone

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

**ACTION:** Final rule.

**SUMMARY:** The nature of this federal action is to convert the Williston, North Dakota, control zone from a part-time status to a full-time status. The intended effect of this action is to ensure segregation of the aircraft using approach procedures in instrument weather conditions from other aircraft operating under visual weather conditions on a 24-hour basis.

**EFFECTIVE DATE:** June 9, 1983.

**FOR FURTHER INFORMATION CONTACT:** Edward R. Heaps, Airspace, Procedures, and Automation Branch, Air Traffic Division, AGL–530, FAA, Great Lakes Region, 2300 East Devon Avenue, Des Plaines, Illinois 60018, telephone (312) 694–7360.

**SUPPLEMENTARY INFORMATION:** This action was initiated as a result of notification from Sloulin Field International Airport officials that required weather reporting is currently available on a 24-hour basis. The National Weather Service operates a full-time weather bureau facility located

at the Sloulin Field International Airport and observes and disseminates weather 24 hours per day, 7 days per week. The alteration in this case deletes the two sentences: "This control zone is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will, thereafter, be continuously published in the Airport/Facility Directory.", from the published description for the Williston, North Dakota, control zone.

Aeronautical maps and charts will continue to reflect the defined area which will enable other aircraft to circumnavigate the area in order to comply with applicable visual flight rule requirements.

History

On page 7468 of the Federal Register dated February 22, 1983, the FAA proposed to amend § 71.171 of the Federal Aviation Regulations (14 CFR Part 71) so as to alter the control zone near Williston, North Dakota. Interested parties were invited to participate in this rulemaking proceeding by submitting written comments on the proposal to the FAA. No objections were received as a result of the Notice of Proposed Rulemaking.

Except for editorial changes, this amendment is the same as that proposed in the notice. Section 71.171 of Part 71 of the Federal Aviation Regulations was published in Advisory Circular AC 70-3A dated January 3, 1983.

List of Subjects in 14 CFR Part 71

Control zones, Aviation safety.

Adoption of the Amendment

PART 71—[AMENDED]

Accordingly, pursuant to the authority delegated to me, § 71.171 of Part 71 of the Federal Aviation Regulations (14 CFR Part 71) is amended, effective 0901 GMT, June 9, 1983, as follows:

Williston, ND

Within a 5-mile radius of the Sloulin International Airport (latitude 48°10'37" N., longitude 103°38'18" W.); within 1.5 miles each side of the Williston VORTAC, and within 2 miles north and 3 miles south of the 126° bearing from the Sloulin International Airport, extending from the 5-mile radius area to 10 miles southeast of the airport.

(Secs. 307(a) and 313(a), Federal Aviation Act of 1958 (49 U.S.C. 1348(a) and 1354(a)); Sec. 6(c), Department of Transportation Act (49 U.S.C. 1655(c)) and 14 CFR 11.69)

Note.—The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, it is certified that this—(1) is not a "major rule" under Executive Order 12291; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Issued in Des Plaines, Illinois, on April 7, 1983.

Monte R. Belger,

*Acting Director, Great Lakes Region.*

[FR Doc. 83-10450 Filed 4-20-83; 8:45 am]

BILLING CODE 4910-13-M

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14 CFR Part 71

[Airspace Docket No. 82-AGL-30]

## Alteration of Transition Area

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

**ACTION:** Final rule.

**SUMMARY:** This notice proposes to alter the Superior, Wisconsin, transition area by designating an additional amount of airspace necessary for a new VOR-A instrument approach procedure to serve Sky Harbor Airport, Duluth, Minnesota.

The intended effect of this action is to insure segregation of the aircraft using approach procedures in instrument weather conditions from other aircraft operating under visual weather conditions in controlled airspace.

**EFFECTIVE DATE:** June 9, 1983.

**FOR FURTHER INFORMATION CONTACT:** Edward R. Heaps, Airspace, Procedures, and Automation Branch, Air Traffic Division, AGL-530, FAA, Great Lakes Region, 2300 East Devon Avenue, Des Plaines, Illinois 60018, telephone (312) 694-7360.

**SUPPLEMENTARY INFORMATION:** The airspace involved would be an area within a 5-mile radius of the Sky Harbor Airport, excluding the portion overlying the Duluth, Minnesota, 700' transition area. The floor of the controlled airspace in this area will be lowered from 1,200' above ground to 700' above ground. The development of the proposed instrument procedure requires that the FAA lower the floor of the controlled airspace to insure that the procedure will be contained within controlled airspace. The minimum descent altitude for this procedure may be established below the floor of the 700' controlled airspace.

Aeronautical maps and charts will reflect the defined areas which will enable other aircraft to circumnavigate the area in order to comply with applicable visual flight rule requirements.

History

On page 7467 of the Federal Register dated February 22, 1983, the FAA proposed to amend § 71.181 of the Federal Aviation Regulations (14 CFR Part 71) so as to alter the transition area airspace near Superior, Wisconsin. Interested parties were invited to participate in this rulemaking proceeding by submitting written comments on the proposal to the FAA. No objections were received as a result of the Notice of Proposed Rulemaking.

Except for editorial changes, this amendment is the same as that proposed in the notice. Section 71.181 of Part 71 of the Federal Aviation Regulations was published in Advisory Circular AC 70-3A dated January 3, 1983.

List of Subjects in 14 CFR Part 71

Transition areas, Aviation safety.

Adoption of the Amendment

PART 71—[AMENDED]

Accordingly, pursuant to the authority delegated to me, § 71.181 of Part 71 of the Federal Aviation Regulations (14 CFR Part 71) is amended, effective 0901 G.m.t., June 9, 1983, as follows:

Superior, WI

That airspace extending upward from 700' above the surface within a 5-mile radius of the Richard I. Bong Airport (latitude 46°40'55"N., longitude 92°05'35"W.); within a 5-mile radius of the Sky Harbor Airport (latitude 46°43'18"N., longitude 92°02'36"W.); excluding those portions within the Duluth, Minnesota, 700' transition area.

(Secs. 307(a) and 313(a), Federal Aviation Act of 1958 (49 U.S.C. 1348(a) and 1354(a)); Sec. 6(c), Department of Transportation Act (49 U.S.C. 1655(c)) and 14 CFR 11.69)

Note.—The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, it is certified that this—(1) is not a "major rule" under Executive Order 12291; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Issued in Des Plaines, Illinois, on April 7, 1983.

**Monte R. Belger,**

*Acting Director, Great Lakes Region.*

[FR Doc. 83-10451 Filed 4-20-83; 8:45 am]

BILLING CODE 4910-13-M

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**14 CFR Part 71**

**[Airspace Docket No. 83-ASO-10]**

## Redesignation of Control Zones, Savannah, Georgia; Correction

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

**ACTION:** Correction of final rule.

**SUMMARY:** This action corrects the descriptions of the amended Savannah, Georgia, control zones. The final rule published in the **Federal Register** (48 FR 10038) on Thursday, March 10, 1983, altered the Savannah, Georgia, control zone by establishing two separate control zones in the vicinity of Savannah Municipal Airport and Hunter AAF. When the control zones were redefined, the geographical coordinates of Hunter AAF and the northern limits of the control zone were erroneously listed. The purpose of this amendment is to correct the defectively written description. Since this action is editorial in nature, further notice and public procedure are not necessary. The effective date of this correction coincides with the effectivity of the original amendment. To avoid confusion, the complete description, as corrected, is presented in the text of this corrective amendment.

**EFFECTIVE DATE:** 0901 G.m.t., June 9, 1983.

**FOR FURTHER INFORMATION CONTACT:** Donald Ross, Airspace and Procedures Branch, Air Traffic Division, Federal Aviation Administration, P.O. Box 20636, Atlanta, Georgia 30320; telephone: (404) 763-7646.

### List of Subjects in 14 CFR Part 71

Aviation safety, Airspace, Control zone.

**SUPPLEMENTARY INFORMATION:**

### Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, § 71.171 of Part 71 of the Federal Aviation Regulations (14 CFR Part 71) (as amended) is further amended, effective 0901 G.m.t., June 9, 1983, as follows:

**Savannah Municipal Airport, GA—Revised**

Within a 5-mile radius of Savannah Municipal Airport (Lat. 32°07'39"N., Long. 81°12'09"W.); within two miles each side of Savannah ILS Runway 36 Localizer south course, extending from the 5-mile radius area to the LOM.

**Savannah Hunter AAF, GA—New**

Within a 5-mile radius of Hunter AAF (Lat. 32°00'35"N., Long. 81°08'45"W.); excluding that airspace north of latitude 32°02'30"N.

**Note.**—The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore, (1) is not a "major rule" under Executive Order 12291; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Issued in East Point, Georgia, on April 7, 1983.

**George R. LaCaille,**

*Acting Director, Southern Region.*

[FR Doc. 83-10557 Filed 4-20-83; 8:45 am]

BILLING CODE 4910-13-M

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**14 CFR Part 71**

**[Airspace Docket No. 83-ASO-2]**

## Alteration of Transition Area, Augusta, Georgia

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

**ACTION:** Final rule.

**SUMMARY:** This amendment increases the size of the Augusta, Georgia, transition area to accommodate Instrument Flight Rule (IFR) operations at Burke County Airport. This action will lower the base of controlled airspace form 1,200 to 700 feet above the surface. An instrument approach procedure, based on a new nondirectional radio beacon which is to be installed on the airport, is being developed to serve the airport and additional controlled airspace is required to protect IFR operations. In addition, the coordinates of several airports already contained within the transition area, as well as the name of an airport, are being revised so that the description will be technically correct.

**EFFECTIVE DATE:** 0901 G.m.t., June 9, 1983.

**FOR FURTHER INFORMATION CONTACT:** Donald Ross, Airspace and Procedures Branch, Air Traffic Division, Federal Aviation Administration, P.O. Box 20636, Atlanta, Georgia 30320; telephone: (404) 763-7646.

**SUPPLEMENTARY INFORMATION:**

### History

On Thursday, January 27, 1983, the FAA proposed to amend Part 71 of the Federal Aviation Regulations (14 CFR Part 71) by increasing the size of the Augusta, Georgia, transition area to provide additional controlled airspace for containment of aeronautical operations in the vicinity of Burke County Airport. A nondirectional radio beacon is being established on the airport to support instrument flight rule activities by aircraft and this action will provide necessary controlled airspace. In addition, the coordinates of several airports already contained within the transition area description, as well as the name of an airport, are being revised so that the description is technically correct (48 FR 3768). Interested parties were invited to participate in this rulemaking proceeding by submitting written comments on the proposal to the FAA. No comments were received in response to circularization. Except for editorial changes, this amendment is the same as that proposed in the notice. Section 71.181 of Part 71 of the Federal Aviation Regulations was republished in Advisory Circular AC 70-3A dated January 3, 1983.

### The Rule

This amendment to Part 71 of the Federal Aviation Regulations increases the size of the Augusta, Georgia, transition area to accommodate aeronautical activities at Burke County Airport.

### List of Subjects in 14 CFR Part 71

Aviation safety, Airspace, Transition area.

### Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, § 71.181 of Part 71 of the Federal Aviation Regulations (14 CFR Part 71) (as amended) is further amended, effective 0901 G.m.t. June 9, 1983, as follows:

**Augusta Bush Field, Georgia—Revised**

That airspace extending upward from 700 feet above the surface within an 11-mile radius of Bush Field (Lat. 33°22'11" N., Long. 81°57'55" W.); within 9.5 miles west and 4.5 miles east of Augusta ILS localizer south course, extending from the 11-mile radius area to 18.5 miles south of the LOM; within a 9-mile radius of Daniel Field (Lat. 33°28'00" N., Long. 82°02'30" W.); within a 7-mile radius of Thomson-McDuffie County Airport (Lat. 33°31'45" N., Long. 82°31'00" W.); within 9.5 miles north and 4.5 miles south of the 090° bearing from McDuffie RBN (Lat. 33°31'45" N., Long 82°26'19" W.), extending from the 7-mile radius area to 18.5 miles east of the RBN;

within a 6.5-mile radius of Burke County Airport (Lat. 33°02'28" N., Long. 82°00'07" W.); within 3.5 miles each side of the 249° bearing from the Burke County RBN (Lat. 33°02'32" N., Long. 82°00'18" W.), extending from the 6.5-mile radius area to 8.5 miles southwest of the RBN.

(Secs. 307(a) and 313(a), Federal Aviation Act of 1958 (49 U.S.C. 1348(a) and 1354(a)); Sec. 6(c), Department of Transportation Act (49 U.S.C. 1655(c)); and 14 CFR 11.69

Note.—The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore, (1) is not a "major rule" under Executive Order 12291; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Issued in East Point, Georgia, on April 6, 1983.

George R. LaCaille,

*Acting Director, Southern Region.*

[FR Doc. 83-10558 Filed 4-20-83; 8:45 am]

BILLING CODE 4910-13-M

## 14 CFR Part 71

[Airspace Docket No. 82-AGL-11]

## Designation of Control Zone

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

**ACTION:** Final rule.

**SUMMARY:** The nature of this Federal action is to designate an airport control zone to serve Grand Rapids/Itasca County Airport, Grand Rapids, Minnesota. This results from a request by the Grand Rapids/Itasca County Airport Commission. The intended effect of this action is to ensure segregation of the aircraft using approach procedures in instrument weather conditions from other aircraft operating under visual weather conditions.

**EFFECTIVE DATE:** June 9, 1983.

**FOR FURTHER INFORMATION CONTACT:** Edward R. Heaps, Airspace, Procedures, and Automation Branch, Air Traffic Division, AGL-530, FAA, Great Lakes Region, 2300 East Devon Avenue, Des Plaines, Illinois 60018, telephone (312) 694-7360.

**SUPPLEMENTARY INFORMATION:** The airspace required would lower the floor of controlled airspace from 700 feet above the surface down to the surface within a five statute mile radius of the geographic center of Grand Rapids/Itasca County Airport. The control zone would be effective during the specific dates and times established in advance by a Notice of Airmen. The effective date and time would thereafter be continuously published in the Airport/Facility Directory. In addition, aeronautical maps and charts will reflect the defined area which will enable other aircraft to circumnavigate the area in order to comply with applicable visual flight rule requirements.

### History

On page 4292 of the **Federal Register** dated January 31, 1983, the FAA proposed to amend § 71.171 of the Federal Aviation Regulations (14 CFR Part 71) so as to establish a control zone near Grand Rapids, Minnesota. Interested parties were invited to participate in this rulemaking proceeding by submitting written comments on the proposal to the FAA. No objections were received as a result of the Notice of Proposed Rulemaking.

Except for editorial changes, this amendment is the same as that proposed in the notice. Section 71.171 of Part 71 of the Federal Aviation Regulations was published in Advisory Circular AC 70-3A dated January 3, 1983.

### List of Subjects in 14 CFR Part 71

Control zones, Aviation safety.

### Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, § 71.171 of Part 71 of the Federal Aviation Regulations (14 CFR Part 71) is amended, effective 0901 G.m.t., June 9, 1983, as follows:

**Grand Rapids, MN**

Within a 5-mile radius of the Grand Rapids-Itasca County Airport (latitude 47°12'45"N., longitude 93°31'00"W.).

(Secs. 307(a) and 313(a), Federal Aviation Act of 1958 (49 U.S.C. 1348(a) and 1354(a)); Sec. 6(c), Department of Transportation Act (49 U.S.C. 1655(c)) and 14 CFR 11.69)

Note.—The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, it is certified that this—(1) is not a "major rule" under Executive Order 12291; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Issued in Des Plaines, Illinois, on April 7, 1983.

Monte R. Belger,

*Acting Director, Great Lakes Region.*

[FR Doc. 83-10479 Filed 4-20-83; 8:45 am]

BILLING CODE 4910-13-M

## 14 CFR Part 71

[Airspace Docket No. 82-AGL-27]

## Alteration of Transition Area

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

**ACTION:** Final rule.

**SUMMARY:** The nature of this Federal action is to alter the Vincennes, Indiana, transition area by designating an additional amount of airspace necessary for a newly established NDB Runway 4 instrument approach procedure to serve Mt. Carmel, Illinois, Municipal Airport.

The intended effect of this action is to insure segregation of the aircraft using approach procedures in instrument weather conditions from other aircraft operating under visual weather conditions in controlled airspace.

**EFFECTIVE DATE:** June 9, 1983.

**FOR FURTHER INFORMATION CONTACT:** Edward R. Heaps, Airspace, Procedures, and Automation Branch, Air Traffic Division, AGL-530, FAA, Great Lakes Region, 2300 East Devon Avenue, Des Plaines, Illinois 60018, telephone (312) 694-7360.

**SUPPLEMENTARY INFORMATION:** The development of the proposed procedure requires that the FAA alter the designated airspace to insure that the procedure will be contained within controlled airspace. The minimum descent altitude for this procedure may be established below the floor of the 700-foot controlled airspace.

The airspace involved would be an area approximately 3.5 miles by 6 miles located southwest of the airport and extending from the 5-mile radius area to 8.5 miles south of the Mt. Carmel Municipal Airport.

Aeronautical maps and charts will reflect the defined areas which will enable other aircraft to circumnavigate the area in order to comply with applicable visual flight rule requirements.

**History**

On page 4799 of the **Federal Register** dated February 3, 1983, the FAA proposed to amend § 71.181 of the Federal Aviation Regulations (14 CFR Part 71) so as to alter the transition area airspace near Vincennes, Indiana. Interested parties were invited to participate in this rulemaking proceeding by submitting written comments on the proposal to the FAA. No objections were received as a result of the Notice of Proposed Rulemaking.

Except for editorial changes, this amendment is the same as that proposed in the notice. Section 71.181 of Part 71 of the Federal Aviation Regulations was published in Advisory Circular AC 70-3A dated January 3, 1983.

**List of Subjects in 14 CFR Part 71**

Transition areas, Aviation safety.

**Adoption of the Amendment**

Accordingly, pursuant to the authority delegated to me, § 71.181 of Part 71 of the Federal Aviation Regulations (14 CFR Part 71) is amended, effective 0901 G.m.t, June 9, 1983, as follows:

**Vincennes, Indiana**

That airspace extending upward from 700 feet above the surface within a 7-mile radius of Lawrenceville-Vincennes Municipal Airport (latitude 38°45'35" N, longitude 87°36'27" W.); within 3 miles each side of the 186° bearing from the airport, extending from the 7-mile radius to 8 miles south; and 3 miles each side of the 352° bearing from the airport, extending from the 7-mile radius to 8 miles north; within 3 miles each side of the 102° bearing from the airport, extending from the 7-mile radius to 8 miles east; and within a 5.5-mile radius of O'Neal Airport (latitude 38°41'29" N., longitude 87°33'08" W.); and within 3 miles each side of the 258° bearing from the O'Neal Airport, extending from the 7-mile and 5½-mile radius area to 8 miles west of the O'Neal Airport; and within a 5-mile radius of the Mt. Carmel Municipal Airport (latitude 38°36'24" N., longitude 87°43'34" W.); within 3 miles either side of the 038° bearing from the Mt. Carmel Airport, extending from the 5-mile radius area northeast to join the Lawrenceville and O'Neal radius areas; and within 3 miles either side of the 196° bearing from the Mt. Carmel Airport extending from the 5-mile radius area to 8.5 miles south of the airport.

(Secs. 307(a) and 313(a), Federal Aviation Act of 1958 (49 U.S.C. 1348(a) and 1354(a)); Sec. 6(c), Department of Transportation Act (49 U.S.C. 1655(c)) and 14 CFR 11.69)

**Note.**—The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, it is certified that this—(1) is not a "major rule" under Executive Order 12291; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Issued in Des Plaines, Illinois, on April 7, 1983.

**Monte R. Belger,**

*Acting Director, Great Lakes Region.*

[FR Doc. 83-10475 Filed 4-20-83; 8:45 am]

BILLING CODE 4910-13-M

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

### 15 CFR Part 909

### Policies and Procedures Regarding Disclosure of Information and NOAA Employee Testimony in Litigation Not Involving the United States

**AGENCY:** National Oceanic and Atmospheric Administration, Commerce

**ACTION:** Final rule; Amendment.

**SUMMARY:** This amendment updates National Oceanic and Atmospheric Administration (NOAA) office addresses for requesting certified copies of NOAA records and/or requesting the appearance of NOAA employees to give testimony in litigation not involving the United States.

**EFFECTIVE DATE:** April 21, 1983.

**FOR FURTHER INFORMATION CONTACT:** John S. Brookbank Jr., Office of General Counsel (GCW), National Weather Service, NOAA, Silver Spring, MD 20910. Telephone: (301) 427-7053.

**SUPPLEMENTARY INFORMATION:**

**List of Subjects in 15 CFR Part 909**

Courts, Administrative practice and procedure.

**PART 909—[AMENDED]**

1. Section 909.2 is amended by revising paragraphs (b) and (c) to read as follows:

**§ 909.2 Disclosure and certification of information and records.**

* * * * *

(b) Certified copies of NOAA records will be provided upon request. Requests for certified copies of these types of information should be referred to the following offices: Weather and Climatological Records; Director, National Climatic Data Center, National Environmental Satellite, Data, and Information Service, NOAA, Federal Building, Asheville, NC 28801. Weather Forecasts and Warnings; Aviation Services Branch (W/OM13), National Weather Service, NOAA, Silver Spring, MD 20910. Aeronautical Charts; Aeronautical Charting Division (N/CG3), National Ocean Service, NOAA, Rockville, MD 20852. Nautical Charts; Chart Information Section (N/GC222), National Ocean Service, NOAA, Rockville, MD 20852. Other; Office of the General Counsel, National Oceanic and Atmospheric Administration, Washington, DC 20230. (c) Requests for the appearance of NOAA employees to give testimony in litigation not involving the United States should be addressed to the Office of General Counsel at the address shown in paragraph (b) of this section.

Dated: April 8, 1983.

**Francis J. Balint,**

*Chief, Information and Management Services Division.*

[FR Doc. 83-10214 Filed 4-20-83; 8:45 am]

BILLING CODE 3510-12-M

## SECURITIES AND EXCHANGE COMMISSION

### 17 CFR Part 270

**[Release No. IC-13163]**

### Filing of Materials With the Commission

**AGENCY:** Securities and Exchange Commission.

**ACTION:** Final rule.

**SUMMARY:** The Commission is adopting a technical amendment to rule 0-2(a) under the Investment Company Act of 1940 that will expand the rule to provide that, when the last day for timely filing of papers required to be filed by the Act falls on a Saturday, Sunday or holiday, the time within which required papers may be filed with the Commission will be extended until the following business day.

**EFFECTIVE DATE:** April 21, 1983.

**FOR FURTHER INFORMATION CONTACT:** Jane A. Kanter, Special Counsel (202) 272-2115, or Larry L. Greene, Esq. (202) 272-7320, Office of Disclosure Legal Services, Division of Investment Management, Securities and Exchange Commission, Washington, D.C. 20549.

**SUPPLEMENTARY INFORMATION:** The Commission is today adopting a technical amendment to rule 0-2(a) [17 CFR 270.0-2(a)] under the Investment Company Act of 1940 (the "1940 Act") [15 U.S.C. 80a-1 *et seq.*] to provide that

when the last day for the timely filing of papers required to be filed by the 1940 Act falls on a Saturday, Sunday or holiday, the time within which required papers may be timely filed with the Commission will be extended until the following business day. Currently, no provision is made in rule 0–2(a) to accommodate situations in which the last day for the timely filing of required papers falls on a Saturday, Sunday or holiday. The amendment adopted today revises that rule to provide if the last day on which papers can be accepted as timely filed falls on a Saturday, Sunday or holiday, such papers may be filed on the following first business day.

**Discussion**

It has come to the Commission's attention that the filing requirements under the 1940 Act may, on occasion, result in a shortening of the filing period for materials required to be filed with the Commission when the last day of the filing period falls on a Saturday, Sunday or holiday. Currently, no provision is made in rule 0–2(a) under the 1940 Act to accommodate situations in which the last day for the timely filing of required papers falls on a Saturday, Sunday or holiday. Consequently, when the last day of the filing period is a Saturday, Sunday or holiday the filing must be made on the prior business day in order to be filed timely. The Commission has previously taken the position that shortened filing periods impose an unnecessary hardship on the responsible party. On May 17, 1971,[1] the Commission amended rule 22(j) [17 CFR 201.22(j)] of its Rules of Practice with respect to proceedings before the Commission. That rule was amended to provide, in pertinent part, that in computing any period of time prescribed or allowed by the Rules of Practice or by order of the Commission for the filing of papers in proceedings before the Commission, the last day of the time period so computed will be included unless that day is a Saturday, Sunday or holiday. In that case, the time period will be permitted to run until the end of the next day that is neither a Saturday, Sunday or legal holiday. Similarly, on March 29, 1974,[2] the Commission adopted an amendment to rule 0–3 [17 CFR 240.0–3] under the Securities Exchange Act of 1934 [15 U.S.C. 78a *et seq.*] relating to the filing of materials with the Commission under that Act. The amendment to rule 0–3 provides that if the last day on which papers can be accepted as timely filed falls on a Saturday, Sunday or holiday, such papers may be filed with the Commission on the next business day.

The Commission finds, in light of these other rules concerning the computation of the time periods prescribed or allowed for filing materials with the Commission, that present rule 0–2(a) under the 1940 Act is inconsistent with the Commission's view that shortened filing periods impose an unnecessary hardship on the responsible party. Consequently, the Commission hereby adopts a technical amendment to rule 0–2(a) to amend the requirements of that rule by providing that if the last day on which papers can be accepted as timely filed falls on a Saturday, Sunday or holiday, such papers may be filed on the first business day following.[3] The amendment also incorporates language that makes rule 0–2 specifically applicable to papers required to be filed pursuant to the Act or the rules and regulations thereunder. As discussed more fully below, in view of the Commission's determination that prior notice and comment are unnecessary under the circumstances, this technical amendment is being adopted without prior notice and comment, and will be effective immediately upon publication in the **Federal Register.**

**Adoption of the Technical Amendment Without Prior Notice**

The Administrative Procedure Act [5 U.S.C. 551 *et seq.*] ("APA") generally requires that any agency or commission publish a notice of proposed rule-making that provides adequate opportunity for comment by interested persons. Section 553(b)(B) of the APA provides an exception from this requirement in situations where the agency for good cause finds that prior notice and comment are "impractical, unnecessary, or contrary to the public interest." These standards are incorporated in rule 4(b) of the Commission's Rules of Practice [17 CFR 201.4(b)], which requires publication of prior notice of proposed rule amendments "[e]xcept where the Commission finds that notice and public procedure are impracticable, unnecessary, or contrary to the public interest."

In addition, the APA provides in section 553(d) that an adopted rule must be published at least 30 days prior to the rule's effective date. However, section 553(d)(1) contains an exception to this required publication of an adopted rule and 30 day delay in effectiveness when the rule is a substantive one that grants an exception or relieves a restriction.

The purpose of this technical amendment to rule 0–2(a) of the 1940 Act is to relieve an unnecessary filing burden. The Commission believes that this amendment to rule 0–2(a), however, would not significantly alter the rule and would have no detrimental impact on the rights of persons subject to the rule. In addition, the Commission believes that there is little likelihood that any interested person would object to the rule's adoption. Accordingly, the Commission has determined that prior notice and comment are unnecessary. Further, the Commission finds that a 30 day delay in effectiveness is not required pursuant to section 553(d)(1) of the APA because this amendment to rule 0–2(a) grants an exception or relieves a restriction. Therefore, this amendment to rule 0–2(a) will become effective immediately upon publication in the **Federal Register.**

**List of Subjects in 17 CFR Part 270**

Investment companies, Reporting and recordkeeping requirements, Securities.

**Text of Technical Amendment to Part 270**

In accordance with the foregoing, Chapter II, Title 17 of the Code of Federal Regulations, Part 270 is amended as follows:

## PART 270—GENERAL RULES AND REGULATIONS UNDER THE INVESTMENT COMPANY ACT OF 1940

In § 270.0–2, paragraph (a) is revised as follows:

**§ 270.0–2 General requirements of papers and applications.**

(a) *Filing of papers.* All papers required to be filed with the Commission pursuant to the Act or the rules and regulations thereunder shall, unless otherwise provided by the rules and regulations in this part, be delivered through the mails or otherwise to the Securities and Exchange Commission, Washington, D.C. 20549. Except as otherwise provided by the rules and regulations, the date on which papers are actually received by the Commission shall be the date of filing thereof. If the last day for the timely filing of such papers falls on a Saturday, Sunday, or holiday, such papers may be filed on the first business day following.

* * * * *

**Statutory Authority**

The technical amendment to rule 0–2(a) [17 CFR 270.0–2(a)] is being adopted

[1] Investment Company Act Release No. 6524 (May 17, 1971) [36 FR 9864 (May 29, 1971)].

[2] Securities Exchange Act Release No. 10707 (March 29, 1974) [39 FR 12861 (April 9, 1974)].

[3] It should be noted, however, that today's amendment to rule 0–2 does not affect the treatment of intermediate Saturdays, Sundays or holidays.

pursuant to section 38 of the 1940 Act [15 U.S.C. 37].

By the Commission.

**George A. Fitzsimmons,**

*Secretary.*

April 15, 1983.

[FR Doc. 83-10622 Filed 4-20-83; 8:45 am]

BILLING CODE 6010-01-M

## DEPARTMENT OF ENERGY

## Federal Energy Regulatory Commission

## 18 CFR Part 282

**[Docket No. RM81-17-000]**

## Definition of Agricultural Use in Section 282.202(a) of the Commission's Incremental Pricing Regulations; Order Denying Rehearing and Request for Exemptive Rule

Issued: April 12, 1983.

**AGENCY:** Federal Energy Regulatory Commission, DOE.

**ACTION:** Order denying rehearing and request for exemption rule.

**SUMMARY:** On November 16, 1981, the Federal Energy Regulatory Commission (Commission) issued a final rule expanding the list of agricultural uses of natural gas set forth in § 282.202(a) which are exempt from incremental pricing surcharges (Order No. 189, 46 FR 57469, Nov. 24, 1981). A timely petition for rehearing of Order No. 189 or, in the alternative, for an exemptive rule under section 206(d) of the Natural Gas Policy Act of 1978 was filed by Humko Chemical. For the reasons discussed below and in Order No. 189, the Commissioin denies the petition for rehearing and request for exemptive rule.

**DATE:** Issued April 12, 1983.

**FOR FURTHER INFORMATION CONTACT:** Barbara K. Christin, Office of General Counsel, 825 North Capitol Street, NE., Washington, D.C. 20426; (202) 357-8033.

**SUPPLEMENTARY INFORMATION:**

On November 16, 1981, the Federal Energy Regulatory Commission (Commission) issued a final rule in this docket amending its regulations on incremental pricing (18 CFR Part 282) under Title II of the Natural Gas Policy Act of 1978 (15 U.S.C. 3301-3432) (NGPA). The final rule (Order No. 189, 46 FR 57469, November 24, 1981) amended § 282.202(a), which contains the list of agricultural uses of natural gas exempt from incremental pricing surcharges. The amendment added additional uses to the list.

A timely petition for rehearing of Order No. 189 was filed by Humko Chemical. On January 15, 1982, the Commission granted the petition solely for purposes of further consideration.

In its petition for rehearing, Humko Chemical requested the Commission to reconsider its decision in the final rule that the production of fatty chemicals from agricultural products and by-products, including tallow, tall oils, fish oils, and vegetable oils is not an agricultural use of natural gas for purposes of an incremental pricing exemption. Petitioner asserts, as it did in comments filed in response to the Notice of Proposed Rulemaking,[1] that its processing activities constitute natural fiber processing, agricultural production, and food processing, and that some of the fatty chemicals which it produces are essential to food quality maintenance.[2]

Although some of the products which Humko processes (such as tallow, tall oils, fish oils, and vegetable oils) may be derived from fibrous materials, they are not natural fiber. Therefore, the processing of these oils and the other materials is not natural fiber processing. Furthermore, the Commission's definition of agricultural use in § 282.202(a) of its regulations as it relates to "agricultural production" is generally limited to the on-farm use of natural gas for the production of crops or the raising of livestock.[3] Thus, although the raw materials which are processed by Humko Chemical may be agricultural in nature, the use of natural gas for this purpose does not fall within the "agricultural production" category as defined by the Commission.

Finally, petitioner's arguments that its use of natural gas to process agricultural products and by-products into chemical intermediates qualifies as food processing and is essential to food quality maintenance were considered by the Commission and addressed in the preamble to the final rule. (*Mimeo* at 12-14.) Further discussion here would not be helpful.

Accordingly, for the reasons discussed above and in the preamble to the final rule, the Commission denies rehearing of the final rule.

Petitioner requests in the alternative that the Commission issue a rule under section 206(d) of the NGPA to exempt its use of natural gas from incremental pricing surcharges. Section 206(d) grants the Commission authority to exempt any industrial facility or category of facilities from incremental pricing. Pursuant to section 206(d)(2), however, any exemptive rule is subject to Congressional review before becoming effective. Petitioner argues that the considerations underlying the Commission's decision in Order No. 177 are applicable here.[4] That order was issued pursuant to section 206(d) of the NGPA and exempted from incremental pricing natural gas used in the manufacture of fertilizer, agricultural chemicals, animal feed and food.

The Commission denies the request for an exemptive rule under section 206(d) Of the NGPA. The exemption granted by Order No. 177 was limited to the group of industries specifically enumerated in section 206(b)(3)(B) of the NGPA.[5] Petitioner's use of natural gas in the processing of agricultural products and by-products into fatty chemicals does not fall within this group.

### The Commission orders

Humko Chemicals' petition for rehearing or, in the alternative, for an exemptive rule under section 206(d) of the NGPA, is denied.

By the Commission.

**Kenneth F. Plumb,**

*Secretary.*

[FR Doc. 83-10613 Filed 4-20-83; 8:45 am]

BILLING CODE 6717-01-M

## 18 CFR Part 385

**[Docket No. RM83-58-000; Order No. 289]**

## Rules of Practice and Procedure; Citation Form

Issued: April 12, 1983.

**AGENCY:** Federal Energy Regulatory Commission, DOE.

**ACTION:** Final rule.

**SUMMARY:** The Federal Energy Regulatory Commission (Commission) is amending its Rules of Practice and Procedure by establishing an official citation form for documents filed with

[1] Issued April 20, 1981, 46 FR 23487 (April 27, 1981).

[2] Section 206(b)(3)(A) defines "agricultural use" as follows:

(b)(3) Agricultural Use Defined.—For purposes of this subsection, the term "agricultural use," when used with respect to natural gas, means the use of natural gas to the extent such use is—

(A) for agricultural production, natural fiber production, natural fiber processing, food processing, food quality maintenance, irrigation pumping, or crop drying; or * * *.

[3] Order No. 114, Docket No. RM80-48, issued December 5, 1980, 45 FR 82915, 82918 (December 17, 1980).

[4] Order No. 177, Docket No. RM80-18, issued September 24, 1981, 46 FR 50080 (October 9, 1981).

[5] Section 206(b)(3)(B) defines, as an agricultural use, the use of natural gas "as a process fuel or feedstock in the production of fertilizer, agricultural chemicals, animal feed, or food."

the Commission. Accordingly, the Commission is adopting *A Uniform System of Citation* as its official citation manual.

**EFFECTIVE DATE:** May 23, 1983.

**FOR FURTHER INFORMATION CONTACT:** Kenneth J. Malloy, Rulemaking and Legislative Analysis Section, Office of General Counsel, 825 North Capitol Street, N.E., Room 8602–A, Washington, D.C. 20426; (202) 357–8033.

**SUPPLEMENTARY INFORMATION:** The Federal Energy Regulatory Commission (Commission) is amending its Rules of Practice and Procedure (18 CFR Part 385) by establishing an official citation form for documents filed with the Commission. The Commission does so by adopting *A Uniform System of Citation* [1] as its official citation manual.

## I. Background

Accurate and uniform citation to legal authority is essential to effective and efficient regulatory writing and research. The Commission frequently receives pleadings, briefs, comments on rulemakings, and other documents that contain incomplete, inaccurate, or misleading citations. These inadequacies often consume time and staff resources and may impede Commission processes. Accordingly, the Commission believes that it is necessary to affirm the importance of citation form by using standard guidelines.

The Commission's rules, opinions, orders, and public information materials are published in a variety of places. For example, the Commission's rules are published in both the Code of Federal Regulations and the **Federal Register;** opinions and orders are published in the *FERC Reports;* and some types of orders and opinions are available only from the Commission in their typographic or photocopied form. The Commission also publishes much of this material in its looseleaf series called *Federal Energy Guidelines,* which is currently marketed to the public in identical looseleaf format by Commerce Clearing House (CCH).[2] The advantage of these "looseleaf" publications is that they contain most of the Commission's documents and thus provide easy accessibility to the primary source material. A standardized method of citing to these materials will be a welcomed aid to the Commission and the public alike.

The CCH publications are convenient for Commission personnel and regular practitioners, and the Commission recommends them. However, the series is not yet readily available to the general public and, therefore, the Commission has decided not to require citation to them. If a person using *FERC Statutes and Regulations* has the correct bluebook citation, it is generally a simple matter to locate the material in the Commission's publication.[3]

## II. The Rule

The Commission is promulgating Rule 2003(c) (to be published at 18 CFR 385.2003(c)) to establish the most current edition of *A Uniform System of Citation* (currently in its 13th edition) as the preferred method of citation in all Commission filings and documents. The Commission believes that *A Uniform System of Citation* (known in the legal community as the "bluebook") is the preeminent authority on citation form and its use will minimize confusion. By invoking the *Uniform System,* this final rule also requires all persons to cite to certain preferred sources when filing documents. For example, statutes should be cited to *United States Code,* regulations to the *Code of Federal Regulations,* opinions and orders to *FERC Reports,*[4] and unpublished material to the Commission's typographic issuance.

This rule departs from *A Uniform System of Citation* in one respect. Rather than permit the use of any of the several citation forms discussed in Rule 1 of the *Uniform System,* the Commission adopts only the form for law reviews,[5] and specifically excepts Rule 1.1 (which applies to briefs and legal memoranda). The law review form is the proper one for any document containing substantial footnotes, as do most documents at the Commission. The bluebook contains numerous examples of footnotes in the law review form. In addition, the use of parallel citations, such as the docket or order numbers, is encouraged.

The following are examples of correct footnote citations for Commission documents.

Orders and Opinions: Tenneco Oil Co., 21 FERC ¶ 61,320 (1982),[6] *on remand of* Air Prod. & Chem., Inc. v. FERC, 650 F.2d 687 (5th Cir. 1981), *remanding and vacating* Tenneco Oil Co., 2 FERC ¶ 61,247 (1978), 3 FERC ¶ 61,257 (1978), and 4 FERC ¶ 61,070 (1978),[7] *modifying* Tenneco Oil Co., 57 F.P.C. 1306 (1977)[8] and 59 F.P.C. 2134 (1977).[9]

Statutes: Natural Gas Act § 7, 15 U.S.C. § 717f (1976 and Supp. IV 1980)

Rules: Settlements Involving Headwater Benefits, 18 CFR 13.1 (1982)

Proposed Rules, Rules not in CFR, and Regulation Preambles: Incremental Pricing: Definition of Agricultural Use, 46 FR 57,469 (1981).[10]

Impact of the NGPA on Current and Projected Natural Gas Markets, 47 FR 19,157, 19,159 (1982) (notice of inquiry issued April 28, 1982).[11]

The Administrative Procedure Act does not require notice and comment for "rules of agency organization, procedure, or practice." 5 U.S.C. 553(b)(A) (1976). Accordingly, this amendment to the Rules of Practice and Procedure is being made without prior notice and comment.

The final rule is effective on May 23, 1983.

(Department of Energy Organization Act, 42 U.S.C. 7101–7352 (Supp. IV 1980); Exec. Order No. 12,009, 3 CFR 142 (1978))

## List of Subjects in 18 CFR Part 385

Administrative rules of practice and procedure.

In consideration of the foregoing, the Commission amends Part 385 of Title 18, Chapter I, *Code of Federal Regulations,* as set forth below.

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[1] Harvard Law Review Ass'n. A Uniform System of Citation (13th ed. 1981). This book is available in most law bookstores.

[2] Inquiries on the Commerce Clearing House publication may be directed to Order Department, Commerce Clearing House, Inc., 4025 West Peterson Avenue, Chicago, Illinois 60646. (Phone: (312)583-8500).

[3] There are instances in which there is a notation in one volume (*e.g., FERC Reports*) that the full text of an order or opinion appears in another volume (*e.g., FERC Statutes and Regulations*). In these instances, the citation to the publication in which the full text appears should be used.

[4] In addition to *FERC Reports, Federal Energy Regulatory Commission Appeals Decisions* is a one volume publication containing Commission decisions reviewing certain Department of Energy matters between August 1978 and June 1981. Decisions after June 1981 are integrated into *FERC Reports.*

[5] Rule 1.3 states that one may use large and small capital letters or regular roman type in footnotes. Since most documents prepared at or for the Commission are typed, ordinary roman type should be used.

[6] A parallel citation might add: Op. No. 10–B, Docket No. CI75–45.

[7] A parallel citation might add: Op. Nos. 10 and 10–A, Dock. No. CI75–45. Tenneco Oil Co., 4 FERC ¶ 61,070 (1978), was not assigned an opinion number. It was an "Order Clarifying Opinion No. 10 and Denying Stay."

[8] A parallel citation might add: Op. No. 789.

[9] A complete citation or prior history such as this example would generally be unnecessary, unless the history of the case were discussed.

[10] A parallel citation might add: [Reg. Preambles 1977–1981] FERC Stat. & Reg. ¶ 30,313 (1981), Order No. 189, Docket No. RM81–17.

[11] A parallel citation might add: 4 FERC Stat. & Reg. ¶ 35,512, Docket No. RM82–26–000.

By the Commission. Commissioner Richard concurred with a separate statement attached.

**Kenneth F. Plumb,**

*Secretary.*

## PART 385—[AMENDED]

Section 385.2003 is amended by adding a new paragraph (c) to read as follows:

**§ 385.2003 Specifications (Rule 2003)**

* * * * *

(c) *Citation form.* Any filing with the Commission should comply with the rules of citation, except Rule 1.1, set forth in the most current edition of *A Uniform System of Citation,* published by The Harvard Law Review Association.

Final Rule to Adopt the *Uniform System of Citation;* Docket No. RM83–58–000.

Issued: April 12, 1983.

**Richard, Commissioner, concurring:**

Administrative Law Judge David Benkin has a speech that he gives on the evils of "secret law" at the Commission. He is referring to the unwritten policies and procedures that are mysterious and inaccessible to those who do not regularly appear before us. In recent years great strides have been taken to dispel that atmosphere. The Commission has resumed publication of its decisions; [1] the Rules of Practice and Procedure for hearings and general matters have been issued; [2] and discovery rules are being developed. (In my personal view, the discovery rules cannot be completed too soon).

Still, the regulatory environment is complex, replete with technical jargon and legal terms. Initiates have a tendency to speak in shorthand of energy regulation. Quick allusions to "the *South Georgia* exemption" [3] or to "Order 30" [4] may be unavoidable in day-to-day conversation, but in written documents, unless they are accompanied by complete and accurate citations, such references only serve to heighten the impression of "secret law" or to confuse novitiates (and new Commissioners). [5]

[1] Due to limited resources, in 1979 publication of the *F.P.C.* and *F.E.R.C. Reports* was backlogged through 1973.

[2] 18 CFR Part 385 (1982).

[3] South Georgia Natural Gas Co., (May 5, 1978) (unpublished letter order in Dock. No. RP77–32). *See* Natural Gas Pipeline of America, 13 F.E.R.C. ¶ 61,266 (Dec. 23, 1980).

[4] Transportation Certificates for Natural Gas for the Displacement of Fuel Oil, 44 FR 30,323 (1979) (codified at 18 CFR 284.200–284.208 (1980)). There are many situations in which the subsequent history of Order 30 should also be included in the citation.

[5] New Commissioners have been surprised to learn that circuit court cases relied upon by outside parties or staff were affirmed or overturned by the Supreme Court, a fact omitted from the participants' footnotes. A few surprises of this sort have made me realize that my staff and I must scrutinize each and every citation of authority.

It is easy to go overboard with rules of form. Satirists have suggested that "the basic belief of the fundamentalists is that every word in the bluebook is literally true * * *. Thus, when the bluebook commands, 'discussions in selective case reports are cited: Annot., 12 A.L.R. 2d 382 (1950) * * * ' they cite 12 A.L.R. 2d 382 (1950) regardless of which annotation they are relying upon." [6] I do not think we need to go this far nor do we need to employ a squad of editors wielding blue pencils to police the proper use of italics. We do not expect strict compliance with the minutiae of the bluebook, however, the adoption of the rule before us today should be viewed as a serious mandate to end secret law at this Commission by fully citing legal authority.

**Oliver G. Richard III,**

*Commissioner.*

[FR Doc. 83-10614 Filed 4-20-83; 8:45 am]

BILLING CODE 6717-01-M

[6] Book Review, 65 Geo. L.J. 871 n. 7 (1977) (reviewing The Columbia Law Review, The Harvard Law Review Association, The University of Pennsylvania Law Review, and the Yale Law Journal, *A Uniform System of Citation* (12th ed. 1976).

## DEPARTMENT OF STATE

### 22 CFR Part 11

**[Dept. Reg. 108.831]**

### Appointment of Members of the Foreign Service; Revised Regulations

*Correction*

In FR Doc. 83–8103 beginning on page 13161 in the issue of Wednesday, March 30, 1983 make the following correction:

On page 13164, column three, line six should read "Dated March 25, 1983."

BILLING CODE 1505-01-M

## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

### 26 CFR Part 401

**[T.D. 7886 ]**

### Temporary Procedure and Administration Regulations Under the Tax Equity and Fiscal Responsibility Act of 1982; Certain Requirements for Release of Liens

**AGENCY:** Internal Revenue Service, Treasury.

**ACTION:** Temporary regulations.

**SUMMARY:** This document provides temporary regulations governing the issuance of a release of a notice of Federal tax lien filed with respect to internal revenue taxes. Changes to the applicable tax law were made by the Tax Equity and Fiscal Responsibility Act of 1982. These regulations affect all persons against whom a notice of Federal tax lien has been filed for outstanding Federal taxes and Internal Revenue Service personnel who file a notice of Federal tax lien and will provide them with guidance necessary to comply with the law.

**DATE:** The regulations apply to a notice of Federal tax lien filed after December 31, 1982, notice of Federal tax lien satisfied after December 31, 1982, and notice of Federal tax lien for which a taxpayer after December 31, 1982, requests that a certificate of release be issued on the grounds that the tax liability was satisfied or has become legally unenforceable.

**FOR FURTHER INFORMATION CONTACT:** Neil W. Zyskind of the Legislation and Regulations Division, Office of the Chief Counsel, Internal Revenue Service, 1111 Constitution Avenue, N.W., Washington, D.C. 20224. Attention: CC:LR:T, (202) 566–3289, not a toll-free call.

**SUPPLEMENTARY INFORMATION:**

**Background**

A new Part 401 , Temporary Procedure and Administration Regulations under the Tax Equity and Fiscal Responsibility Act of 1982, is added by this document to Title 26 of the Code of Federal Regulations. In addition, this document contains temporary regulations under new Part 401 relating to certain requirements for the issuance of a release of a notice of Federal tax lien under section 6325(a) of the Internal Revenue Code of 1954, as amended by section 348 of the Tax Equity and Fiscal Responsibility Act of 1982 (Pub. L. 97–248, 96 Stat. 638). The temporary regulations provided by this document will remain in effect until superseded by the final regulations on this subject.

The temporary regulations contain provisions relating to the issuance of a certificate or release of a notice of Federal tax lien under section 6325(a) of the Code. Section 401.6325–1(a) sets forth the general requirements for the release of a notice of Federal tax lien.

Section 401.6325–1(b) grants the district director the authority to file a notice of Federal tax lien containing a certificate of release which will become effective as a release as of a date prescribed in the document containing the notice of Federal tax lien and certificate of release. The authority to combine these documents will reduce the administrative difficulties in monitoring tax liens which have become legally unenforceable and will relieve the district director of the burden of

issuing a separate certificate of release. Furthermore, the cost of filing a release, which is charged to a taxpayer, will be reduced by combining the documents.

Section 6325(a) requires that the Secretary issue a certificate of release of a notice of Federal tax lien no later than 30 days after the day on which the Secretary finds that the liability for the tax has been fully satisfied or has become legally unenforceable. Under paragraph (c) of § 401.6325–1, satisfaction of the tax liability occurs either when (1) the district director determines, as soon as practicable after tender of payment, that the entire tax liability has been satisfied in full, or (2) when the taxpayer provides the district director with proof of full payment of the tax liability. Section 401.6325–1(d) defines the term "proof of full payment."

Paragraph (e) of § 401.6325–1 provides that when a notice of Federal tax lien lists multiple tax liabilities, the district director shall issue a certificate of release when all of the tax liabilities have been fully satisfied or have become legally unenforceable. In addition, if the taxpayer requests that a certificate of release be issued for one of the liabilities listed in the notice of Federal tax lien and such liability has been fully satisfied or has become legally unenforceable, the district director shall issue a certificate of release. Thus, for example, if a notice of Federal tax lien is filed in 1983 covering an employment tax liability assesed for the third quarter of 1982 and an employment tax liability assessed for the fourth quarter of 1982, a release will not automatically be issued until the entire employment tax liabilities for the third and fourth quarters of 1982 have been satisfied or have become legally unenforceable. However, if the taxpayer paid the employment tax liability for the third quarter of 1982, the taxpayer can request that a certificate of release be issued for the third quarter tax liability and the district director shall issue a release. This provision will substantially reduce the burden, both administratively and economically, on the taxpayer and district director.

Section 401.6325–1(f) contains provisions relating to the necessary information required to be set forth in the taxpayer's request for the issuance of a certificate of release from a notice of Federal tax lien. Section 401.6325–1(g) contains the effective dates for the changes made to section 6325(a).

### Non-Applicability of Executive Order 12291

The Treasury Department has determined that this temporary regulation is not subject to review under Executive Order 12291 or the Treasury and OMB implementation of the Order dated April 28, 1982.

### Regulatory Flexibility Act

No general notice of proposed rulemaking is required by 5 U.S.C. 553 (b) for temporary regulations. Accordingly, the Regulatory Flexibility Act does not apply and no Regulatory Flexibility Analysis is required for this rule.

### Drafting Information

The principal author of these temporary regulations is Neil W. Zyskind of the Legislation and Regulations Division of the Office of Chief Counsel, Internal Revenue Service. However, personnel from other offices of the Internal Revenue Service and Treasury Department participated in developing the regulation, both on matters of substance and style.

### List of Subjects in 26 CFR Part 401

Release of liens, Tax Equity and Fiscal Responsibility Act of 1982.

### *Adoption of Amendments to the Regulations*

Accordingly, a new Part 401, Temporary Procedure and Administration Regulations under the Tax Equity and Fiscal Responsibility Act of 1982, is added to Title 26 of the Code of Federal Regulations. Part 401 reads as follows:

## PART 401—TEMPORARY PROCEDURES AND ADMINISTRATION REGULATIONS UNDER THE TAX EQUITY AND FISCAL RESPONSIBILITY ACT OF 1982 (PUB. L. 97–248)

Sec.

401.6325–1 Release of liens.

Authority. Sections 6325(a) and 7805 of the Internal Revenue Code of 1954 (68A Stat. 781, 917; 26 U.S.C. 6325(a), 7805).

### § 401.6325–1 Release of liens.

(a) *In general.* The district director shall issue a certificate of release for a filed notice of Federal tax lien not later than 30 days after the date on which the district director finds that the entire tax liability listed in such notice of Federal tax lien has been fully satisfied (as defined in paragraph (c) of this section) or has become legally unenforceable.

(b) *Certificate of release for a lien which has become legally unenforceable.* The district director shall have the authority to file a notice of Federal tax lien which also contains a certificate of release pertaining to those liens which become legally unenforceable. Such release will become effective as a release as of a date prescribed in the document containing the notice of Federal tax lien and certificate of release.

(c) *Satisfaction of tax liability.* For purposes of paragraph (a) of this section, satisfaction of the tax liability occurs when—

(1) The district director determines that the entire tax liability listed in a notice of Federal tax lien has been fully satisfied. Such determination will be made as soon as practicable after tender of payment; or

(2) The taxpayer provides the district director with proof of full payment (as defined in paragraph (d) of this section) with respect to the entire tax liability listed in a notice of Federal tax lien together with the information and documents set forth in paragraph (f) of this section. See paragraph (e) of this section if more than one tax liability is listed in a notice of Federal tax lien.

(d) *Proof of full payment.* As used in paragraph (c)(2) of this section, the term "proof of full payment" means—

(1) An internal revenue cashier's receipt reflecting full payment of the tax liability in question;

(2) A canceled check in an amount sufficient to satisfy the tax liability for which the release is being sought; or

(3) Any other manner of proof acceptableto the district director.

(e) *Notice of a Federal tax lien which lists multiple liabilities.* When a notice of Federal tax liens lists multiple tax liabilities, the district director shall issue a certificate of release when all of the tax liabilities listed in the notice of Federal tax lien have been fully satisfied or have become legally unenforceable. In addition, if the taxpayer requests that a certificate of release be issued with respect to one or more tax liabilities listed in the notice of Federal tax lien and such liability has been fully satisfied or has become legally unenforceable, the district shall issue a certificate of release. For example, if a notice of Federal tax lien lists two separate liabilities and one of the liabilities is satisfied, the taxpayer may request the issuance of a certificate of release with respect to the satisfied tax liability and the district director shall issue a release. See paragraph (c) of this section in determining when a tax lien has been fully satisfied. A request made by the taxpayer shall be made to the district director in accordance with the procedures in paragraph (f) of this section.

(f) *Taxpayer requests.* A request for a certificate of release with respect to a notice of Federal tax lien shall be submitted in writing to the district director (marked for the attention of the

Chief, Special Procedures Function) of the district in which the notice of Federal tax lien was filed. The request shall contain the following—

(1) Name and address of the taxpayer;

(2) A copy of the notice of Federal tax lien affecting the property; and

(3) The grounds upon which the issuance of a release is sought.

(g) *Effective date.* The provisions of this section are effective with respect to a notice of Federal tax lien (1) which is filed after December 31, 1982, (2) which is satisfied after December 31, 1982, or

(3) with respect to which the taxpayer after December 31, 1982, requests that district director to issue a certificate of release on the grounds that the liability was satisfied or legally unenforceable.

There is a need for immediate guidance with respect to the provisions contained in this Treasury decision. For this reason, it is found impracticable to issue it with notice and public procedure under section (b) of section 553 of Title 5 of the United States Code or subject to the effective date limitation of subsection (d) of that section.

This Treasury decision is issued under the authority contained in sections 6325(a) and 7805 of the Internal Revenue Code of 1954 (68A Stat. 781, 917; 26 U.S.C. 6325(a), 7805).

**Roscoe L. Egger, Jr.,**

*Commissioner of Internal Revenue.*

Approved: April 6, 1983.

**John E. Chapoton,**

*Assistant Secretary of the Treasury.*

[FR Doc. 83-10654 Filed 4-20-83; 8:45 am]

BILLING CODE 4830-01-M

## PENSION BENEFIT GUARANTY CORPORATION

### 29 CFR Part 2606

### Rules for Administrative Review of Agency Decisions

**AGENCY:** Pension Benefit Guaranty Corporation.

**ACTION:** Final rule.

**SUMMARY:** This final rule amends the Pension Benefit Guaranty Corporation's regulation on Administrative Review of Agency Decisions by changing the definition of the PBGC's Appeals Board to provide for a Board consisting of three senior agency officials, one of whom is designated chairperson, and to provide for three ex officio members. The purpose of this rule is to provide for a more effective appeals process.

**EFFECTIVE DATE:** April 21, 1983.

**FOR FURTHER INFORMATION CONTACT:** Deborah West, Attorney, Office of the General Counsel, Pension Benefit Guaranty Corporation, 2020 K Street, N.W., Washington, D.C. 20006; (202) 254-3010. (This is not a toll-free number.)

**SUPPLEMENTARY INFORMATION:** On July 19, 1979, the PBGC published a final rule regarding administration review of agency decisions (44 FR 42181). The purpose of the regulation is to ensure that persons who are adversely affected by certain initial determinations of the PBGC are provided with an opportunity to obtain review of those determinations. The current regulation applies to eleven types of determinations and provides for two types of agency review. Seven types of initial determinations are subject to appeal to the Appeals Board; four are subject to reconsideration by an official in the office that issued the initial determination, at a level higher than that of the person who issued the initial determination.

The term "Appeals Board" is defined in § 2606.2 of the regulation to mean a board consisting of the Director of the Office of Program Operations, the Director of the Office of Financial Operations, and the General Counsel, or their designees. The regulation is being amended to provide that the Appeals Board will consist of three senior agency officials appointed by the PBGC's Executive Director, one of whom shall be designated chairman by the Executive Director. If a person is unable to serve on the Appeals Board with respect to a particular case, he or she will be replaced by another senior agency official designated by the Executive Director. The purpose of this change is to provide for a chairperson and to ensure that Appeals Board matters are considered by an Appeals Board comprised of senior agency officials. The definition also provides that the Executive Director or, if unavailable, the Deputy Executive Director and the General Counsel are ex officio members of the Appeal Board and that the General Counsel may vote on any matter before the Board. If a tie results, the appeal will be referred to the Executive Director.

The Pension Benefit Guaranty Corporation has determined that this amendment is not a "major rule" for the purposes of Executive Order 12291, because it will not have an annual effect on the economy of $100 million or more; or create a major increase in costs or prices for consumers, individual industries, or geographic regions; or have significant adverse effects on competition, employment, investment, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets. This conclusion is based on the fact that the amendment is procedural, and advises the public of a change in agency organization.

Because this regulation deals only with matters of agency organization and procedure, a general notice of proposed rulemaking is not required. See 5 U.S.C. 553(b). Further, since a general notice of proposed rulemaking is not required, this rule is not covered by the Regulatory Flexibility Act, 5 U.S.C. 601(2).

Pursuant to 5 U.S.C. 553(d), the agency finds that an immediate effective date for this amendment is needed to effectively administer the PBGC's appeals process and further finds that because it is a rule of agency organization, there is no public advantage in delay. Accordingly, the agency finds good cause to waive the 30-day service period.

**List of Subjects in 29 CFR Part 2606**

Pensions and pension insurance.

In consideration of the foregoing, Part 2606 of Chapter XXVI of Title 29, Code of Federal Regulations is hereby amended as follows:

1. The authority citation for Part 2606 is revised to read as follows:

**Authority:** Sec. 4002(b)(3), Pub. L. 93-406, as amended by sec. 403(e), Pub. L. 96-364, 94 Stat. 1208, 1302 (1980) (29 U.S.C. 1302(b)(3)).

2. In § 2606.2, the definition of "Appeals Board" is revised to read as follows:

**§ 2606.2 Definitions**

* * * * *

"Appeals Board" means a board consisting of a Chairperson appointed by the Executive Director of the PBGC and two senior agency officials appointed by the Executive Director to serve as regular members. Other senior agency officials may serve as alternate members in the event that a regular member is not available to serve or is unable to serve. Such alternates shall be appointed pursuant to a list designated by the Executive Director and shall serve in the order designated in that list. The General Counsel and the Executive Director or Deputy Executive Director shall be ex officio members. The General Counsel as an ex officio member of the Appeals Board may, if he or she chooses, vote on any matter before the Board for a decision. Appeals shall be decided by a majority vote of the Board members, but if the General Counsel votes on an appeal and that results in a tie vote, the appeal will be

referred to the Executive Director as specified in Section 2606.61. A person may not serve on the Appeals Board with respect to any case in which he or she made a determination with respect to the merits of the initial determination.

* * * * *

Issued at Washington, D.C. on this 15th day of April 1983.

Edwin M. Jones,

*Executive Director, Pension Benefit Guaranty Corporation.*

[FR Doc. 83-10524 Filed 4-20-83; 8:45 am]

BILLING CODE 7708-01-M

## DEPARTMENT OF THE INTERIOR

### Office of Surface Mining Reclamation and Enforcement

### 30 CFR Part 946

### Approval of Modification of the Virginia Permanent Regulatory Program Under the Surface Mining Control and Reclamation Act of 1977

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

**ACTION:** Interim final rule.

**SUMMARY:** OSM is announcing interim final approval of a modification of the Virginia permanent regulatory program under the Surface Mining Control and Reclamation Act of 1977 (SMCRA) which would subject interim program operations to the penalty and enforcement provisions of the Virginia program. By letter dated March 22, 1983, Virginia submitted a proposed program amendment consisting of amendments to the Virginia Surface Mining Control and Reclamation Act of 1979.

**DATES:** Effective April 21, 1983. Public comment is invited on the action set forth herein. Written comments must be received on or before 4:00 p.m. on May 23, 1983, to be considered.

**ADDRESSES:** Written comments should be mailed or hand delivered to: Ralph Cox, Director, Virginia Field Office, Office of Surface Mining Reclamation and Enforcement, Highway 23, South, P.O. Box 626, Big Stone Gap, Virginia 24219, Telephone: (703) 523-4303.

Copies of the Virginia program, the March 22, 1983, letter containing the modification to the program, and all written comments received in response to this notice will be available for review at the OSM Offices and the Office of the State regulatory authority listed below, Monday through Friday, 8:00 a.m. to 4:00 p.m., excluding holidays:

Office of Surface Mining Reclamation and Enforcement, Room 5315, 1100 "L" Street, N.W., Washington, D.C. 20240;
Office of Surface Mining Reclamation and Enforcement, Highway 23, South, Big Stone Gap, Virginia 24219;
Office of Surface Mining Reclamation and Enforcement, Flannagan and Carroll Streets, Lebanon, Virginia 24266;
Virginia Division of Mined Land Reclamation, 620 Powell Avenue, Big Stone Gap, Virginia 24219.

**FOR FURTHER INFORMATION CONTACT:** Ralph Cox, Director, Virginia Field Office, Office of Surface Mining, P.O. Box 626, Big Stone Gap, Virginia 24219, Telephone: (703) 523-4303.

**SUPPLEMENTARY INFORMATION:** The Virginia program was conditionally approved by the Secretary of the Interior on December 15, 1981 (46 FR 61088-61115). Information pertinent to the general background, revisions, modifications, and amendments to the proposed permanent program submission, as well as the Secretary's findings, the disposition of comments and a detailed explanation of the conditions of approval of the Virginia program can be found in the December 15, 1981 **Federal Register** (46 FR 61088-61115).

#### Background

When Virginia's permanent regulatory program was conditionally approved on December 15, 1981, it was OSM's understanding, pursuant to Section 506(a) of SMCRA, that a coal mining operation did not have to meet the permanent program *performance standards* until a permanent program permit was obtained.

However, this delay in the applicability of the permanent program performance standards does not apply to the *enforcement* aspects of State programs; Section 506(a) states that after eight months from program approval or longer if the operator submitted his permit application on time but the State has not yet processed it, no one is to mine without a permanent program permit. The purpose of the Section 506(a) exemption is to prevent the termination of ongoing operations due to bureaucratic delay. This exemption from the permanent program permit requirement should not be construed to allow the interim program enforcement mechanisms to continue. States with approved programs must have adequate staff and authority to carry out enforcement similar to Sections 517 and 521 of SMCRA and sanctions which meet the requirements of Section 518. State enforcement is to begin as soon as the program is approved. This enforcement must include cessation orders and notices of violation and must comply with the other Federal inspection and enforcement requirements mandated by SMCRA and approved in the State program.

Section 45.1-226, Article 1, Chapter 19 of the Virginia Code states in part that the provisions of Chapter 17, Title 45.1, will continue in effect for the regulation of operations which have been permitted pursuant to Chapter 17 until the completion of the processing of their applications for permanent program permits under Chapter 19 of Title 45.1. (Chapter 19 of the Virginia Code is the permanent regulatory program; Chapter 17, the interim regulatory program.) Virginia interpreted this section to mean that *all* aspects of the permanent coal surface mining regulatory program in Virginia take effect on the date on which the surface mining operation receives its permanent program permit. Due to this interpretation, questions were raised concerning how the State could implement, enforce and maintain its program, as required by SMCRA.

Pursuant to an ongoing dialogue between OSM and Virginia, an agreement was reached in November 1982 whereby the State would introduce legislation in the Virginia General Assembly to amend the Virginia Surface Mining Control and Reclamation Act (Virginia SMCRA) to provide Virginia officials with immediate authority to issue notices of violation and cessation orders, to impose civil penalties, etc. against existing mine permits prior to repermitting those operations under the State's permanent regulatory program. Upon enactment of this legislation, OSM agreed to withdraw all of the additional Federal inspectors sent into Virginia in July 1982 to ensure adequate inspection and enforcement of mining operations in the State.

On March 22, 1983, Virginia submitted as a program amendment an act passed by the Virginia General Assembly which amends Section 45.1-234.A. of the Virginia Surface Mining Control and Reclamation Act (Virginia SMCRA) to subject interim program operations to the penalty and enforcement provisions of Sections 45.1-245, 45.1-246, 45.1-247, 45.1-249, 45.1-250, 45.1-251 of the Virginia SMCRA and the penalty and enforcement regulations implementing those Sections (Administrative Record No. VA 463).

Also, in the March 22, 1983 letter, Virginia submitted two additional proposed revisions to the Virginia SMCRA. One of the proposed revisions

amends Section 45.1–240 to correct an erroneous cross-reference in the Virginia SMCRA. The other proposed revision amends Sections 45.1–249 and 45.1–251 of the Virginia SMCRA to satisfy condition "q" set by the Secretary in his conditional approval. These additional proposed amendments are the subject of a separate **Federal Register** notice.

**Findings**

The Director finds, in accordance with SMCRA and 30 CFR 732.17 and 732.15, that the program amendment, which subjects interim program operations to the penalty and enforcement provisions of the Virginia SMCRA and its implementing regulations, submitted by Virginia on March 22, 1983, meets the requirements of SMCRA and 30 CFR Part VII.

The approval of this amendment is effective April 21, 1983. To satisfy the public participation requirements for approval or disapproval of State program amendments, the Director is inviting public comment for 30 days on the action set forth herein. Following OSM's review of the comments received, OSM will issue a final rule to announce the Director's final decision on this modification of the Virginia program.

**Additional Determinations**

1. *Compliance with the National Environmental Policy Act:* The Secretary has determined that, pursuant to Section 702(d) of SMCRA, 30 U.S.C. 1292(d), no environmental impact statement need be prepared on this rulemaking.

2. *Executive Order No. 12291 and the Regulatory Flexibility Act:* On August 28, 1981, the Office of Management and Budget (OMB) granted OSM an exemption from Sections 3, 4, 7, and 8 of Executive Order 12291 for actions directly related to approval or conditional approval of State regulatory programs. Therefore, this action is exempt from preparation of a Regulatory Impact Analysis and regulatory review by OMB.

The Department of the Interior has determined that this rule would 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 rule would not impose any new requirements; rather, it would ensure that existing requirements established by SMCRA and the Federal rules will be met by the State.

3. *Paperwork Reduction Act:* This rule does not contain information collection requirements which require approval by the Office of Management and Budget under 44 U.S.C. 3507.

**List of Subjects in 30 CFR Part 946**

Coal mining Intergovernmental relations, Surface mining, Underground mining.

Dated: April 15, 1983.

**Carson W. Culp, Jr.,**

*Acting Director, Office of Surface Mining.*

Part 946 of Title 30 is amended by revising § 946.10 to read as follows:

**§ 946.10 State regulatory program approval.**

(a) The Virginia State Program, as submitted on March 3, 1980, as amended and clarified on June 16, 1980, as resubmitted on August 13, 1981, and clarified in a meeting with OSM on September 21 and 22, 1981, and in a letter to the Director of the Office of Surface Mining on October 15, 1981, was conditionally approved, effective December 15, 1981. Beginning on that date, the Department of Conservation and Economic Development, Division of Mined Land Reclamation, was deemed the regulatory authority in Virginia for all surface coal mining and reclamation operations and all exploration operations on non-Federal and non-Indian lands. Beginning on July 21, August 19, September 21, and December 13, 1982, January 18, and February 28, 1983, the program also included program amendments submitted on January 28, July 9, July 8, August 13, September 30, and December 20, 1982, respectively. Further, beginning on (Insert: date of publication of this notice) the program includes a program amendment submitted on March 22, 1983.

(b) Copies of the conditionally approved program, as amended, are available for review at:

Virginia Division of Mined Land Reclamation, Drawer U, 622 Powell Avenue, Big Stone Gap, Virginia 24219;

Virginia Department of Conservation and Economic Development, 1100 State Office Building, Richmond, Virginia 23219;

Office of Surface Mining Reclamation and Enforcement, Flannagan and Carroll Streets, Lebanon, Virginia 24266;

Office of Surface Mining Reclamation and Enforcement, Room 5315, 1100 L Street, N.W., Washington, D.C. 20240.

[FR Doc. 83-10641 Filed 4-20-83; 8:45 am]

BILLING CODE 4310-05-M

## DEPARTMENT OF DEFENSE

### Office of the Secretary

### 32 CFR Part 366

**[DoD Directive 5141.1]**

### Director, Program Analysis and Evaluation

**AGENCY:** Office of the Secretary, DoD.

**ACTION:** Final rule.

**SUMMARY:** The Secretary of Defense has assigned responsibilities and functions to the Director, Program Analysis and Evaluation (DPA&E), and has delegated specific authorities. This rule (DoD Directive 5141.1) serves as the instrument that authorizes the DPA&E to carry out his charter.

**EFFECTIVE DATE:** This rule was approved and signed by the Deputy Secretary of Defense on September 2, 1982, and is effective as of that date.

**FOR FURTHER INFORMATION CONTACT:** Mr. Arthur H. Ehlers, Director for Organizational and Management Planning, Office of the Deputy Assistant Secretary of Defense (Administration), Washington, D.C. 20301; telephone 202–695–4278.

**SUPPLEMENTARY INFORMATION:** In FR Doc. 79–2233 appearing in the **Federal Register** on January 22, 1979 (44 FR 4470), the Office of the Secretary of Defense (OSD) published the charter of the then Assistant Secretary of Defense (Program Analysis and Evaluation) (ASD(PA&E)). The OSD has revised this part to update the charter and to reflect the renaming of the position from ASD(PA&E) to DPA&E.

**List of Subjects in 32 CFR Part 366**

Organization and functions (government agencies), DoD programs.

Accordingly, 32 CFR is amended by revising Part 366, reading as follows:

## PART 366—DIRECTOR, PROGRAM ANALYSIS AND EVALUATION

Sec.



**Authority:** 10 U.S.C. 125.

**§ 366.1 Purpose.**

This part is reissued and establishes, pursuant to the authority vested in the Secretary of Defense under 10 U.S.C. 125, the position of Director, Program Analysis and Evaluation (DPA&E), with

the responsibilities, functions, and authorities as prescribed herein.

**§ 366.2 Definition.**

*DoD Components.* The Office of the Secretary of Defense, the Military Departments, the Organization of the Joint Chiefs of Staff, the Unified and Specified Commands, and the Defense Agencies.

**§ 366.3 Responsibilities.**

*The Director, Program Analysis and Evaluation,* as the principal staff assistant to the Secretary of Defense for DoD program analysis and evaluation, shall:

(a) Develop policies, provide advice, make recommendations, and participate in the preparation of planning, fiscal, and materiel support guidance upon which DoD program projections are based.

(b) Perform analyses and evaluations of plans, programs, and budget submissions in relation to projected threats, estimated costs, resource constraints, and U.S. defense objectives and priorities.

(c) Identify issues and evaluate alternative programs.

(d) Initiate programs, actions, and taskings to ensure adherence to DoD policies and national security objectives; ensure that programs are designed to accommodate operational requirements and promote the readiness and efficiency of the U.S. Armed Forces.

(e) Review, analyze, and evaluate programs for carrying out approved policies and standards.

(f) Ensure that the costs of DoD programs are presented accurately and completely.

(g) Assess the effects of DoD spending on the U.S. economy, and evaluate alternative policies to ensure that the DoD program can be implemented efficiently.

(h) Provide leadership in developing and promoting improved methods for analyzing national security planning and the allocation of resources.

(i) Serve on boards, committees, and other groups pertaining to the DPA&E's functional areas, and represent the Secretary of Defense on PA&E matters outside the Department of Defense.

(j) Perform such other duties as the Secretary of Defense may assign.

**§ 366.4 Functions.**

In executing assigned responsibilities, the DPA&E shall:

(a) Carry out the responsibilities described in § 366.3 for the following functional areas:

(1) General purpose force structure, both active and reserve.

(2) Strategic and theater nuclear force structure.

(3) Mobility force structure and prepositioning plans.

(4) Force readiness and capabilities.

(5) Weapon systems and major items of materiel.

(6) Implications for manpower resources of specific force structure plans.

(7) Support systems.

(8) Contingency plans.

(9) Materiel support programs and war reserve stocks.

(10) Deployment plans and overseas basing requirements.

(11) Mobilization plans.

(12) Effects of the DoD program on the economy and the industrial base.

(13) Security assistance programs.

(14) Allied and foreign military requirements and capabilities.

(15) Nuclear warhead requirements.

(16) Such other areas as the Secretary of Defense may from time to time prescribe.

(b) Perform critical reviews of requirements, performance, and life-cycle costs of current and proposed weapon systems.

(c) Provide leadership and support to the Cost Analysis Improvement Group in accordance with DoD Directive 5000.4.

**§ 366.5 Relationships.**

(a) In the performance of his duties, the DPA&E shall:

(1) Coordinate and exchange information with other DoD organizations having collateral or related functions.

(2) Use existing facilities and services of the Department of Defense or other federal agencies to avoid duplication and achieve maximum efficiency and economy.

(b) Heads of DoD Components shall coordinate with the DPA&E on all matters related to the functions cited in § 366.4.

**§ 366.6 Authorities.**

The DPA&E is hereby delegated authority to:

(a) Issue instructions and one-time directive-type memoranda, consistent with DoD Directive 5025.1, that carry out policies approved by the Secretary of Defense in assigned fields of responsibility. Instructions to the Military Departments shall be issued through their Secretaries or designees. Instructions to Unified and Specified Commands will be issued through the Joint Chiefs of Staff.

(b) Obtain such reports, information, advice, and assistance consistent with the policies and criteria of DoD Directive 5000.19, as necessary.

(c) Communicate directly with heads of DoD Components. Communications to the Commanders of the Unified and Specified Commands shall be coordinated with the Joint Chiefs of Staff.

(d) Establish arrangements for DoD participation in those nondefense governmental programs for which the DPA&E has been assigned primary cognizance.

(e) Communicate with other government agencies, representatives of the legislative branch, and members of the public, as appropriate, in carrying out assigned functions.

April 18, 1983.

**M. S. Healy,**

*OSD Federal Register Liaison Officer, Department of Defense.*

[FR Doc. 83-10656 Filed 4-20-83; 8:45 am]

BILLING CODE 3810-01-M

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## Department of the Army

## 32 CFR Part 632

## Army Regulation 190-28, Use of Force by Personnel Engaged in Law Enforcement and Security Duties

**AGENCY:** Department of the Army, DOD.

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes policy and procedures governing the use of force by personnel engaged in law enforcement and security duties. It requires that only the minimum amount of force needed to accomplish law enforcement and security duties will be used and further identifies situations where deadly force is authorized. This regulation also delineates training requirements that must be completed by all personnel assigned to law enforcement, security, or U.S. military prisoner guard duties prior to performing these duties.

**EFFECTIVE DATE:** April 21, 1983.

**FOR FURTHER INFORMATION CONTACT:** Major Ronald S. Phillips, (202) 756-1896.

**SUPPLEMENTARY INFORMATION:** Proposed rulemaking was published on pages 8790-8791 of the **Federal Register** of March 2, 1982, and invited comments to be submitted on or before April 1, 1982. Comments were received from one source. The following summarizes the comments, suggestions, and actions taken.

*Comment One:* Some doubt was created relative to the applicability of the proposed rule on civilian contract

guards who perform security duties for the Department of the Army.

*Action Taken:* Section 632.2(a) was revised to include civilian contract guards.

*Comment Two:* The authority citation should be 10 USC 3012.

*Action Taken:* The authority citation was changed to read 10 USC 3012.

*Regulatory Review:* This regulation is not significant under the requirements of Executive Order 12044, and a regulatory analysis is not required. The Department of the Army has also determined as required by the Regulatory Flexibility Act (Pub. L. 96–354) that the proposed rule poses no burden upon small entities.

**List of Subjects in 32 CFR Part 632**

Law enforcement, Security measures, Military personnel.

Dated: April 15, 1983.

**John O. Roach II,**

*Army Liaison Officer with the Federal Register.*

Accordingly, 32 CFR is amended by adding new Part 632.

## PART 632—USE OF FORCE BY PERSONNEL ENGAGED IN LAW ENFORCEMENT AND SECURITY DUTIES

Sec.



**Authority:** 10 U.S.C. 3012.

### § 632.1 Purpose.

This regulation implements DOD Directive 5210.65. It sets uniform policy for use of force by DA law enforcement and security personnel.

### § 632.2 Applicability.

(a) This regulation applies to all DA including Army National Guard and Army Reserve and civilian personnel engaged in law enforcement or security duties, and those civilian contract guard personnel performing security duties. These duties include guarding U.S. Military prisoners and interior guard duties.

(b) Except for personnel guarding U.S. military prisoners, this regulation does not apply to persons assigned to—

(1) A wartime combat zone.

(2) A non-wartime hostile fire area.

(3) Duties with the U.S. Secret Service.

(4) Civil disturbance control. (See para 4–12, FM 19–15.)

### § 632.3 Policy.

(a) Law enforcement and security personnel will use force only when they cannot fulfill their duties without it. They will use the minimum force needed; only as a last resort will they use deadly force. (See § 632.3(c), 632.4, and 632.5.)

(b) Commanders are encouraged to substitute nonlethal devices (such as night sticks) for firearms when adequate for law enorcement and security personnel to safely fulfill their duties.

(c) In evaluating the degree of force needed for specific law enforcement or security situations, consider these options:

(1) Verbal persuasion.

(2) Unarmed defense techniques.

(3) Chemical aerosol irritant projectors (M36). (May be subject to host nation or local restrictions.)

(4) MP club.

(5) MP working dogs.

(6) Deadly force. (§ 632.4)

(d) Entrapment, i.e., inducing someone to commit an offense in order to prosecute that person, is not permitted in law enforcement or security duties.

(e) Use MP working dogs in accordance with the provisions of AR 190–12. Release dogs only if a lesser measure of force would not be effective.

(1) Releasing a sentry dog to apprehend a suspect is a greater measure of force than releasing a patrol dog.

(2) Before releasing a military dog for attack, give a challenge or order to halt.

### § 632.4 Deadly force.

(a) Deadly force is destructive physical force directed against a person or persons (e.g., firing a lethal weapon). Use it only in extreme need, when all lesser means have failed or cannot reasonably be used. Use deadly force for one or more of the following reasons only:

(1) In self-defense, when in imminent danger of death or serious injury.

(2) To protect property related to national security, when reasonably necessary to prevent—

(i) Threatened theft, damage, or espionage aimed at property or information specified by a commander or other competent authority as vital to national security. (See § 632.4(b) below.)

(ii) Actual theft, damage, or espionage aimed at property or information which, though not vital, is substantially important to national security. (See § 632.4(b) below.)

(iii) Escape of an individual whose unauthorized presence near property or information vital to national security is a reasonable threat of theft, sabotage, or espionage.

(3) To prevent actual theft or sabotage of property (such as operable weapons or ammunition) which could cause deadly harm to others in the hands of an unauthorized person.

(4) To prevent serious offenses against a person or persons (e.g., armed robbery, rape, or violent destruction of property by arson, bombing).

(5) To apprehend a suspect believed to have committed any of the types of offenses named in (a) (2), (3), and (4) of this section.

(6) To prevent the escape of a prisoner (when authorized by a commander or other competent authority and reasonably necessary).

(7) To obey lawful orders from higher authority governed by this regulation.

(b) A commander or other competent authority will specify that property or information is—

(1) Vital to national security only when its loss, damage, or compromise would seriously harm national security or an essential national defense mission.

(2) Substantially important to national security based on the mission and the material or information required to perform it.

(c) To comply with local law or international agreement or arrangements, a commander may impose further restrictions on using deadly force. (Restrictions should not unduly compromise U.S. security interests).

(d) Security criteria and standards for protection of nuclear weapons (§ 632.4(c) AR 50–5–1) and for chemical agents (§ 632.4(c) AR 50–6–1) also apply.

### § 632.5 Use of firearms.

(a) If it becomes necessary to use a firearm in any of the circumstances described in § 632.4 above, observe the following precautions when possible:

(1) Give an order to halt before firing.

(2) Do not fire if shots are likely to harm innocent bystanders.

(3) Since warning shots could harm innocent bystanders, avoid firing them. However, when lesser degrees of force have failed, the law enforcement or security person may judge that warning shots would help to control the situation without using deadly force. If able to avoid hazards to innocent persons in these cases, fire warning shots.

(4) Aim to disable. At times it may be difficult to fire with enough precision to ensure disabling rather than killing. If the use of firearms are otherwise authorized by this regulation, such circumstances will not rule out their use.

**§ 632.6 Administrative instructions.**

(a) Commanders will ensure that all persons assigned to law enforcement, security, or US military prisoners' guard duties will, before performing these duties—

(1) Receive instructions on regulations regarding use of force.

(2) Show knowledge and skill in the use of—

(i) Unarmed defense techniques.

(ii) MP club.

(iii) Individual chemical aerosol irritant projectors.

(iv) Their assigned firearms.

(b) Commanders will also—

(1) Provide periodic refresher training to ensure continued proficiency and updated knowledge in these skills. (Include applicable host nation requirements.)

(2) Require MPs with law enforcement duties to qualify yearly with their assigned handguns.

(3) Require interior guards to receive instructions regarding use of force. (Give periodic refresher training to ensure continued familiarity with regulations.)

(c) Requirements concerning use of the MP club and chemical aerosol irritant projectors apply only when these weapons are issued items or are carried on duty.

(d) FM 19–5 contains procedures and methods for using unarmed defense techniques and the MP club.

[FR Doc. 83-10487 Filed 4-20-83; 8:45 am]

BILLING CODE 3710-92-M

## DEPARTMENT OF TRANSPORTATION

### Coast Guard

### 33 CFR Part 100

[CGD11 11-27-83]

### Establishment of Special Local Regulations for the "Annual Spring Regatta"

**AGENCY:** Coast Guard, DOT.

**ACTION:** Final rule.

**SUMMARY:** Special local regulations are being adopted for the Annual Spring Regatta on the Colorado River. This event will be held on 7 and 8 May 1983, at Headgate Rock Dam. The regulations are needed to provide for the safety of life on navigable waters during the event.

**EFFECTIVE DATE:** These regulations become effective on 7 May 1983 and terminate on 8 May 1983.

**FOR FURTHER INFORMATION CONTACT:** Lt N. M. Turner, Commander(bpa), Eleventh Coast Guard District, 400 Oceangate, Long Beach, California 90822, (213) 590–2213.

**SUPPLEMENTARY INFORMATION:** A notice of proposed rule making has not been published for these regulations and they are being made effective in less than 30 days from the date of publication. There was not sufficient time to publish proposed rules in advance of the event or to provide for a delayed effective date.

Drafting Information: The principal individuals involved in drafting this rule are Lt Noris M. Turner, Chief, Boating and Public Affairs Branch, Eleventh Coast Guard District, and Lt Catherine M. Kelly, Project Attorney, Legal Office, Eleventh Coast Guard District.

Discussion of Regulations: The Southern California Speedboat Club's "Annual Spring Regatta" will be conducted beginning 7 May 1983, starting from Headgate Rock Dam. This event will have 50 to 60 13- to 22-foot racing hydroplanes and runabouts that could pose hazards to navigation. Vessels desiring to transit the regulated area may do so only with clearance from a patrolling law enforcement vessel or an event committee boat.

Evaluation: These regulations have been reviewed under the provisions of Executive Order 12291 and have been determined not to be a major rule. This conclusion follows from the fact that the regulated area will be open for the passage of commercial vessels and can be opened periodically to recreational vessels.

**List of Subjects in 33 CFR Part 100**

Marine safety, Navigation (water).

### PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

Final Regulations: In consideration of the foregoing, Part 100 of Title 33, Code of Federal Regulations, is amended by adding the following section:

**§ 100.35–11–1127 Southern California Speedboat Club/Annual Spring Regatta.**

(a) *Regulated area:* The following regulated area will be closed intermittently to all vessel traffic from 8:00 am to 7:00 pm each day on 7 and 8 May 1983: That portion of the Colorado River north of the city of Parker, Arizona, starting from Headgate Rock Dam, thence northeasterly along the natural flow of the river for one (01) mile, on Moovalya Lake.

(b) *Special Local Regulations:* (1) No person or vessel may enter or remain in the regulated area unless participating in the event or authorized by the sponsor of the event to do so.

(2) Procedures For Transiting: The regulated area will be opened every hour on the hour or after each heat or race for minimum of ten (10) minutes for the safe transit of nonparticipant water craft.

(3) These regulations are temporary in nature and shall cease to be in effect or further enforced at the end of the period set forth.

(46 U.S.C. 454; 49 U.S.C. 1655(b)(1); 33 CFR 1.46(b))

Dated: April 12, 1983.

**A. P. Manning,**

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

[FR Doc. 83-10648 Filed 4-20-83; 8:45 am]

BILLING CODE 4910-14-M

### 33 CFR Part 117

[CGD3 (83-007)]

### Drawbridge Operation Regulations; Appoquinimink River, Delaware

**AGENCY:** Coast Guard, DOT.

**ACTION:** Final rule, Revocation.

**SUMMARY:** This amendment revokes the regulations for the Delaware State Highway Route 9 drawbridge, mile 3.5 at Fennimores, Delaware because the bridge has been removed and replaced by a fixed bridge as authorized by Coast Guard Bridge Permit 162–71. Notice and public procedure have been omitted from this action due to the removal of the drawbridge concerned.

**EFFECTIVE DATE:** This rule becomes effective on April 21, 1983.

**FOR FURTHER INFORMATION CONTACT:** William C. Heming, Bridge Administrator, Third Coast Guard District, (212) 668–7994.

**SUPPLEMENTARY INFORMATION:** This action has no economic consequences. It merely revokes regulations that are now meaningless because they pertain to a drawbridge that no longer exists. Consequently, this action cannot be considered to be a major rule under Executive Order 12291. Furthermore, it has been found to be nonsignificant under the Policies and Procedures for Simplification, Analysis, and Review of Regulations (DOT Order 2100.5 of 5–2–80), and does not warrant preparation of an economic evaluation. Because no notice of proposed rulemaking is required under 5 U.S.C. 553, this action is exempt from the Regulatory Flexibility Act (5 U.S.C. 605(b)). It is certified that this action will not have a significant effect on a substantial number of small entities.

**Drafting Information:**

The drafters of this rule are Ernest J. Feemster, project manager, and LCDR Frank E. Couper, project attorney.

**List of Subjects in 33 CFR Part 117**

Bridges.

**PART 117—[AMENDED]**

**§ 117.236 [Removed]**

In consideration of the foregoing, Part 117 of Title 33, Code of Federal Regulations, is amended by removing § 117.236.

(33 U.S.C. 499; 49 U.S.C. 1655(g)(2) 49 CFR 1.46(c)(5) 33 CFR 1.05-1(g)(3))

Dated: April 4, 1983.

**W. E. Caldwell,**

*Vice Admiral, U.S. Coast Guard Commander, Third Coast Guard District.*

[FR Doc. 83-10695 Filed 4-20-83; 8:45 am]

BILLING CODE 4910-14-M

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**33 CFR Part 165**

**[Reg. 83-02]**

## COTP Wilmington, NC, Safety Zone Regulations; Port of Morehead City, North Carolina

**AGENCY:** Coast Guard, DOT.

**ACTION:** Emergency rule.

**SUMMARY:** The Coast Guard is establishing Safety Zones around the perimeter of the State Ports at Morehead City, North Carolina and Radio Island at Beaufort, North Carolina. These zones are needed to conduct training in special port operations. Entry into these zones is prohibited unless authorized by the Captain of the Port.

**EFFECTIVE DATE:** This regulation becomes effective at 1900, Eastern Standard Time, April 17, 1983. It terminates at 1600, Eastern Daylight Savings Time, April 27, 1983.

**FOR FURTHER INFORMATION CONTACT:** LT K. C. Olds, Chief, Operations Department, Coast Guard Marine Safety Office, Wilmington, North Carolina, 28401, Phone: 919-343-4892.

**SUPPLEMENTARY INFORMATION:** A notice of proposed rule making was not published for this regulation and is being made effective in less than 30 days after **Federal Register** publication. Publishing a NPRM and delaying its effective date would be contrary to the public interest since immediate action is needed to prevent possible damage to the port facilities and vessels involved.

*Drafting Information:* The drafters of this regulation are Lieutenant K. C. Olds, project officer, for the Captain of the Port and Commander D. J. Kanter, project attorney, Fifth Coast Guard District Legal Office.

*Discussion of Regulations:* The port operations requiring this regulation will begin at 1900, Eastern Standard Time, April 17, 1983. Due to training exercises by various military units in the vicinity of State Ports and Radio Island, the need exists to control access and control vessel movement within these areas. Landside and waterborne traffic will be prohibited from entering or remaining in the safety zone without prior proper identification and authorization from the Captain of the Port or his designated representative.

**List of Subjects in 33 CFR Part 165**

Harbors, marine safety, Navigation (water) Security measures, Vessels, Waterways.

**PART 165—[AMENDED]**

In consideration of the foregoing, Part 165 of Title 33, Code of Federal Regulations is amended by adding a new § 165.T502 to read as follows:

**§ 165.T502 Safety zone**

(a) *Location:* The following locations are safety zones: The area of the State Ports at Morehead City, North Carolina and the perimeter waters extending out to 500 feet; the area of Radio Island, Beaufort, North Carolina and the perimeter waters extending out to 500 feet.

(b) *Regulations:* (1) In accordance with the General Regulations in § 165.23 of this part, entry into these zones is prohibited unless authorized by the Captain of the Port.

(33 U.S.C. 1225 and 1231; 49 CFR Part 146; 33 CFR 165.3)

Dated: April 18, 1983.

**C. M. Holland,**

*Capt, USCG Executive Secretary, Maine Safety Council.*

[FR Doc. 83-10651 Filed 4-20-83; 8:45 am]

BILLING CODE 4910-14-M

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**33 CFR Part 165**

**[Reg. 83-07]**

## COTP Hampton Roads, VA; Safety Zone Regulations; James River, Newport News, Virginia

**AGENCY:** Coast Guard, DOT.

**ACTION:** Emergency rule.

**SUMMARY:** The Coast Guard is establishing a safety zone in the James River, Newport News, Virginia. The zone is needed to protect watercraft from possible damage during the launching of the submarine USS OLYMPIA from Newport News Shipbuilding Shipway No. 6. Entry into this zone is prohibited unless authorized by the Captain of the Port.

**EFFECTIVE DATE:** This regulation becomes effective at 11:00 AM, Eastern Daylight Time, 30 April 1983. It terminates at 1:30 PM, Eastern Daylight Time, 30 April 1983.

**FOR FURTHER INFORMATION CONTACT:** Lieutenant Commander W. K. Six, Chief, Port Operations Department, Coast Guard Marine Safety Office, Hampton Roads, Norfolk, Virginia 23510, (804) 441-3296.

**SUPPLEMENTARY INFORMATION:** A notice of proposed rulemaking was not published for this regulation and it is being made effective in less than 30 days after **Federal Register** publication. Publishing an NPRM and delaying its effective date would be contrary to the public interest since immediate action is needed to safeguard watercraft and their occupants.

*Drafting Information:* The drafter of this regulation is Lieutenant Commander W. K. Six, project officer for the Captain of the Port.

*Discussion of Regulation:* To prevent possible damage to watercraft and possible injury to their occupants during the launching, no watercraft will be permitted to remain in, enter, moor in, anchor in, or transit this safety zone unless specifically authorized by the Captain of the Port, Hampton Roads, Virginia. U. S. Coast Guard patrol vessels will be on scene to enforce the safety zone monitoring VHF-FM channels 16 and 13. This action is necessary due to the hazards involved in moving a vessel the size of the USS OLYMPIA into a restricted waterway such as the James River. During the launching the USS OLYMPIA will be out of control until assisting tugs can secure the vessel. This rule is in response to a request by the Newport News Shipbuilding and Drydock Company for Coast Guard assistance in providing traffic control and vessel escorts for the launching of the USS OLYMPIA. This action is designed to prevent damage to watercraft and injury to their occupants in the event of collision with the USS OLYMPIA and will accomplish this end by preventing all such traffic from entering the safety zone.

**List of Subjects in 33 CFR Part 165**

Harbors, Marine safety, Navigation (water), Security measures, Vessels, Waterways.

*Regulation:* In consideration of the foregoing, Part 165 of Title 33, Code of Federal Regulations, is amended by

adding a new § 165.T518 to read as follows:

**§ 165.T518 Safety Zone: James River, Newport News, Virginia.**

(a) *Location:* The waters and waterfront facilities located within the following boundaries constitute a safety zone: A line beginning at 36–58–48N Latitude, 76–26–26W Longitude, thence to 36–58–14N Latitude, 76–27–06W, Longitude, thence to 36–59–06N Latitude, 76–28–00W Longitude, thence to 36–59–12N Latitude, 76–26–39W Longitude, thence along the shoreline to the point of beginning. The safety zone will commence at 11:00 AM, Eastern Daylight Time, 30 April 1983 and terminates at 1:30 PM, Eastern Daylight Time, 30 April 1983.

(b) *Regulations:* (1) In accordance with the general regulations in 165.23 of this part, entry into this zone is prohibited unless authorized by the Captain of the Port.

(33 U.S.C. 1225 and 1231; 49 CFR 1.46; 33 CFR 165.3)

Dated: April 8, 1983.

D. C. O'Donovan,

*Captain, U. S. Coast Guard, Captain of the Port, Hampton Roads, U.S. COAST GUARD.*

[FR Doc. 83-10650 Filed 4-20-83; 8:45 am]

BILLING CODE 4910-14-M

## 33 CFR Part 165

[Reg. 83-01]

## COTP Wilmington, NC, Safety Zone Regulations; Approaches to Cape Fear River at Southport, North Carolina

**AGENCY:** Coast Guard, DOT.

**ACTION:** Emergency rule.

**SUMMARY:** The Coast Guard is establishing a safety zone covering the area of Lockwood's Folly Inlet, North Carolina Explosive Anchorage (as defined in 33 CFR 110.170) and around U.S. Army LCU's transiting the Cape Fear River from Military Ocean Terminal Sunny Point south to Cape Fear River lighted bouy #3 thence in a straight line to the eastern most point of the Lockwood's Folly Inlet Explosive Anchorage. This zone is needed to protect watercraft from possible damage during the transiting operations of the U.S. Army LCU's. Entry into these zones is prohibited unless authorized by the Captain of the Port.

**EFFECTIVE DATES:** This regulation becomes effective at 0700, Eastern Daylight Savings Time, May 7, 1983. It terminates at 0700, Eastern Daylight Savings Time, May 13, 1983.

**FOR FURTHER INFORMATION CONTACT:** Lt K. C. Olds, Chief, Operations Department, U.S. Coast Guard Marine Safety Office, Suite 20, 201 N. Front St., Wilmington, North Carolina 28401, Phone: 919–343–4892.

**SUPPLEMENTARY INFORMATION:** A notice of proposed rulemaking was not published for this regulation and is being made effective in less than 30 days after **Federal Register** publication. Publishing a NPRM and delaying its effective date would be contrary to the public interest since immediate action is needed to prevent possible damage to the vessels involved.

*Drafting Information:* The drafters of this regulation are Lieutenant K. C. Olds, project officer, for the Captain of the Port and Commander D. J. Kanter, project attorney, Fifth Coast Guard District Legal Office.

*Discussion of Regulations:* The hazard requiring this regulation will begin at 0700, Eastern Daylight Savings Time, May 7, 1983. The restricted nature of the Cape Fear River, the carriage of hazardous cargo and the reduced amount of visibility and maneuverability of the loaded U.S. Army LCU's pose a threat to other watercraft in the area. This safety zone will only be in effect for U.S. Army LCU's transiting in a loaded condition from the Explosive Anchorage east to the Cape Fear River bouy #3 and thence north to Military Ocean Terminal Sunny Point. Waterborne traffic will be prohibited from entering or remaining in the safety zone when in effect without prior Captain of the Port approval.

**List of Subjects in 33 CFR Part 165**

Harbors, Marine safety, Navigation (water), Security measures, Vessels, Waterways.

## PART 165—[AMENDED]

In consideration of the foregoing, Part 165 of title 33, Code of Federal Regulations is amended by adding a new § 165.T501 to read as follows:

**§ 165.T501 Safety Zone: Cape Fear River and approaches, Southport, North Carolina.**

(a) *Location.* The following locations are safety zones: The Lockwood Folly Inlet, North Carolina Explosive Anchorage (as defined in 33 CFR 110.170). Circles with a radius of 500 yards with the U.S. Army LCU's as their center while transiting easterly from the Explosive Anchorage to Cape Fear River Bouy #3 thence north in the Cape Fear River to Military Ocean Terminal Sunny Point, Southport, North Carolina.

(b) *Regulations:* (1) In accordance with the General Regulations in § 165.23 of this part, entry into this zone is prohibited unless authorized by the Captain of the Port.

(33 U.S.C. 1225 and 1231; 49 CFR Part 146; 33 CFR 165.3)

Dated: April 18, 1983.

C. M. Holland,

*Capt, USCG, Executive Secretary, Marine Safety Council.*

[FR Doc. 83-10653 Filed 4-20-83; 8:45 am]

BILLING CODE 4910-14-M

## ENVIRONMENTAL PROTECTION AGENCY

## 40 CFR Part 52

[A-1- FRL 2331-6; Docket No. NH-1087]

## Approval and Promulgation of Implementation Plans New Hampshire; PSD Permit Notice and Hearing Procedures

**AGENCY:** Environmental Protection Agency (EPA)

**ACTION:** Final rule.

**SUMMARY:** EPA is approving a State Implementation Plan (SIP) revision submitted by the State of New Hampshire. This revision will allow the State to carry out its Prevention of Significant Deterioration (PSD) program delegation in accordance with federal requirements.

**DATES:** This action will be effective June 20, 1983, unless notice is received on or before May 23, 1983, that adverse or critical comments will be submitted.

**ADDRESSES:** Comments may be mailed to Harley F. Laing, Director, Air Management Division, Room 2312, JFK Federal Building, Boston, MA 02203. Copies of the State submittal are available for public inspection during normal business hours at the Environmental Protection Agency, Room 2111, JFK Federal Building, Boston, MA 02203; Public Information Reference Unit, Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460; Office of the Federal Register, 1100 L Street, NW Room 8401, Washington, DC 20408 and the New Hampshire Air Resources Commission, Health and Welfare Building, Hazen Drive, Concord, NH 03301.

**FOR FURTHER INFORMATION CONTACT:** Miriam R. Fastag, State Air Programs Branch, Environmental Protection Agency, Region I, JFK Federal Building, Boston, MA 02203, (617) 223–5130.

**SUPPLEMENTARY INFORMATION:** On November 19, 1982, New Hampshire submitted a revision to its SIP. This revision specifies that the State shall

follow the federal permit notice and hearing procedures of 40 CFR 52.21 in processing new source permit applications subject to federal regulations governing PSD. The purpose of this revision is to comply with the condition in EPA's delegation of authority for implementing the PSD program to New Hampshire on March 18, 1982, that the State would follow the public notice and hearing procedures of the federal rules.

EPA is approving this revision without prior proposal because the Agency views this as a noncontroversial amendment and anticipates no adverse comments. This action will be effective 60 days from the date of this **Federal Register** unless, within 30 days of its publication, notice is received that adverse or critical comments will be submitted. If such notice is received, this action will be withdrawn before the effective date by publishing two subsequent notices. One notice will withdraw the final action and another will begin a new rulemaking by announcing a proposal of the action and establishing a comment period. If no such comments are received, the public is advised that this action will be effective (60 days from today).

### Action

EPA is approving the revision to New Hampshire's permit notice and hearing procedures for permit applications subject to federal PSD requirements.

The Office of Management and Budget has exempted this rule from the requirements of Section 3 of Executive Order 12291.

Under section 307(b)(1) of the Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by (60 days from today). This action may not be challenged later in proceedings to enforce its requirements (see section 307(b)(2)).

Pursuant to the provisions of the Regulatory Flexibility Act, I certify that this rule will not have a significant economic impact on a substantial number of small entities.

### List of Subjects in 40 CFR Part 52

Air pollution control, Ozone, Sulfur oxides, Nitrogen dioxide, Lead, Particulate matter, Carbon monoxide, and Hydrocarbons.

(Secs. 110(a) and 301(a) of the Clean Air Act, as amended (42 U.S.C. 7410(a) and 7601(a)))

Note.—Incorporation by reference of the State Implementation Plan for the State of New Hampshire was approved by the Director of the Federal Register on July 1, 1982.

Dated: April 12, 1983.

**Lee L. Verstandip,**

*Acting Administrator.*

## PART 52—[AMENDED]

Part 52 of Chapter I, Title 40 of the Code of Federal Regulations is amended as follows:

### Subpart EE—New Hampshire

Section 52–1520 is amended by adding paragraph (c)(24) as follows:

**§ 52.1520 Identification of plan.**

* * * * *

(c) * * *

(24) A revision specifying the State will follow federal permit notice and hearing procedures for applications subject to PSD requirements was submitted by the Air Resources Commission on November 19, 1982.

[FR Doc. 83–10456 Filed 4–20–83; 8:45 am]

BILLING CODE 6560–50–M

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## 40 CFR Part 86

**[AMS–FRL 2279–8]**

## Revised Motor Vehicle Exhaust Emission Standards for Oxides of Nitrogen ($NO_x$) for 1981 Through 1984 Model Year Light-Duty Diesel Vehicles; Summary of Decision

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This amended regulation establishes interm oxides of nitrogen ($NO_x$) emission standards for 1984 model year light-duty vehicles belonging to three classes or categories of light-duty vehicles ("engine families") for which EPA has granted waivers from standards otherwise applicable under section 202(b)(6)(B) of the Clean Air Act, as amended ("Act"), 42 U.S.C. 7521(b)(6)(B). Specifically, this amendment applies to one new diesel engine family of American Motors Corporation ("AMC") and two new diesel engine families of Toyota Motor Corporation ("Toyota") which I have determined qualify under the statutory criteria for waivers of the $NO_x$ standard for model year 1984. This action has the effect of setting interim $NO_x$ standards at the most stringent level that will permit AMC and Toyota to market their diesel engine families in model year 1984.

**EFFECTIVE DATE:** May 23, 1983.

**ADDRESSES:** Information relevant to this rule, including the accompanying decision document, is contained in Public Docket EN–82–08 at the Central Docket Section of the Environmental Protection Agency, Gallery I, 401 M Street, SW., Washington, D.C. 20460, and is available for review between the hours of 8:00 a.m. and 4:00 p.m. As provided in 40 CFR Part 2, EPA may charge a reasonable fee for copying services. Interested parties may also obtain the decision document by contacting the Manufacturers Operations Division as indicated below.

**FOR FURTHER INFORMATION CONTACT:** Peter J. Murtha, Attorney/Adviser, Manufacturers Operations Division (EN–340), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, D.C. 20460, (202) 382–2521.

**SUPPLEMENTARY INFORMATION:** Section 202(b)(1)(B) of the Act requires that light-duty vehicles or engines manufactured during or after the 1981 model year shall be subject to regulations containing standards limiting $NO_x$ emissions from such vehicles or engines to no more than 1.0 grams per vehicles mile (g/mi).

Section 202(b)(6)(B) of the Act authorizes the Administrator, upon application by any manufacturer, to waive the statutory $NO_x$ standard for the 1981 through 1984 model years for any light-duty diesel engine families for which the Administrator can make the required statutory finding. I am required to promulgate interim $NO_x$ standards applicable to the subject engine families for those model years for which I have granted waivers.

AMC and Toyota have each submitted a waiver application for their new diesel engine families for model year 1984. My decision to grant the waiver applications is based on the statutory criteria and my determinations about the engine families covered by the applications. My reasoning is explained in detailed in a decision document which may be obtained as noted above.

In that decision document, I granted waivers covering AMC's 1.6 liter (L) new diesel engine family and Toyota's 1.8L new naturally aspirated and turbocharged diesel engine families for the 1984 model year. AMC and Toyota each demonstrated, and I concluded, that these waivers are necessary to permit the use of diesel technology because there is a substantial risk that these new engine families would not be able to meet the $NO_x$ emission standard during the waiver period without encountering significant engine durability and performance problems as well as increased particulate and hydrocarbon emissions.

Moreover, granting these waivers for these engine families will not endanger

public health, because there will not be a significant increase in ambient $NO_x$ levels. In fact, denying these waivers could result in the production of diesel vehicles emitting more particulate matter. Finally, AMC and Toyota have demonstrated that these engine families have met the fuel economy and long-term air quality benefit criteria for receiving waivers.

Having decided to grant these waiver applications, I am simultaneously promulgating regulations adopting emission standards prohibiting $NO_x$ emissions from 1984 model year vehicles of these engine families from exceeding 1.5 g/mi. EPA has afforded interested parties an opportunity to comment on the waiver applications and to participate in a public hearing to consider these requests. No testimony or comments were received. For these reasons, I find that providing notice and an opportunity to comment on this rulemaking before final promulgation is unnecessary. *See* 5 U.S.C. 553(b).

Note.—The Office of Management and Budget (OMB) has exempted this action from the requirements of sections 3 and 7 of Executive Order 12291.

Under the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, EPA is required to determine whether a regulation will have a significant economic impact on a substantial number of small entities so as to require a regulatory flexibility analysis. The interim $NO_x$ standards established by this rulemaking apply to AMC and Toyota only, which are not "small entities" under the Regulatory Flexibility Act. Therefore, pursuant to 5 U.S.C. 605(b), I hereby certify that this rule will not have a significant economic impact on a substantial number of small entities.

These amendments are issued pursuant to sections 202 and 301(a) of the Clean Air Act, as amended, 42 U.S.C. 7521 and 7601(a).

### List of Subjects in 40 CFR Part 86

Administrative practice and procedure, Labeling, Motor vehicle pollution, Reporting and recordkeeping requirements.

Dated: April 15, 1983.

Lee Verstandig,

*Acting Administrator.*

## PART 86—[AMENDED]

For the reasons set forth above, 40 CFR 86.082–8(a)(1)(iii) is revised to read as follows:

**§ 86.082–8 Emissions standards for 1982 and later model year light-duty vehicles.**

(a)(1) * * *

(ii) * * *

(iii) Oxides of nitrogen—1.0 grams per vehicle mile, except that: (A) Oxides of nitrogen emissions from 1982 model year light-duty vehicles manufactured by American Motors Corporation shall not exceed 2.0 grams per vehicle mile; (B) oxides of nitrogen emissions from light-duty diesel vehicles of the following 1982 and later model year engine families shall not exceed the prescribed levels:

| Manufacturer and engine family | Model years | Standard (g/mi) |
|---|---|---|
| General Motors Corp.: | | |
| 1.8 Liter (L) | 1982, 1983, 1984 | 1.5 |
| 4.3L | 1982, 1983, 1984 | 1.5 |
| 5.7L | 1982, 1983, 1984 | 1.5 |
| EF–C | 1983, 1984 | 1.5 |
| Daimler-Benz AG: | | |
| 2.0L | 1984 | 1.5 |
| 2.4L-Naturally aspirated (NA) | 1982, 1983, 1984 | 1.25 |
| 3.0L–NA | 1982 | 1.5 |
| 3.0L–turbocharge (TC) | 1982, 1983, 1984 | 1.5 |
| AB Volvo: | | |
| 2.4L–NA | 1982, 1983, 1984 | 1.5 |
| 2.4L–TC | 1983, 1984 | 1.5 |
| Peugeot: | | |
| 2.3L–TC–XD2S | 1982 | 1.5 |
| XD2S/XD3S–TC | 1983, 1984 | 1.5 |
| 2.3L–NA–XD2C | 1982, 1983 | 1.2 |
| 1.9L–NA–XUD9 | 1983, 1984 | 1.5 |
| Volkswagen AG: | | |
| 1.6L–NA–2250 pound inertia weight class (I.W.) | 1982, 1983, 1984 | 1.3 |
| 1.6L–TC–2250 I.W. | 1982, 1983, 1984 | 1.3 |
| 1.6L–NA 2500 and 2750 I.W. | 1982, 1983, 1984 | 1.4 |
| 1.6L–TC–2500 and 2750 I.W. | 1982, 1983, 1984 | 1.4 |
| 2.0L–NA | 1982, 1983, 1984 | 1.5 |
| 2.0L–TC | 1982, 1983, 1984 | 1.5 |
| Nissan Motor Co.: | | |
| 2.9L | 1982, 1983, 1984 | 1.5 |
| XM1 | 1983, 1984 | 1.5 |
| Isuzu Motors Ltd., 1.8L | 1982, 1983, 1984 | 1.5 |
| Renault, 2.0L | 1982, 1983, 1984 | 1.5 |
| BL Cars, Ltd.: | | |
| 2.4L–TC | 1983, 1984 | 1.5 |
| 3.6L–TC | 1983, 1984 | 1.5 |
| Chrysler Corp., 1.9L–NA | 1984 | 1.5 |
| Ford Motors Co.: 2.4L–TC TX1 | 1984 | 1.5 |
| BMW, 2.4L–TC | 1984 | 1.5 |
| Vehicle Technology, Inc.: | | |
| 4–88 HTA | 1982, 1983 | 1.5 |
| 4–92 HTA | 1982, 1983 | 1.5 |
| 5–92 HTA | 1982, 1983 | 1.5 |
| 6–92 HTA | 1982, 1983 | 1.5 |
| Toyo Kogyo Co., Ltd., TX1 | 1984 | 1.5 |
| American Motors Corp., 1.6L | 1984 | 1.5 |
| Toyota Motor Corp.: | | |
| 1.8L–NA | 1984 | 1.5 |
| 1.8L–TC | 1984 | 1.5 |

[FR Doc. 83-10619 Filed 4-20-83; 8:45 am]

BILLING CODE 6560-50-M

## DEPARTMENT OF AGRICULTURE

### Office of the Secretary

### 41 CFR Part 4–1

### Amendment of Agriculture Procurement Regulations

**AGENCY:** Office of Operations, USDA.

**ACTION:** Final rule.

**SUMMARY:** This rule amends the Agriculture Procurement Regulations by revising the section covering debarment, suspension and the resulting ineligibility of government contractors. It implements the new govermentwide debarment regulations issued by the Office of Federal Procurement Policy. The intent of this amendment is to establish responsibilities, authorities, and procedures to conduct debarment and suspension activity for the purpose of ensuring that contracts are awarded to responsible contractors.

**EFFECTIVE DATE:** April 21, 1983.

**FOR FURTHER INFORMATION CONTACT:** Douglas I. Metzger, Office of Operations, United States Department of Agriculture, Washington, D.C. 20250, (202) 447–5729.

**SUPPLEMENTARY INFORMATION:** This amendment to the Agriculture Procurement Regulations implements the new governmentwide debarment and suspension regulations contained in FPR Temporary Regulation 65 (47 FR 43692, October 4, 1982). The basis for the temporary regulation is Office of Federal Procurement Policy (OFPP) Policy Letter 82–1 which was issued on June 24, 1982, (47 FR 28854, July 1, 1982).

These regulations are prescribed for contracts involving personal property (including agricultural commodities), leases of real property, and nonpersonal services, including construction. While these regulations are applicable only to procurement transactions governed by the Federal Procurement Regulations, they may be adopted by any agency within the Department having the authority to conduct debarment and suspension actions relating to their programs, including the Commodity Credit Corporation.

This rule relates to agency contracting. Therefore, pursuant to 5 U.S.C. 553, it is found upon good cause that notice and other public procedures with respect thereto are impracticable and contrary to the public interest, and good cause is found for making this rule effective less than 30 days after publication in the **Federal Register.** Furthermore, rules relating to agency contracting have been exempted from

the provisions of Executive Order 12291. Lastly, this action is not a rule as defined in Pub. L. 96-354, the Regulatory Flexibility Act, thus, it is exempt from the provisions of that Act.

**Lists of Subjects in 41 CFR Part 4-1**

Government procurement and administration practices and procedures. Accordingly, Part 4-1, Title 41, Code of Federal Regulations, is amended as follows:

1. The authority citation for Part 4-1 reads as follows:

**Authority:** 5 U.S.C. 301, 40 U.S.C. 486(c).

## PART 4-1—GENERAL

2. The Table of Contents for Subpart 4-1.6 is revised to read as follows:

**Subpart 4-1.6—Debarment, Suspension, and Ineligibility**



3. Subpart 4-1.6 is revised to read as follows:

## Subpart 4-1.6—Debarment, Suspension, and Ineligibility

**§ 4-1.600 Scope of subpart.**

(a) This subpart implements and supplements Subpart 1-1.6 of this title by prescribing policies and procedures related to debarment and suspension of contractors under contracts involving personal property (including agricultural commodities), leases of real property, and nonpersonal services, including construction. The policies and procedures in this subpart and Subpart 1-1.6 of this title are not prescribed for sales contracting, however, agencies involved in such activity may wish to adopt these regulations.

(b) Pursuant to the Secretary's delegations of authority in 7 CFR 2.25 and 2.75, the Director, Office of Operations, has been designated as the Department Debarring Officer. The Department Debarring Officer serves as the debarring official as defined in § 1-1.602(h) of this title and is authorized to perform the functions of this subpart and Subpart 1-1.6 of this title. The Department Debarring Officer has delegated debarring authority to the Agricultural Marketing Service for contracts under the School Lunch and Surplus Removal Programs (42 U.S.C. 1755 and 7 U.S.C. 612c).

**§ 4-1.603 Establishment and maintenance of a list of debarred, suspended, and ineligible contractors and agency records.**

**§ 4-1.603-1 Consolidated list of debarred, suspended, and ineligible contractors.**

The Department Debarring Officer shall be the Department's single point of contact with GSA for debarment and suspension actions taken under this subpart. The debarring officer in the Agricultural Marketing Service shall notify the Department Debarring Officer of each debarment and suspension action by promptly submitting a copy of the debarment or suspension notice and any later changes to the debarment or suspension status. The Department Debarring Officer will forward a copy of the notice to GSA for inclusion in the governmentwide consolidated list.

**§ 4-1.604 Treatment to be accorded listed contractors.**

**§ 4-1.604-1 General.**

Contracting officers shall not knowingly solicit offers or bids from, award contracts to, review or otherwise extend the duration of an existing contract with, or consent to a subcontract with any contractor currently listed on the consolidated list, unless there is a compelling reason for such action. Compelling reasons are considered to be present where failure to contract with the debarred or suspended contractor would seriously harm the agency's programs and prevent them from accomplishing their mission requirements. Such an action must be fully justified, and a written determination made by the appropriate agency head of the procuring agency or authorized designee.

**§ 4-1.604-3 Continuation of current contracts.**

Determinations to terminate a contract under § 1-1.604-3 of this title shall be made by the appropriate agency head of the procuring agency or authorized designee.

**§ 4-1.605 Debarment.**

**§ 4-1.605-3 Procedures.**

Whenever a contracting officer becomes aware of possible irregularities or any information which may be sufficient cause for debarment, the case should be immediately referred through agency channels to the appropriate debarring official. The case must be accompanied by a complete statement of the facts (including a copy of any criminal indictments, if applicable) along with a recommendation for action. Where the statement of facts indicates the irregularities to be possible criminal offenses, or for any other reason further investigation is considered necessary, debarring officials should request the Office of Inspector General to assume the investigation. The Office of Inspector General shall advise the debarring official of its findings.

**§ 4-1.606 Suspension.**

**§ 4-1.606-3 Procedures.**

Whenever a contracting officer becomes aware of possible irregularities or any information which may be sufficient cause for suspension, the case should be immediately referred through agency channels to the appropriate debarring official. The case must be accompanied by a complete statement of the facts along with a recommendation for action. Where the statement of facts indicates the irregularities to be possible criminal offenses, or for any other reason further investigation is considered necessary, the debarring official shall request the Office of Inspector General to assume the investigation. The Office of Inspector General shall advise the debarring official of its findings.

**§ 4-1.650 Appeals.**

Decisions of the debarring officer may be appealed by mailing or otherwise furnishing a written notice within 90 days from the date of the decision to the U.S. Department of Agriculture Board of Contract Appeals, Washington, D.C. 20250. A copy of the notice of appeal shall be furnished to the debarring officer from whose decision the appeal is taken. Appeals under this Subpart, 4-1.6 of this title, shall be governed by the rules and procedures of the U.S. Department of Agriculture Board of Contract Appeals set forth in 7 CFR Part 24.

**Authority:** This amendment is made under the authority of 5 U.S.C. 301, 40 U.S.C. 486(c).

Done at Washington, DC, this 18th day of April, 1983.

**Frank Gearde, Jr.,**

*Director, Office of Operations.*

[FR Doc. 83-10632 Filed 4-20-83; 8:45 am]

BILLING CODE 3410-98-M

## DEPARTMENT OF THE INTERIOR

### Bureau of Land Management

### 43 CFR Public Land Order 6374

[CA-13275]

### California; Partial and Total Revocation of Executive Orders

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Public land order.

**SUMMARY:** This order partially and totally revokes two Executive orders which reserved 34.75 acres of public land for lighthouse purposes for use by the U.S. Coast Guard. The lands are included in a pending Recreation and Public Purposes Application and therefore remain closed to operation of the public land laws and mining. The lands will be opened to mineral leasing.

**EFFECTIVE DATE:** April 21, 1983.

**FOR FURTHER INFORMATION CONTACT:** Marie M. Getsman, California State Office, 916-484-4431.

By virtue of the authority contained in Section 204(a) of the Federal Land Policy and Management Act of 1976, 90 Stat. 2751; 43 U.S.C. 1714; it is ordered as follows:

1. Executive Orders of June 8, 1866, and September 10, 1902, which reserved public lands for use of the U.S. Coast Guard, Department of Commerce, for lighthouse purposes are hereby revoked so far as they affect the following described lands:

Humboldt Meridian

Lot 37, Section 26, Township 8 North, Range 1 West, Humboldt Meridian. Humboldt County, California, containing 42.79 acres.

Excluding the following described parcels as shown on that certain Record of Survey prepared by Hansa Engineering Corporation at the request of the Commander, Twelfth Coast Guard District and filed September 29, 1978, at Book 33 of Surveys at Page 46, Humboldt County Records:

*Parcel 1*

Beginning at Point P.I.C; thence S 52°23'40" E 87.62 feet to point P.I.D; thence East 850 feet more or less to the mean high tide line of the Pacific Ocean; thence southwesterly and northwesterly along said tide line to a point which is S 32°08'56" W from the Point of Beginning; thence 275 feet more or less to the Point of Beginning; containing 7.1 acres more or less.

*Parcel 2*

Beginning at Point P.I.F.; thence N 19°37'45" E 216.20 feet to Point P.I.G; thence S 71°12'24" E 185.38 feet to Point P.I.H.; S 18°44'56" W 215.79 feet to Point P.I.I.; thence N 71°19'31" W 188.70 feet to the Point of Beginning; containing 0.94 acres more or less.

The area described aggregates approximately 34.75 acres in Humboldt County.

2. The surface estate of these lands has been classified suitable for disposal to the City of Trinidad under the Recreation and Public Purposes Act of June 14, 1926, as amended, 43 U.S.C. 869; therefore, unless and until appropriate rules and regulations are issued, the lands will not be open to location under the United States mining laws.

3. These lands shall immediately be made available for issuance of patent under the Recreation and Public Purposes Act to the City of Trinidad, California.

4. At 10 a.m., on May 20, 1983, the lands will be open to applications and offers under the mineral leasing laws.

Inquiries concerning these lands should be addressed to the Bureau of Land Management, Room E-2841, Federal Office Building, 2800 Cottage Way, Sacramento, California 95825.

Dated: April 14, 1983.

**Garrey E. Carruthers,**

*Assistant Secretary of the Interior.*

[FR Doc. 83-10005 Filed 4-20-83; 8:45 am]

BILLING CODE 4310-84-M

## FEDERAL COMMUNICATIONS COMMISSION

### 47 CFR Part 74

[BC Docket No. 81-794; RM-3893; FCC 83-153]

### Experimental, Auxiliary and Special Broadcast and Other Program Distributional Services; Rules To Permit Shared Use of Broadcast Auxiliary Facilities With Other Broadcast and Non-Broadcast Entities and To Establish New Licensing Policies for Television Broadcast Auxiliary Stations

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule.

**SUMMARY:** This action amends several rules in Part 74, Subpart F of the Commission's Rules relating to the operation of televison broadcast auxiliary stations. Specifically, the rules are amended to permit shared use of auxiliary facilities with other broadcast licensees and non-licensees. Broadcasters choosing to share their facilities will be permitted to do so for a profit. Several changes in licensing policy are also made, including the elimination of exclusive channel assignments, the elimination of the limit on the number of channels any one licensee can use, and the establishment of a use priority system for resolving interference disputes. These actions are taken to promote the more efficient and cost-effective use of the increasingly crowded electromagnetic spectrum.

**EFFECTIVE DATE:** May 23, 1983.

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

**FOR FURTHER INFORMATION CONTACT:** Michael A. McGregor, Mass Media Bureau, (202) 632-7792.

### List of Subjects in 47 CFR Part 74

Television auxiliary broadcast.

### Report and Order (Proceeding Terminated)

In the matter of an amendment of Part 74, Subpart F of the Commission's Rules to Permit Shared Use of Broadcast Auxiliary Facilities with Other Broadcast and Non-broadcast Entities and to Establish New Licensing Policies for Television Broadcast Auxiliary Stations; BC Docket No. 81-794, RM-3893.

Adopted: April 7, 1983.

Released: April 15, 1983.

By the Commission: Commissioner Fogarty absent; Commissioner Rivera concurring and issuing a statement.

### I. Introduction

1. Before the Commission is a *Notice of Proposed Rule Making*, 46 FR 60024 (1981), in which we solicited comment on a number of proposed amendments to Part 74, Subpart F of our Rules dealing with television broadcast auxiliary stations. The *Notice* was divided into three major sections. The first section, prompted by a petition for rule making filed by the Public Broadcasting Service and a request for waiver submitted by Westinghouse Broadcasting Company, proposed to amend the auxiliary station rules to permit licensees to share their facilities with other entities. The second section proposed to expand the permissible uses of multiplexed audio signals transmitted on broadcast auxiliary stations. The third section of the *Notice* proposed various changes in our auxiliary station licensing policies. We concluded that the proposed amendments, if adopted, would represent a substantial deregulation of the television broadcast auxiliary service.

2. A total of 23 comments representing 42 parties was received. Four parties filed reply comments. A list of those parties submitting comments is included as Appendix C.[1] Not all parties

[1] The text of the rules amended as a result of this proceeding is included as Appendix A. Appendix B contains amendments to FCC Form 313, the application form for auxiliary stations.

addressed every proposal set forth in the *Notice*. Rather than presenting an initial detailed comment summary, we will summarize the comments pertaining to each issue as we address that issue in this *Report and Order*.

**II. The PBS and Westinghouse Proposals To Permit Shared Use of Television Auxiliary Facilities**

3. *Channel Sharing—The Proposal.* Current Commission rules provide that television auxiliary stations are intended primarily for the transmission of program material to be broadcast by television stations owned by or under common control of the licensee of the auxiliary station. When the material transmitted is so used by the licensee, the programming also may be broadcast by any other television station. With limited exceptions, additional uses of auxiliary stations are forbidden. In the *Notice*, we proposed to broaden significantly the permissible use of broadcast auxiliary facilities yet retain the primary broadcast-related purpose of the service. Under the proposed rule, licensees of television auxiliary stations would be permitted to transmit any material—broadcast or non-broadcast—to any other entity whenever the auxiliary station is not being used to feed the licensee's broadcast station. The proposed rule contained no limitations on the amount of time that a facility could be used for alternative purposes. We sought comment on whether such unrestricted shared use ultimately might subvert the nature of the broadcast auxiliary service.

4. *The Comments.* The proposal to permit shared use of auxiliary facilities resulted in nearly unanimous support from the commenters. Of the parties commenting on this issue, only NBC asserts that auxiliary frequencies should be reserved exclusively for broadcast use. The commenters generally express the opinion that permitting shared use of existing facilities would promote the more efficient use of the spectrum and would obviate the need to construct costly parallel facilities. Because some auxiliary stations are used to transmit material to and from satellite earth facilities, Group W states that unlimited shared use will help develop a nationwide domestic satellite network and promote competitive sources of television programming. Educational broadcasters in particular express strong support for the time-sharing proposal. A group of noncommercial licensees filing jointly ["noncommercial licensees"] states that by permitting the collection of additional revenues, the proposed amendments could aid in the formation of new statewide educational television networks and the strengthening of existing networks. PBS adds that facility sharing will further Congressional objectives by allowing public broadcasters to enhance their revenue-generating activities.

5. NBC, however, claims that the proposals will have an adverse effect on already crowded microwave frequencies in larger urban areas. NBC opines that where excess capacity is exhausted or unavailable, intense demand for additional spectrum could siphon frequencies from their primary intended use. According to NBC, the time-sharing proposals could exacerbate congestion in many markets to the point where use of frequencies for broadcast purposes may become impossible "* * * such as when a news emergency creates peak load pressure." If non-broadcast use of auxiliary facilities is allowed, NBC urges that the Commission take necessary precautions to preserve the essential character of the service.

6. Although arguing in favor of shared use arrangements, many commenters express some concern that excessive shared use may subvert the primary function of the broadcast auxiliary service. The Commission expressed similar concerns in the *Notice* and asked for suggestions on how to prevent misuse of auxiliary frequencies. We specifically sought comment on whether a particular limitation should be placed on alternate uses of facilities, such as a 50 percent limit on the total time that a facility could be used for non-broadcast purposes. Cox, Fetzer, and Multimedia, filing jointly ("Cox"), support a 50 percent use limitation. They contend that such a limit represents the minimum protection necessary to prevent a *de facto* reallocation of frequencies. They also assert that a limitation would deter broadcasters from acquiring "or even stockpiling" auxiliary licenses. Cox would enforce the 50 percent limitation by adding a "yes/no" box to the broadcast renewal form asking whether a licensee had complied with the policy. NAB supports a 50 percent limitation on the secondary use of mobile stations licensed in the broadcast auxiliary service. NAB claims that without some limit, unused mobile facilities might be turned into *de facto* fixed links used exclusively for non-broadcast purposes. NAB states that such exclusive non-broadcast use might create prolonged interference. NBC suggests that, if non-broadcast use of auxiliary stations is permitted, television pickup facilities should be restricted to broadcast use between the hours of 3:00 p.m. and 7:00 p.m. According to NBC, such a restriction would ensure the legitimate broadcast use of the service during peak news periods.

7. The other parties specifically addressing this issue argue against the adoption of any percentage limitations. The limitations are opposed as preventing the maximum efficient use of the spectrum. It is asserted that such artifical limitations would encourage wasteful construction of parallel facilities or force the use of high-cost alternatives that would prevent experimentation and the development of specialized uses. Group W states that essential broadcast demands will ensure the integrity of the service. According to Group W, basic broadcast needs and growing scarcity will ensure that only truly excess capacity is utilized for non-broadcast purposes. The commenters representing noncommercial broadcasting interests argue most strenuously against any limitations. According to PBS, about one-half of all public stations use broadcast auxiliary stations to receive regional and national programming. Frequently, these stations are used less than nine hours per day. A 50 percent limitation would limit further use of the facilities for non-broadcast purposes to only 12 of the remaining 15 hours per day. The Ohio Educational Bradcasting Network Commission states that a 50 percent limitation on the use of auxiliary stations "* * * creates burdensome responsibilities on broadcasters in terms of record keeping and reporting without so much as a scintilla of evidence that there is any corresponding public benefit." In reply comments, PBS rebuts NAB's concerns about misuse of mobile facilities as a largely conjectural problem that should be dealt with on an *ad hoc* basis. PBS suggests that such a limitation would not reduce interference unless the total number of pick-up authorizations is reduced.

8. Several commenters indicate that concern over the misuse of broadcast auxiliary facilities could be addressed best through the licensing process. Bonneville International states that broadcasters must be prevented from obtaining auxiliary licenses for the sole purpose of transmitting non-licensee or non-broadcast materials. NAB adds that new authorizations should be granted only to those broadcasters needing a facility for broadcast-related uses. PBS agrees and would require all applicants for new facilities to demonstrate a legitimate broadcast need for the facility. The noncommercial licensees suggest that renewal applicants should be required to show that only excess capacity was leased.

9. *Discussion.* After careful review of the comments, we believe that broadcasters should be given the widest possible latitude in the use of excess capacity on license broadcast auxiliary facilities. We will therefore permit broadcasters to share their facilities with any other entity for the transmission of any material, broadcast or non-broadcast.[2] These measures are intended to promote the more efficient use of the increasingly crowded electromagnetic spectrum. Allowing such shared use, without limitation, should prevent any necessity to construct costly parallel facilities where existing facilities can handle an increased load. These measures also will make the construction of new facilities more cost-effective because the expenses incurred to build and operate new facilities can be partially recouped through shared use.[3]

10. In order to take the fullest advantage of the spectrum efficiencies that shared use will provide, and to afford broadcast licensees maximum flexibility in offering excess capacity to other entities, we will adopt no time limitations on the shared use of television auxiliary facilities. So long as a licensee utilizes its auxiliary stations primarily for legitimate and essential broadcast use, we see no reason to restrict the licensee's station-sharing activities. Forcing auxiliary stations to remain idle when legitimate demands for frequencies exist is precisely the situation that we are attempting to avoid. In the context of this proceeding, we believe shared use limitations would be inefficient and counterproductive to the attainment of our objectives.

11. We have also decided to delete from proposed § 74.631(f) the restriction limiting alternative uses to times when the station is not being used to transmit program material to its associated broadcast station. Technology is available that allows the simultaneous transmission of two video channels on one microwave link. Thus, one channel could feed the licensee's associated broadcast station while the second could be used for alternative purposes. The above-noted restriction, however, would preclude such simultaneous transmissions. We wish to encourage the development of these spectrum-efficient technologies, and the deletion of the proposed restriction clearly facilitates this policy.[4]

12. As indicated in the comment summary, several parties suggest that use limitations are necessary to preserve the primary purpose and continued utility of the television auxiliary service. Although we share some of the concerns voiced by the proponents of such limitations, we believe other, less obtrusive, means should be implemented to assure that the primary function of the service is maintained. To this end we are establishing several safeguards designed to ensure the integrity of the auxiliary service. First and foremost, we will not change our policy of granting broadcast auxiliary authorizations only to licensed television broadcasters. Thus, we will not allow non-broadcast entities to receive licenses in the television auxiliary service.[5] As a result, the television broadcast industry itself will retain complete control over, and responsibility for, the proper use of television auxiliary facilities. Individual television licensees will specify the conditions under which they will share their equipment. If use of a licensee's equipment by another party causes harmful interference, it is the responsibility of the sharing licensee to correct the problem expeditiously. The Commission will hold the broadcast licensee responsible for any interference or misuse of the facilities that occurs during operation by the non-licensed user. We fully expect that television licensees will take these responsibilities seriously since the willful or repeated misuse of auxiliary facilities would certainly impact upon a licensee's qualifications to hold a broadcast authorization.

13. Second, it is important to keep in mind the fact that we are authorizing only the shared use of an existing station's excess capacity. We will not grant new authorizations to licensees seeking only to provide secondary service. Also, we will not permit licensees to obtain additional authorizations in order to divide their primary transmissions between two or more facilities, thereby generating additional excess capacity. Such activity would not only tend to subvert the primary function of the broadcast auxiliary service, but it would also negate much of the spectrum efficiency we are seeking to promote. As suggested by several commenters, oversight of these licensing restrictions will be accomplished by the addition of three questions to the broadcast auxiliary station application, FCC Form 313. The first new question will request a brief statement regarding the primary purpose of the requested auxiliary link. The second question will seek information on the amount of sharing that the applicant anticipates for the new link. Third, we will ask the applicant to tell us the number of auxiliary authorizations already held and the approximate amount of time that these existing stations are being used by other entities. We readily admit that in most instances we are hesitant to add new reporting requirements. However, these new requirements represent a miniscule burden on the licensee while allowing the Commission to implement its important new facility-sharing policies.

14. We also wish to make it clear that the non-broadcast uses authorized in this proceeding are strictly secondary to the primary function of the broadcast auxiliary service. To emphasize this point, we are making two additions to the rules as proposed in the *Notice.* First, we are adding a "non-broadcast use" category to the newly established set of priorities found in § 74.604(c). This addition makes it clear that for the purpose of interference protection, any facility being used for non-broadcast purposes must give way to other facilities being used for *bona fide* transmissions to a licensee's associated broadcast station.[6] Second, we are adding language to new § 74.631(f) that obligates licensees to coordinate their channel sharing activities with other broadcast licensees in the area. This requirement is similar to the provisions recently adopted in BC Docket 81-497, in which we authorized broadcasters to utilize auxiliary frequencies for up to 30 days per year without notifying the Commission.[7] With respect to fixed link

[2] Facility sharing will not be permitted on the four Band B channels between 6.425 MHz and 6.525 MHz that were recently allocated to the Broadcast Auxiliary Service on a secondary basis. *Amendment of Part 2 of the Commission's Rules Governing Frequency Allocations,* 50 RR 2d 1106 (1982). The 6.425 MHz—6.525 MHz band is still allocated primarily to the Local Television Transmission Service, and it would be inappropriate to allow broadcast licensees to share those frequencies to which they have only secondary rights.

[3] In the Notice, we solicited comments concerning the degree to which the instant proposal could satisfy several requests for additional spectrum for aural broadcast STL and intercity relay stations. Although no comment was received in this issue, we encourage aural broadcasters, wherever possible, to use channels that may become available as a result of our action in this docket.

[4] At their current state of development, these channel compression techniques decrease picture quality somewhat. Although we doubt that such operations will become widespread due to this decrease in quality, in particular situations a licensee may deem the quality loss acceptable. So long as the use of these techniques does not interfere with the licensee's primary broadcast-related transmissions or other licensee's uses of the spectrum, we see no reason to prohibit the utilization of these new technologies.

[5] See also paragraph 30, *infra.*

[6] The priority system established in this *Report and Order* is discussed in detail in Section IV, *infra.*

[7] *Amendment of Part 74 of the Commission's Rules to Provide for Short-Term Operation Without Prior Approval,* 50 RR 2d 1492 (1982); § 74.24.

services, this notification process should not pose any particular hardship on the licensee. The obligation to notify other area licensees is most crucial with respect to the shared use of mobile facilities, which have a greater potential for causing interference. We believe this process is more desirable than the restrictions on the use of mobile facilities urged by NAB and NBC. No absolute restrictions are placed on mobile facility sharing, but licensees offering excess capacity for shared use have an affirmative responsibility to inform other licensees of proposed uses. This should enable all area licensees to coordinate the use of their auxiliary facilities in order to prevent interference and disruption of service.[8]

15. The flexible facility-sharing activities that we are authorizing herein represent a significant deregulation of the broadcast auxiliary service. However, with this increased freedom comes increased responsibility. Licensees choosing to share their facilities must be willing to accept that responsibility and conduct their channel sharing affairs accordingly. Certainly we will not hesitate to revisit our actions if it appears that licensees are misusing their auxiliary facilities to the detriment of the broadcast auxiliary service.

16. *Profit Making vs. Nonprofit Sharing of Facilities—The Proposal.* At paragraph 10 of the *Notice*, we solicited comment on whether licensees should be able to sell their excess capacity to other entities for a profit or instead be limited to nonprofit, cost-sharing arrangements. We noted our concern that licensees operating on a for-profit basis may take on certain characteristics of communications common carriers, but that broadcast licensees had traditionally not been subject to common carrier regulation under Title II of the Communications Act. Before deciding this issue, we noted that "* * * a record should be developed that adequately addresses all the relevant legal and policy ramifications and associated common carrier implications * * *" of the proposal to sell excess capacity for a profit.

17. *The Comments.* With one exception, all parties commenting on this issue urge that licensees be free to make a profit on their shared use of broadcast auxiliary facilities.[9] As a matter of policy, Cox contends that allowing licensees to charge for their excess time is consistent with a marketplace approach. Cox also asserts that profit making will allow greater licensee flexibility while creating more incentives for efficiency, innovation and experimentation. The Christian Broadcasting Network states that in addition to encouraging new links and program services, permitting profit making will avoid economic distortions that might develop if cost-sharing were mandated. According to CBN, cost sharing may result in overdemand for broadcast auxiliary facilities. PBS adds that there is no compelling regulatory interest to justify a prohibition on profit making so long as auxiliary facilities are used and obtained primarily for broadcast purposes. Group W contends that the line between cost sharing and profit making is sufficiently blurred to preclude restrictions on profit making. Group W avers that the differences between costs saved and dollars earned are more semantic than real. According to Group W, the record keeping and accounting burdens on licensees plus the policing burden on the FCC are further reasons not to adopt the cost-sharing option. The noncommercial licensees filing jointly aver that making a profit on the sale of excess capacity is essential. They contend that the measure will provide sorely needed revenues at a time of diminishing federal support for noncommercial stations. Several other noncommercial entities suggest that the profit-making option is consistent with Commission attempts to promote the financial self-sufficiency of public broadcasters and is just what Congress had in mind when it passed Section 399B of the Communications Act which permits public broadcasters to engage in the offering of services for remuneration. The Ohio Educational Broadcasting Network Commission states that auxiliary facilities should join earth stations, studios, towers, and remote equipment among the facilities available for resale.

18. *Discussion.* We are of the opinion that broadcast licensees should be permitted to offer the excess capacity of their auxiliary facilities to others on a for-profit basis. Several factors lead us to this conclusion. First, it clearly reflects the intent of Congress in its recent decision to permit noncommercial broadcast stations to offer their facilities to others for remuneration.[10] The noncommercial broadcasters commenting on this issue indicate that the additional revenues gained through offering their auxiliary stations to others may prove crucial in their efforts to overcome reduced federal funding. By allowing profit making, we are continuing our efforts to develop a regulatory environment that permits public broadcasters to make the most efficient use of their facilities and thereby supplement their revenues in the face of dwindling federal financial support.

19. The argument of Group W, that the distinction between dollars earned and costs saved is often more semantic than real, also supports our decision. Group W intends to transmit a programming package to various buyers across the country via its interconnected auxiliary station/satellite earth station network. Consumers will be purchasing a delivered finished product. It makes little sense to require Group W, for example, to charge for the distribution of the package on a cost-sharing basis when the company can then charge a higher price for the programming component. The total price to the buyer would remain the same. Because it would be nearly impossible to allocate monies consistently to one function or the other, establishing a cost-sharing scheme for the distribution segment of such a service would be meaningless at best and possibly counterproductive due to increased administrative costs.

20. Finally, we do not anticipate that profit making will impede the proper functioning of the broadcast auxiliary service. Any broadcasters who may be tempted to subordinate the public interest to their own private pecuniary interests run the risk of jeopardizing their standing as licensees. Also, our resolve not to permit new authorizations for secondary uses forecloses the possibility of licensees seeking additional facilities solely to engage in profit making channel sharing activities. In short, profit making offers potential

[8] We also note that, although available to broadcasters only on a secondary basis, licensees may utilize the spectrum between 6.425 MHz and 6.525 MHz solely for television broadcast operations. Of course, use of those channels must be cleared first with the local LTTS operator. See n. 2, *supra*.

[9] The California State Communications Division was the only commenter supporting nonprofit, cost-sharing use of auxiliary facilities. The Division, however, offered no reasons for its position. Bonneville International, while having no fundamental objection to profit making in this context, believes that guidelines should be established to prevent broadcasters from subverting public interest programming considerations to profit-making objectives. Bonneville, however, offered no suggestions as to the content of any such guidelines.

[10] Omnibus Budget Reconciliation Act of 1981, section 1231, 47 U.S.C. 399B(b)(1). The Act further requires that such an offering "shall not interfere with the provision of public television services." Because we are enacting several safeguards to prevent the misuse of auxiliary frequencies, we do not believe that permitting channel sharing will in any way interfere with the provision of public television services.

benefits to all licensees—particularly noncommercial broadcasters—without, we believe, adversely affecting the auxiliary service.

21. *Common Carrier Regulation—The Comments.* With nearly unanimous agreement, the commenters contend that offering broadcast facilities on a for-profit basis does not require the Commission to engage in common carrier regulation of such activity.[11] The parties claim that licensees will be highly selective in allowing use of auxiliary facilities by others so as not to disturb the facilities' principal broadcast use. Licensees must retain control of their facilities in order to make them available for essential broadcast purposes. Therefore, licensees will not hold out their facilities indiscriminately on a first come, first serve basis, but will make individualized decisions for each potential user. The parties argue that, under the rationale of *National Association of Regulatory Utility Commissioners* v. *FCC*, 525 F. 2d 630 (D.C. Cir. 1976), *cert. denied*, 425 U.S. 992 (1976) (*"NARUC I"*), entities that make individualized decisions whether and on what terms to deal are not common carriers subject to Title II regulations.

22. Individual commenters make several other arguments against the imposition of common carrier status. According to the Florida Public Broadcasting Service ("FPBS"), the intent of the Omnibus Budget Reconciliation Act and the Public Telecommunications Financing Act is to allow public stations to hold out facilities for hire without incurring common carrier status. FPBS also states that selling excess capacity on satellite earth stations is not a common carrier activity, and that selling excess capacity on broadcast auxiliary stations should be accorded similar treatment. Finally, Christian Broadcasting Network and Fisher suggest that any instances of common carrier activity arising from the sale of broadcast auxiliary capacity would be infrequent. Fisher adds that there is no danger of monopoly pricing practices because there will be an abundance of competition. CBN and Fisher conclude that if common carrier activity becomes substantial, the Commission can revisit the area and take appropriate action at that time.

23. *Discussion.* As most of the commenting parties stressed, the District of Columbia Circuit Court of Appeals in *NARUC I* specifically stated that a carrier will not be a common carrier where its pratice is to make individualized decisions, in particular cases, whether and on what terms to deal. 525 F. 2d at 641. The Court noted that a common carrier need not serve the whole public, and private carriers may serve a significant clientele. The Court then proceeded:

> Since given private and common carriers may therefore be indistinguishable in terms of the clientele actually served, it is difficult to envision a sensible line between them which does not turn on the manner and terms by which they approach and deal with their customers. *Id.* at 642.

The Court then stated that in determining whether a particular carrier should be accorded common carrier status, a finding must be made as to whether any legal compulsion to serve indifferently exists, or whether there are resons implicit in the nature of the operation to expect an indifferent holding out.

24. Clearly there exists no legal compulsion for licensees to offer their facilities in an indifferent manner. Such a requirement would be directly contrary to the primary broadcast-related purpose of the broadcast auxiliary service, which is intended to serve the program distribution needs of the television industry. Thus, we can not discern, nor would we establish, any legal requirement that broadcast licensees offer their broadcast auxiliary facilities on an indifferent basis.

25. With respect to the second test for classifying common carriers, whether there are reasons implicit in the nature of the operation to expect an indifferent holding out, we believe that such holding out is unlikely to occur. The demands of the licensee's broadcast transmission needs should preclude a general and indifferent holding out to all potential users. We suspect, and the commenters on this issue state, that licensees will negotiate with and select users on a highly selective basis due to licensees' own demands for the facilities. Because licensees must retain complete control of their facilities to ensure the integrity of their broadcast services, it does not appear that they will be in a position to offer indifferently their facilities to other users.[12] Moreover, with respect to the distribution services envisioned by Group W and PBS, it appears that they would be marketed on the basis of long-term syndication contracts with potential buyers. Both of these factors—the individualized selection of clients and the establishment of service through long-term contracts—were factors thought by the Court in *NARUC I* to be inconsistent with common carrier status. 525 F. 2d at 643. We can find no basis for believing that anything inherent in the channel sharing activities of broadcast licensees will lead them to make indifferent offerings of excess channel capacity. Thus, we find the imposition of common carrier regulation inappropriate in this context.

26. The Court in *NARUC I* warned that, if common carrier activity did ensue, it would be incumbent on the Commission to determine the extent to which traditional Title II regulation should be applied. *Id.* at 644. Because of the essential nature of the broadcast services performed by auxiliary facilities, and because of the safeguards we are establishing to prevent licensees from obtaining new stations solely for nonbroadcast use, we do not anticipate that our initial analysis will be proven wrong. However, in the event that licensees do begin behaving like common carriers, by indiscriminately offering their facilities to all potential users, we can certainly revisit this issue and make appropriate changes in our treatment of licensee channel sharing activities, either by treating the activity as a common carrier offering subject to Title II and state regulation, or by not permitting it to continue.

27. *Reporting Requirements/Oversight of Sharing Agreements—The Comments and Discussion.* In response to our queries regarding whether the Commission should institute any continuing reporting requirements or undertake to review any facilities-sharing agreements, the commenters universally state a lack of need for any such regulations. With respect to facility-sharing agreements, PBS notes that similar agreements concerning the use of satellite facilities are no longer submitted routinely to the Commission. PBS states that because many distribution systems utilize satellite earth stations and auxiliary stations, the Commission's treatment of both types of facilities should be the same. Aside from

[11] PBS suggests that even if common carrier regulation is imposed, broadcasters should have the option of filing tariffs and making a profit or offering their facilities on a nonprofit, cost-sharing basis.

[12] We realize that it is technologically possible, using channel compression techniques, for a licensee to transmit two video signals simultaneously on a single microwave link. Thus, a licensee theoretically could use these techniques to generate a full-time video channel of excess capacity. We do not anticipate, however, that licensees will make widespread or routine use of these channel compression techniques because at this stage of their development they result in decreased picture quality. Nor do we expect, given broadcasters' continuing need for a high quality video signal pathway, that licensees will be any less selective in their offering of such compression-based capacity than they would if only a single video channel were available to them. Thus, we do not believe that our common carrier analysis will be significantly affected.

the minimal additions we are making to the auxiliary station application form discussed at paragraph 12, we will not initiate any continuing reporting requirements to monitor the use of auxiliary facilities. We do not expect any problems to arise from our rule amendments, and reporting requirements would constitute a needless and costly burden on licensees. Because we are imposing no restrictions on the shared use of licensee facilities, we see no valid purpose in requiring licensees to submit copies of their shared use agreements to the Commission. Again, such a requirement would exact a burden on licensees with no corresponding benefit to the Commission or the public. Therefore, user agreements need not be filed with the Commission.[13]

28. *Miscellaneous Issues.* Several commenters raise additional issues concerning shared use of auxiliary facilities. The California State Communication Division urges the Commission to allow broadcast auxiliary licensees to interconnect their facilities with terrestrial microwave stations in the Private Operational Fixed Microwave Service (POFMS) that are operated by public entities. To the extent that broadcast auxiliary licensees utilize only their excess capacity, nothing would prevent such interconnection. However, as stated previously, we will not license new broadcast auxiliary stations for non-broadcast purposes. Thus, we would not authorize a new auxiliary station merely for interconnection with, or extension of, a POFMS network.

29. Gill Industries and Hughes Aircraft Company, Microwave Communications Products ("Hughes"), ask that the time sharing proposals being implemented in this docket be extended to Community Antenna Relay Service (CARS) operators licensed under Part 78 of the Commission's Rules. They contend that the same reasons supporting shared use for broadcast facilities also apply to CARS facilities. We agree that the logic of our actions easily might be extended to CARS. However, CARS facilities are utilized by an entirely different set of licensees, and we believe that it would be both unfair and unwise to extend our actions to CARS without first notifying those licensees of our intentions. Nothing in the instant *Notice* remotely suggested that we might extend our actions to CARS facilities, and, absent such prior notice, we will not do so.[14]

30. In the same vein, Entertainment and Sports Program Network (ESPN) asserts that non-broadcast entities should be permitted to obtain licenses in the broadcast auxiliary service. ESPN states that, because they are neither broadcasters nor cable system operators, certain entities such as ESPN which produce and distribute programming are not eligible to receive auxiliary licenses. However, because their material is intended for broadcast or cablecast purposes, they likewise are precluded from obtaining facilities in the private radio services. ESPN avers that the shared use proposals will not adequately remedy this problem, and that the only satisfactory answer is for such program producers to receive their own authorizations. We recognize ESPN's problem, but we do not believe that this proceeding is the proper forum for resolving it. As with the proposal to expand our actions to CARS, the *Notice* contained no reference to expansion of the entities eligible for broadcast auxiliary authorizations. Indeed, one of the principal safeguards against misuse of broadcast auxiliary facilities is our resolve to limit licensing to broadcast station licensees. Further, allowing non-broadcast entities to receive Part 74 licenses surely would constitute a reallocation of frequencies that must be preceded by public notice. For these reasons, we decline to act on ESPN's request in this docket.

### III. Expanded Use of Multiplexed Audio Signals Transmitted Over Television Auxiliary Broadcast Stations

31. *The Proposal.* Under current Commission policy, the transmitter of a television broadcast auxiliary station may be multiplexed to provide additional communication channels for the transmission of aural program material and operational communications. However, multiplexed audio material may be used only by AM, FM, or TV broadcast stations owned by or under the common control of the licensee of the broadcast auxiliary station. Thus, broadcast or non-broadcast entities may not utilize the multiplexed audio material transmitted over another licensee's auxiliary facilities. By contrast, video programming transmitted over auxiliary facilities may be utilized by any other broadcaster if the subject programming is broadcast by the transmitting licensee. In the *Notice* we stated that the discrepancy in the permitted uses between audio and video programming transmitted via television broadcast auxiliary stations made little sense, and we proposed to allow the greatest possible latitude in the use of audio signals transmitted over television broadcast auxiliary stations.

32. *The Comments.* Fourteen of the comments filed in this proceeding specifically addressed this topic. Most of those comments merely express support for the proposal for much the same reasons they supported the facility-sharing proposals discussed above. However, several parties offer more specific comments. National Public Radio supports the proposals as promoting spectrum efficiency and providing opportunities for licensees to recoup some of the cost of maintaining auxiliary facilities. NPR specifically favors the multiplexing proposal because facilities then could be made available to public radio which would aid in the production and distribution of radio programming. The Christian Broadcasting Network argues against placing any restrictions on the type of material transmitted over broadcast auxiliary stations or on the permissible receiver of multiplexed material. Such a nonrestrictive policy would have clear spectrum and cost efficiencies, according to CBN.

33. The National Association of Broadcasters considers parallel regulation of audio and video transmission essential. NAB notes that either the multiplexed audio channels or the primary video transmission (or both) may possess excess capacity, and it concurs in the Commission's proposal to permit the greatest possible latitude in the use of multiplexed audio signals. However, NAB points out that proposed § 74.631(d) makes no specific reference to the number of audio channels or control signals that may be multiplexed, except for the general provision against causing harmful interference to stations transmitting television broadcast material. NAB contends that interference can be caused to facilities on adjacent channels by exceeding the allowable emission bandwidth and that the number of possible channels that can be multiplexed without exceeding that bandwidth is limited. NAB suggests that the Commission consider specific technical requirements "which do not preclude the number and nature of available multiplexed transmissions, yet provide a mechanism whereby a licensee can ensure that its auxiliary facility cannot reasonably be expected

[13] As suggested in the *Notice*, we will also delete the reporting requirements from § 74.631(h) of the Commission's Rules.

[14] We note that Westinghouse Broadcasting and Cable, Inc. recently filed a petition for rule making proposing, *inter alia*, that channel sharing be permitted for CARS licensees.

to cause adjacent channel interference to other television auxiliary facilities."

34. *Discussion.* The comments clearly demonstrate that greater discretion should be afforded broadcasters in their use of multiplexed audio signals transmitted over broadcast auxiliary stations. No commenter opposed expanding the permissible uses of such signals, and those commenters favoring the rule amendments argued for the widest possible latitude in the transmission of multiplexed material. In the *Notice* we proposed the unrestricted use of multiplexed audio material. However, at this time we see no need to limit multiplexed signals to audio material. We will therefore permit the transmission of all multiplexed material, such as data, telemetry, or facsimile. Thus, aside from the prevention of harmful interference to other broadcast auxiliary station licensees, we will impose no restrictions on a broadcaster's use of multiplexed signals. To the extent that a licensee has excess capacity, that capacity may be utilized to transmit any type of material to any entity. Also, for the same reasons outlined in Section II, above, licensees will be permitted to sell their excess capacity to other users on whatever basis they choose. We also do not intend to institute any reporting or oversight regulations of these secondary uses of broadcast auxiliary stations. As with sharing of the primary video channel, licensees must retain complete control of their facilities and are wholly responsible for their proper use.

35. With respect to the suggestion of NAB that we adopt specific technical standards to prevent adjacent channel interference, we believe such standards are unnecessary. As NAB notes in its comments, there is a limited number of channels that can be multiplexed without exceeding the emission limitations set forth in § 74.637 of the Rules. These emission limitations have proved adequate in the past and there is no evidence that they will be less so in the face of more intensive multiplexing. Accordingly, in view of the flexibility provided by the proposed rule, we believe that no additional action on this question is warranted at the present time.

## IV. Licensing Policy

36. *The Proposals.* The final section of the *Notice* dealt with various aspects of our licensing policy and proposed to bring the Commission's rules in line with actual Commission licensing practice. First we noted that due to increased demand for auxiliary channels, exclusive channel assignments were no longer granted. We therefore sought comment on our proposals to eliminate any reference in our rules to exclusive assignments and to rescind all existing exclusive assignments. In order to further promote the more efficient use of the spectrum, we proposed to grant only single frequency authorizations for fixed link services. We also proposed to end current restrictions on the number of authorizations any one licensee could possess. In recognition of the fact that the Commission staff no longer conducts frequency coordination for every application for a new authorization that is submitted, we proposed relying on licensee assurances that the frequency selected for a proposed station was appropriate and calculated to avoid creating interference to existing services. Under the proposed rule, applicants for new stations would be free to conduct their own frequency coordination studies or rely on information provided them from local frequency coordination committees where they exist. We stated that whether the frequency coordination was done through a committee or individually, assuming the other aspects of the application were in order, the application would be granted on the assumption that the frequencies requested would not interfere with existing services.

37. Assuming that some interference complaints would be brought to the Commission, we proposed implementing a priority system as a mechanism for resolving interference disputes between existing licensees. The priority system would also be used to determine which channels would be withdrawn in case over-crowding resulted in a new licensee being unable to obtain a vital auxiliary link. Under the system proposed, STLs and CARS links were afforded highest priority. Intercity relay stations and television pickup stations tentatively were assigned the second and third priorities, respectively. Fourth priority was proposed for fixed links operating outside a licensee's local service area and translator relay stations. Lowest priority was proposed for normally unused alternate or backup facilities and television pickup stations operating outside a licensee's local service area. In the *Notice*, we anticipated utilizing the priority list for resolving interference disputes and for withdrawing existing authorizations in the unlikely event that overuse of the spectrum made additional channels unavailable.

38. *Exclusive Channels—The Comments.* The Commission's rules provide that licensees may request and obtain the right to operate exclusively on a particular frequency in a given market. In the *Notice* we sought comment on our proposal to eliminate these exclusive channel assignments. Comments in response to this proposal were mixed. CBS, Cox, Fisher, Gill, and Hughes support the elimination of exclusive assignments while NAB, two sets of noncommercial educational licensees, and NBC favor retaining at least some exclusive authorizations. Acknowledging that the Commission has not granted exclusive assignments in several years, CBS asserts that the rules should be amended to reflect the actual practice of the Commission. CBS further contends that exclusive assignments are not an efficient use of the spectrum. CBS argues that existing exclusive authorizations should be allowed to expire at the end of the licensee's current license term. Cox suggests that existing exclusive assignments could be terminated prior to expiration of the license term since the termination would be the result of a rule making of general applicability. Based on its experience in the use of Band D frequencies, Hughes states that the same frequencies can be reused extensively in the same geographic area on different azimuths. According to Hughes, exclusives preclude such reuse and are therefore wasteful.

39. NAB opposes the rescission of existing exclusive assignments and suggests that such assignments should be "grandfathered" subject to voluntary relinquishment by agreement of the licensee. NAB states that if existing exclusive authorizations are eliminated, licensees should be given advance notice of the rescissions. NBC avers that, at the very least, every licensee should be granted one exclusive assignment for use as the licensee sees fit. The noncommercial licensees state that we should retain exclusive authorizations for STLs, but otherwise allow nonexclusive grants on a strict, non-interfering basis. A second group of noncommercial licensees, represented by Schwartz, Woods & Miller (hereinafter "Schwartz"), asserts that Commission policy must be founded on the protection of essential auxiliary services, and that elimination of exclusive authorizations would preclude these necessary protections. Schwartz contends that exclusive assignments must be maintained to guarantee a legitimate expectancy of continued uninterrupted use. According to Schwartz, severe economic costs will result from disruptions in service and instability if exclusive assignments are eliminated. Schwartz states that frequency coordination costs will

increase and program disruptions will become more common and opines that these factors will offset any resulting gains in spectrum efficiency.

40. *Discussion.* As stated in the *Notice*, due to the increasing demand for channels in the bands allocated to the television broadcast auxiliary service, the Commission has not granted exclusive channels for the past several years. The commenters present no evidence that the absence of additional exclusive authorizations has jeopardized in any way the proper functioning of television broadcast stations. Further, as Hughes correctly points out, the same frequencies can be used within a market so long as the transmit and receive points are taken into consideration. For these reasons, we will formalize our recent practice and eliminate any reference in our rules to the issuance of new exclusive authorizations in the television broadcast auxiliary service. Further, nothing in the comments persuades us that existing exclusive assignments should be retained. Those existing exclusive assignments represent an inefficient use of increasingly crowded spectrum. We wish to emphasize that all licensees still will have the protected use of a particular frequency on a specific pathway. Proper frequency coordination in a given market effectively should preclude interference on those protected pathways. Thus, we do not foresee any change in circumstances for those licensees losing the "exclusive" status of their existing authorizations. At the expiration of a licensee's present license period, any exclusive authorization held by that licensee will lapse. Those auxiliary licenses will be renewed as usual, but not on an exclusive basis. This action should help alleviate the congestion arising in the use of auxiliary frequencies without making any perceptible change in the level of interference that licensees currently experience.[15]

41. *Frequency Coordination and Application Procedures—The Comments.* Section 74.604(a) of the current rules states that the Commission no longer conducts frequency coordination for the auxiliary service. We stated in the *Notice* that we grant licenses on an inference of noninterference to existing users and sought comment on whether our inferences were well-founded. We also asked interested parties to respond to our proposal to acknowledge formally the existence of local frequency coordination committees and rely on those committees to provide frequency selection information to applicants for new authorizations. Again, we received mixed reactions to our proposals and no consensus among the commenters exists. Most of the parties addressing this issue agree that frequency coordination at the local level makes sense, and they support the use of local frequency coordination committees as a reliable clearinghouse for area frequency use information. Fisher specifically endorses the use of local frequency coordination committees and adds that in Seattle and Portland local coordination is an ongoing process which to date has been quite successful. With respect to frequency selection, CBS would require applicants to make a reasonable search of other auxiliary licensees in an area and the frequencies assigned to those licensees. CBS states that the approval and recommendation of certain frequencies by a local coordinating committee should be considered *prima facie* evidence of reasonableness. In an effort to facilitate local frequency coordination, several parties suggest that the Commission establish and make available a nationwide auxiliary frequency data base, with users reimbursing the Commission for costs.

42. Although the noncommercial licensees filing jointly do not oppose local frequency studies by prospective licensees, they do object to giving local coordination committees any authority to assign frequencies or resolve disputes. According to these licensees, such committees are susceptible to local political pressures that could conceivably affect their impartiality. Another group of noncommercial licensees (Schwartz) opposes giving local committees any authority. Schwartz asserts that the Commission should not shirk its statutory responsibilities nor abdicate its essential licensing role. Cox argues that the FCC must retain an active role in frequency assignment and coordination. Citing Sections 303(a)-(d) of the Communications Act of 1934, as amended, Cox contends that the Commission is obligated to assign frequencies and locations in the public interest. Cox maintains that our proposals give local frequency coordination committees too much power. Instead, local committees should be limited to providing information. Cox suggests that any rule adopted should emphasize that the role of local coordination committees is advisory and that the Commission has ultimate authority to assign frequencies.

43. *Discussion.* After carefully reviewing the comments, we continue to believe that local frequency coordination remains the most efficient process for licensees to select appropriate television auxiliary frequencies. The Commission simply does not have the resources to coordinate every auxiliary application submitted, and the comments contain no implications that this system of local frequency coordination has created any problems for licensees. However, in light of the fears expressed by some parties over the authority we proposed to give local coordination committees, we will modify slightly the rules which we initially proposed. First, we will not include in new § 74.602(b) any reference to who may perform a frequency coordination study. Instead, we merely have added a requirement that applicants for auxiliary frequencies comply with the frequency selection provisions of § 74.604 of the Rules. Applicants must also affirm that the requested frequency will cause no interference to existing users in the area. Section 74.604, which deals with frequency selection to avoid interference, indicates that frequency selection is the primary responsibility of the applicant. This section does permit an applicant to consult a local frequency coordination committee where one exists, but such consultation is at the option of the applicant. Section 74.602(b) makes it clear that the Commission has ultimate licensing authority and that frequencies other than those requested will be assigned if the Commission deems such action appropriate.

44. This system guarantees that area licensees will retain great flexibility in the way they handle their frequency coordination matters. In areas where committees exist and function effectively, coordination of additional auxiliary authorizations should be as simple as consulting a master file of those frequencies already in use in the area.[16] Where committees do not exist, or where a particular applicant chooses not to work with an existing committee, the licensee must take it upon himself to select a frequency that will cause no interference to other users. Whichever procedure is utilized, it is clear that the Commission retains the ultimate

[15] It appears that most existing exclusive assignments are for fixed link services. As discussed below, such services retain the highest priority for purposes of interference protection.

[16] We note that private frequency coordination has worked well in the private radio service for many years. Indeed, the authority given to frequency coordinating committees in the private radio service is at least as extensive as the advisory role contemplated for such committees in this proceeding.

licensing authority and may reject the request for a particular frequency if such action is warranted.

45. With respect to the idea that a nationwide auxiliary frequency data base be established to facilitate frequency coordination, the Commission at this time does not have the resources to make such information widely available. We are in the process of expanding and updating our master frequency data base. Public access to this data base has been and will continue to be available. Concerning regional coordination, if broadcast auxiliary service coordination committees advise us as to the markets or areas they serve and provide us with information concerning their name, address, telephone number, principal staff members, geographic area, participating broadcast stations, and spectrum coordinated, we will attempt to make this information available to other broadcasters or spectrum users.

46. *Interference Protection and Channel Priorities—The Comments.* Recognizing that no system of frequency coordination is foolproof, we stated that some mechanism should be established to settle those few cases in which existing stations cause interference to one another. In response to our proposals concerning the resolution of interference disputes, several commenters opine that such disputes are handled better at the local level. For example, NAB suggests that any interference dispute mechanism adopted by the Commission should be flexible enough to take account of local procedures instituted by area coordination committees. The Ohio Educational Broadcasting Network Commission agrees that local coordination committees are the proper forum for resolving interference problems and states that in the past interference has been resolved through a "limited number of telephone calls among television chief engineers."

47. With respect to our proposed priority scheme for interference protection, most parties support the priority concept and agree that STLs and CARS stations should be afforded highest priority in terms of protection from interference. However, virtually every noncommercial licensee addressing this issue urges that intercity relay stations receive a similar priority. They reason that ICRs perform the exact same function as STLs in that they provide a "life blood" link from a central production center to noncommercial stations throughout the state. CBS and Cox argue that, because STLs are essential to maintaining a reliable signal to the public, STL backup facilities should be given the same priority as the primary STL facility. CBS states that backup facilities must be free of interference when used and that a lower priority endangers a backup's reliability while increasing the risks of interruption. Cox submits that auxiliary facilities for low power television stations should receive a lower priority than backup facilities for full service stations. Cox avers that this is consistent with the secondary status of the low power service. NBC adds that at least some provision should be made for activating backup facilities on a first priority basis if the primary facilities fail.

48. Several other suggestions were offered with respect to our interference resolution procedures. Hughes would grant second priority to all other fixed links in regular use, third priority to mobile facilities of all kinds, and fourth priority to back-up facilities. PBS suggests giving priority to all existing services over new entrants. NBC states that when ICRs and television pickups operate together to produce news material, the pickup frequency should acquire the same priority as the ICR. The Ohio Educational Broadcasting Network Commission and a group of noncommercial licensees indicate that mobile facilities present the greatest potential for interference. The noncommercial licensees urge that mobile facilities should not be authorized to operate on frequencies used by STLs within the STL's geographic area. The Ohio Commission asserts that the obligation to correct interference should rest with mobile users in disputes between mobile and fixed services. Finally, Cox and CBN state that a final priority should be added to the list indicating that non-broadcast uses of auxiliary facilities have the lowest priority with respect to interference disputes.

49. In addition to providing a mechanism for resolving interference disputes between existing stations, the priority list we proposed also was to be used as a guide for withdrawing channels in a given area. If no additional channels are available in a market, we stated that we would withdraw authorizations being utilized for low priority purposes in order to provide licensees with channels for a higher priority use. In deciding which channels to withdraw, we stated that we would take into consideration the number of channels authorized to individual licensees. Those licensees with the most channels would be more likely to lose an authorization. We also proposed to consider the recommendation of a local coordination committee as to which channel to withdraw in an area. These proposals came under sharp attack from two noncommercial commenters, Schwartz and the WGBH Educational Foundation ("WGBH"). Schwartz states that forcing existing licensees to terminate operations that conflict with proposed higher priority uses clearly is inefficient and patently unfair. Lower priority users then will be forced to seek alternative frequencies, leading to investment instability and uncertainty. This scenario will deter the operation of lower priority facilities which, Schwartz opines, is antithetical to the public interest. Schwartz suggests a requirement that higher priority users compensate and underwrite the continuation of any lower priority service forced to relinquish the use of its channel. WGBH states that existing microwave systems are fundamental to public broadcasting. WGBH asserts that deleting channels from the licensee holding the most channels ignores the reality that licensees covering the entire state are apt to have the most assignments. Further, elimination of existing microwave relays would damage WGBH by loss of capital investment and would leave it without an economically feasible alternative. As a result, WGBH claims that proven broadcast service would be traded for unproven new services such as STLs for low power television stations. WGBH concludes that the Commission should recognize the importance of microwave systems to educational broadcasting by preserving the priority of existing microwave networks.

50. *Discussion.* Based on the comments of the parties, we have decided to make a number of changes in the interference protection and channel withdrawal mechanisms proposed in the *Notice*. Briefly, the priority system we are adopting will apply only to those complaints brought to the Commission for resolution. Individual licensees acting together either on an *ad hoc* basis or through a formal coordinating committee may adopt whatever interference resolution procedures they choose. Also, the actual priority listing we are adopting is more simplified than the proposed set of priorities. Finally, we have decided against adopting any formal channel withdrawal mechanism. The following paragraphs explain these decisions more fully.

51. In the *Notice*, we stated that local frequency coordination of new authorizations should eliminate the possibility of harmful interference. In

the unlikely event that licensed stations did cause interference, we felt that some mechanism should be in place for resolving those disputes. To this end, we proposed a priority system for interference protection. In fashioning our proposed channel priorities, we asked for comment on the possibility of allowing local frequency coordination committees to set their own standards. We believe that resolving interference disputes at the local level should be encouraged. Those licensees who addressed the issue indicate that local procedures are effective and that eliminating interference often can be as easy as making a few well-placed telephone calls. We therefore see no reason to impose on all licensees a rigid interference resolution mechanism that may be inappropriate for local needs and conditions. Accordingly, licensees who choose to act together to resolve interference disputes will be afforded the utmost discretion. This decision complements our determination to leave initial frequency coordination at the local level. With respect to resolving interference disputes, the interference resolution priority system described below will be utilized only when the affected parties cannot agree among themselves and petition the Commission.

52. While most parties support the creation of an interference protection priority system, there is some disagreement on the actual prioritizing of the various broadcast auxiliary services. In an effort to make our priority system more equitable and easier to administer, we have simplified the priority listing. First priority will be given to all fixed link stations that serve full service broadcast stations and cable systems. This includes STLs, CARS links, and intercity relays. We have taken this action primarily for the reasons expressed in the comments by the noncommercial entities. Regardless of the label placed on fixed links, if the practical use of the links essentially is the same, we see no reason to distinguish between the stations.[17] Second priority for the purpose of resolving interference disputes will be accorded television pickup stations utilized in a licensee's local service area. We will also include cable television relay service pickup stations because the services share the same frequencies and have similar purposes. Third priority belongs to translator relay stations and those links used to feed low power television stations. This priority is appropriate for translators and low power stations as it recognizes that these services are secondary to full service broadcast stations.[18] Fourth priority will be given to backup facilities and television pickup stations operating outside a licensee's local service area. Although several commenters argued strenuously that backup facilities should be given the same priority as primary facilities, we conclude that the present crowding of the spectrum does not allow us the luxury of providing each licensee with two or more high priority fixed link authorizations.[19] The final and lowest priority is given to the transmission of material during times when the station is not being used to transmit program material to its associated broadcast station. Thus, the expanded uses of auxiliary facilities, which we discussed in Section II of this decision, are accorded secondary status and must always give way to *bona fide* broadcast transmissions. Disputes involving stations in the same priority category will be resolved in favor of the licensee that has held its authorization on a particular path the longest.

53. The establishment of these priorities should address adequately many of the concerns advanced by the commenting parties. For example, several parties indicate that mobile facilities present the greatest interference threat. The noncommercial licensees filing jointly suggest that mobile facilities should not be authorized to operate on frequencies used by STLs within the STL's geographic area. The priority system we have devised makes it clear that mobile facilities must yield to fixed links when interference is present. Yet, this system retains the flexibility necessary for the efficient functioning of television pickup stations. Many television pickups are authorized on multiple frequencies to take advantage of frequency-agile transmission equipment. It would be impractical to force broadcasters to refrain from using those frequencies in situations where interference is not likely to occur as, for example, when a news crew operates outside the local market. Adopting the position of the noncommercial licensees would foreclose this flexibility.

54. After careful consideration, we have decided not to implement the channel withdrawal procedures proposed in the *Notice*. We believe that summarily withdrawing an existing authorization would have a destabilizing effect on the industry and would create legal and practical problems that far outweigh any countervailing benefits. Accordingly, we will leave questions of possible channel withdrawal to local determination in the context of initial frequency coordination for new channels. As previously stated, we believe that frequency coordination matters are handled best at the local level, either by the individual applicant or through a local coordination committee. Should a case arise where existing usage in a market precludes additional uses on a particular frequency, we believe that the parties involved are well situated to come to a reasonable accommodation. If a new entrant desires the use of an unavailable frequency, the new user could negotiate with existing users for relief that could take a variety of forms, including channel sharing or offering to reimburse an existing licensee for the expenses necessary to move to another channel.[20] As we stated in the *Notice*, we do not anticipate the spectrum becoming so crowded that an existing authorization will have to be withdrawn permanently from one licensee to accommodate another licensee's use. Nonetheless, should such a situation arise, we prefer giving the parties directly involved in the matter the flexibility to fashion the most appropriate and reasonable solution possible. Our decision not to

[17] We recognize that by lumping all fixed links together, we may be including some links that do not perform "life blood" functions, but for administrative convenience we choose not to attempt to subcategorize every conceivable fixed link use. Should a dispute arise involving a non-essential fixed link station, we can certainly take that fact into account in resolving the dispute.

[18] In some cases, translators may be providing a network service otherwise not available in an area. In those instances, it may be argued that the translator relay providing the network feed is a higher priority than, for example, a third or fourth TV pickup for a full service station in the area. We intend to remain flexible in our administration of the priority system so that such conflicts can be resolved equitably. Similarly, a fixed link providing a "life blood" service to a low power television station might also, in a given situation, be considered a higher priority than additional pickups for a full service television station. We are confident that most disputes concerning such conflicting uses will be resolved locally. However, if a situation does arise where a low power station is not able to function because of an inability to acquire an auxiliary link, we will give expedited treatment to any request for relief brought to our attention.

[19] Of course, backup facilities providing "hot standby" on the same frequency as the primary transmitter would assume the same priority by virtue of its operating on the same frequency. Also, we recognize that several areas of the country at times experience atmospheric inversions that necessitate using alternate frequencies. We encourage licensees in such areas to come to their own agreements regarding the priority that should be given to alternate facilities in those situations.

[20] The Commission long has recognized the propriety of one licensee reimbursing another for changes in operating frequency when such changes permit the initiation of additional services. This concept is particularly useful in the area of FM and television assignments. *See, e.g., Circleville, Ohio*, 8 F.C.C. 2d 159, 163–64 (1967).

apply a rigid set of channel priorities to such disputes gives the affected licensees that necessary flexibility. Of course, in those instances when the parties cannot agree, the Commission retains the authority to take whatever action is necessary to resolve the situation.

55. *Miscellaneous Amendments.* Two proposed rule changes suggested in the *Notice* received little or no comment. The first involved our proposal to end our present limitations on the number of channels any one licensee may obtain. As a practical matter, the restrictions have not been followed in recent years, and in the absence of comments opposing this change, we will amend our rules to reflect our actual practice. A second change in the rules would limit fixed link services to single frequency authorizations. No party commented on this amendment, and we will adopt it as proposed in order to maximize the efficient use of the spectrum. Finally, because the priority system adopted today has more to do with the avoidance of interference than frequency assignment, we are placing the interference resolution procedures in § 74.604 rather than § 74.602 as originally proposed. We are also making an editorial change in the title of § 74.604 to conform the title to the new addition.

## V. Conclusion

56. The actions taken today serve to deregulate substantially the television broadcast auxiliary service. By allowing licensees to utilize the excess capacity heretofore unused, we are promoting the efficient use of the increasingly crowded spectrum and giving licensees an additional revenue generating opportunity. This is important especially for noncommercial licensees faced with cutbacks in federal financial support. Our decision recognizes that in appropriate circumstances, the marketplace is an effective substitute for government regulation, and that market forces should be allowed to operate freely when possible. This concept also is evident in our revised licensing procedures, which acknowledge that individual licensees working together can act efficiently and expeditiously to assure their common interests. As broadcast operations become more efficient and the costs associated with government regulation are reduced, licensees can direct more resources to serving television consumers. Thus, the viewing public is the ultimate beneficiary of our actions.

57. *Regulatory Flexibility Act Final Analysis.* The action taken in this proceeding significantly deregulates the use of television broadcast auxiliary stations by expanding their permissible uses and allowing licensees to generate additional revenues by sharing excess capacity with other users. The amendments to our auxiliary station licensing policies for the most part conform the rules to existing Commission practice and do not constitute a substantive change in policy. Greater emphasis on local frequency coordination and interference resolution gives licensees greater flexibility in the conduct of their affairs and substantially reduces the government's presence in this area. These actions may benefit the approximately 900 Commission licensees currently holding broadcast auxiliary authorizations.

58. No party participating in this proceeding raised any regulatory flexibility issues. With minor exceptions, the rules are being adopted essentially as proposed. Those significant options not adopted are options which, in the judgement of the Commission, are more burdensome than necessary to meet our established objectives. Such options would either increase the burdens on licensees without any corresponding public benefit or result in unnecesary Commission oversight of licensee conduct.

59. Accordingly, pursuant to the authority contained in sections 4(i) and 303(r) of the Communications Act of 1934, as amended, it is ordered, That effective May 23, 1983, Part 74 of the Commission's Rules is amended as set forth in Appendix A.

60. It is further ordered, that subject to approval by the Office of Management and Budget, FCC Form 313 is amended as set forth in Appendix B.

61. It is further ordered, That this proceeding is terminated.

62. For further information concerning this proceeding, contact Michael A. McGregor, Mass Media Bureau, (202) 632-7792.

(Secs. 4, 303, 48 Stat., as amended, 1066, 1082; 47 U.S.C. 154, 303)

Federal Communications Commission.

William J. Tricarico,

*Secretary.*

## Appendix A

## PART 74—[AMENDED]

Part 74 of Chapter I of Title 47 of the Code of Federal Regulations is amended as follows:

1. Section 74.601 (a), (b), (c), and (d) are revised as follows:

**§ 74.601 Classes of TV broadcast auxiliary stations.**

(a) *TV pickup stations.* A land mobile station used for the transmission of TV program material and related communications from scenes of events occurring at points removed from TV broadcast station studios to TV broadcast or low power TV stations or other purposes as authorized in § 74.631.

(b) *TV STL station (studio-transmitter link).* A fixed station used for the transmission of TV program material and related communications from the studio to the transmitter of a TV broadcast or low power TV station or other purposes as authorized in § 74.631.

(c) *TV relay station.* A fixed station used for transmission of TV program material and related communications for use by TV broadcast and low power TV stations or other purposes as authorized in § 74.631.

(d) *TV translator relay station.* A fixed station used for relaying programs and signals of TV broadcast stations to LPTV, TV translator, and to other communications facilities that the Commission may authorize or for other purposes as permitted by § 74.631.

* * * * *

2. Section 74.602 (b), (c), and (g) are revised and paragraphs (d) and (e) are removed and reserved as follows:

**§ 74.602 Frequency assignment.**

* * * * *

(b) Subject to the conditions of paragraph (a) of this section, frequency assignments will normally be made as requested, provided that the frequency selection provisions of § 74.604 have been followed and that the frequency requested will cause no interference to existing users in the area. The Commission reserves the right to assign frequencies other than those requested if, in its opinion, such action is warranted.

(c) Fixed link stations will be authorized to operate on one channel only.

* * * * *

(g) In the event that a TV broadcast station licensee engages a communications common carrier to provide TV pickup or TV STL service, the frequencies available to the licensee may be assigned to the communications common carrier for the purpose of providing such service to that licensee.

* * * * *

3. Section 74.604 is revised as follows:

**§ 74.604 Interference avoidance.**

(a) Because the Commission does not undertake frequency coordination, applicants for new TV broadcast

auxiliary authorizations are responsible for selecting the frequency assignments that are least likely to result in mutual interference with other licensees in the same area. Applicants may consult local coordination committees, where they exist, for information on frequencies available in the area. In selecting frequencies, consideration should be given to the relative locations of receiving points, normal transmission paths, and the nature of the contemplated operation.

(b) Where two or more licensees are assigned a common channel for TV pickup, TV STL, or TV relay purposes in the same area and simultaneous operation is contemplated, they shall take such steps as may be necessary to avoid mutual interference, including consultation with the local coordination committee, if one exists. If a mutual agreement to this effect cannot be reached, the Commission must be notified and it will take such action as may be necessary, including time sharing arrangements, to assure an equitable distribution of available frequencies.

(c) For those interference disputes brought to the Commission for resolution, TV broadcast auxiliary channels will have the following priority for purposes of interference protection:

(1) All fixed links for full service broadcast stations and cable systems.

(2) TV and CARS pickup stations.

(3) Fixed or mobile stations serving translator or low power TV stations.

(4) Backup facilities; TV pickup stations used outside a licensee's local service area.

(5) Any transmission, pursuant to § 74.631(f), that does not involve the delivery of program material to a licensee's associated TV broadcast station.

(d) Interference between two stations having the same priority shall be resolved in favor of the station licensed first on a particular path.

4. Section 74.631 (d), (f), and (h) are revised as follows:

**§ 74.631 Permissible service.**

* * * * *

(d) The transmitter of an STL, TV relay station or TV translator relay station may be multiplexed to provide additional communication channels. A TV broadcast STL or TV relay station will be authorized only in those cases where the principal use is the transmission of television broadcast program material for use by its associated TV broadcast station. However, STL or TV relay stations so licensed may be operated at any time for the transmission of multiplexed communications whether or not visual program material is being transmitted, provided that such operation does not cause harmful interference to TV broadcast pickup, STL or TV relay stations transmitting television broadcast program material.

* * * * *

(f) A TV broadcast pickup, STL, or TV relay station may be used for the transmission of material to be used by others, including but not limited to other broadcast stations, cable television systems, and educational institutions. This use shall not interfere with the use of these broadcast auxiliary facilities for the transmission of programs and associated material intended to be used by the television station or stations licensed to or under common control of the licensee of the TV pickup, STL, or TV relay station. This use of the broadcast auxiliary facilities must not cause harmful interference to broadcast auxiliary stations operating in accordance with the basic frequency allocation, and the licensee of the TV pickup, STL, or TV relay station must retain exclusive control over the operation of the facilities. Prior to operating pursuant to the provisions of this Section, the licensee shall, for the intended location or area-of-operation, notify the appropriate frequency coordinatioin committee or any licensee(s) assigned the use of the proposed operating frequency, concerning the particulars of the intended operation and must provide the name and telephone number of a person who may be contacted in the event of interference.

* * * * *

(h) TV broadcast auxiliary stations authorized pursuant to this subpart may additionally be authorized to supply programs and signals of TV broadcast stations to cable television systems or CARS stations. Where the licensee of a TV broadcast auxiliary station supplies programs and signals to cable television systems or CARS stations, the TV auxiliary licensee must have exclusive control over the operation of the TV auxiliary stations licensed to it. Contributions to capital and operating expenses may be accepted only on a cost-sharing, non-profit basis, prorated on an equitable basis among all parties being supplied with program material.

5. Section 74.632(a) is revised as follows:

**§ 74.632 Licensing requirements.**

(a) A license for a TV pickup, TV STL, or TV relay station will be issued only to licensees of TV broadcast stations and, on a secondary basis, licensees of low power TV stations. A separate application is required for each fixed station and the application shall be specific with regard to the frequency requested. A mobile station license may be issued for any number of mobile transmitters to operate in a specific area or frequency band and the applicant shall be specific with regard to the frequencies requested. In lieu of specifying specific transmitter types, applicants shall certify that the transmitter used or to be used at the requested facility is type accepted, or was manufactured before October 1, 1981. Applications for consolidation of individual mobile station licenses into a system license will be accepted only at the time application is made for renewal of the main (Part 73) station license.

* * * * *

**Appendix B**

1. Form 313, Application for Authorization in the Auxiliary Radio Broadcast Service, is amended by adding the following three questions:

* * * * *

17. Describe briefly the primary broadcast-related purpose of the requested authorization.

18. For television auxiliary stations, state the anticipated percentage of time for which the station will be used for secondary uses. Secondary uses are transmissions of material at times when the station is not being used to transmit program material to its associated broadcast station.

19. For television auxiliary licensees, list the total number of existing auxiliary authorizations and indicate the combined percentage of time for which these stations are presently used for secondary uses.

**Appendix C**

*Parties Submitting Comments in BC Docket No. 81-794*

Bonneville International Corporation
California State Communications Division
California Public Broadcasting Commission
CBS Inc.
Christian Broadcasting Network, Inc.
Dow, Lohnes & Albertson Joint Comments
  Cox Broadcasting Corporation
  Fetzer Television Corporation
  Multimedia, Inc.
Entertainment and Sports Programming Network, Inc.
Fisher Broadcasting Inc.
Florida Public Broadcasting Service, Inc.
Gill Industries
Hughes Aircraft Company, Microwave Communications Products
National Association of Broadcasters
National Association of Public Television Stations
National Public Radio

Noncommercial Television Licensees Joint Comments
Central California Educational Television
Connecticut Educational Telecommunications Corporation
KQED, Inc.
University of Maine
University of New Hampshire
New Jersey Public Broadcasting Authority
The Ohio State University
School District No. 1, City and County of Denver and State of Colorado
South Carolina Educational Television Commission
South Central Education Broadcasting Council
University of Vermont and State Agricultural College
Virginia Department of Telecommunications
Ohio Educational Broadcasting Network Commission
Oklahoma Educational Television Authority
Public Service Satellite Consortium
The Public Broadcasting Service
Schwartz, Woods & Miller Joint Comments
Arizona Board of Regents for Arizona State University
Maryland Public Broadcasting Commission
Mississippi Authority for Educational Television
Mohawk-Hudson Council on Educational Television, Inc.
Rhode Island Public Telecommunications Authority
The Greater Toledo Educational Television Foundation
Western New York Public Broadcasting Association
Storer Broadcasting Company
Westinghouse Broadcasting Company, Inc.
WGBH Educational Foundation

Reply comments

National Association of Broadcasters
National Broadcasting Company, Inc.
The Public Broadcasting Service
Westinghouse Broadcasting Company, Inc.

[FR Doc. 83-10512 Filed 4-20-83; 8:45 am]
BILLING CODE 6712-01-M

## DEPARTMENT OF TRANSPORTATION

### Research and Special Programs Administration

### 49 CFR Parts 107, 173, and 177

**[Docket No. HM-138A; Amdt. Nos. 107-11, 173-161, 177-58]**

### Exemption and Enforcement Procedures and Related Miscellaneous Provisions; Corrections

**AGENCY:** Materials Transportation Bureau (MTB), Research and Special Programs Administration, DOT.

**ACTION:** Final rule; corrections.

**SUMMARY:** This document makes four editorial corrections to section or office designations as published in the **Federal Register** on January 20, 1983 (48 FR 2646) under Docket HM-138A (FR Document 83-1241) relating to exemptions and enforcement procedures. In addition, a reference is added to § 173.22(a)(2)(i) to reflect Department of Defense (DOD) hazardous materials regulations, and two references to § 173.22 in Part 177 are corrected. Finally, § 107.319 is amended to provide that requests for hearings are made to the official who issued the notice of probable violation.

**EFFECTIVE DATE:** These corrections and additions are effective April 21, 1983.

**FOR FURTHER INFORMATION CONTACT:** George W. Tenley, Jr., Office of Chief Counsel, Research and Special Programs Administration, Room 8420, 400 Seventh Street, S.W., Washington, D.C. 20590 (202) 755-4973.

**SUPPLEMENTARY INFORMATION:** Three of the corrections made herein are necessary to reflect proper references, either to the assignment of responsibilities within the MTB or to the appropriate cross referenced section.

At 48 FR 2651, under Subpart C—Preemption, the blanket change of "OE" and "OOE" to "HMR" and "OHMR" failed to recognize language in § 107.205(b) which referred to "OHMR or OOE." Consequently, in order to make complete within Part 107 the assignment of the inconsistency ruling responsibility to the Office of Hazardous Materials Regulation, § 107.205(b) has been amended to delete the words "or OOE."

At 48 FR 2655, under Part 173, there is an incorrect reference in § 173.22(a)(3) to "paragraph (a)(1) of this section." The correct reference is to "paragraph (a)(2) of this section," and is changed accordingly.

Also with regard to § 173.22, the redesignation of paragraph (b) to paragraph (c) inadvertently changed a reference to § 173.22(b) appearing in § 177.825(e) and paragraph VI. A of Appendix A to Part 177 which was adopted under HM-164 (46 FR 5317; January 19, 1981). Accordingly, in order to keep the requirements of HM-164 complete, the reference in § 177.825(e) and the Appendix reference to "§ 173.22(b)" have been changed to read "§ 173.22(c)."

In addition to the corrections noted above, two additional changes have been made. First, in adopting the provisions of § 107.319 pertaining to hearing requests, the official to whom the request should be made was not identified. Although under previous requirements in § 107.353 it was the Associate Director for Operations and enforcement to whom requests were submitted, the change adopted herein requires hearing requests to be made to the official who issued the notice. This is appropriate because in a hearing matter, the Associate Director is not involved in the proceeding. The general language adopted will cover any administrative reorganizations or redelegations that might occur in the future.

Second, an additional change to § 173.22 has been made at the recommendation of the Department of Defense. As adopted under HM-138A, § 173.22(a)(2) required that the person offering a package for transportation determine that it had been manufactured, assembled, and marked in accordance with Part 178 or 179, a DOT specification in effect on the date of manufacture, or an exemption or approval. However, as noted by the DOD, and as adopted, this section presently fails to recognize shipments made by DOD in accordance with DOD requirements, as provided in § 173.7(a). Therefore, in paragraph (a)(2)(i) of § 173.22 a reference to § 173.7(a) is being added.

**I. Classification of Rule; Reporting Requirements; and Impact on Small Entities**

A. *Non-Major Rule.* The Materials Transportation Bureau has determined that this regulatory amendment is not a major rule under terms of Executive Order 12291 or significant under DOT's regulatory procedures (44 FR 11034), and does not require a Regulatory Impact Analysis, nor does it require an environmental impact statement under the National Environmental Policy Act (42 U.S.C. 4321 et. seq.) This determination is made on the basis that: (1) The final rule will have an annual effect on the economy not exceeding $100 million, (2) there will be no major increase in costs or prices for consumers, individual industries, Federal, State, or local governmental agencies, or geographic regions, (3) it will not result in significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets, and (4) no impacts (negative or positive) on the environment are anticipated by these minor rule changes and corrections. A regulatory evaluation is not warranted since the anticipated impact would be so minimal.

B. *Paperwork Reduction Act.* The rule change contains no information collection requirements nor does it result in any paperwork reduction.

C. *Impact on Small Entities.* Based on limited information available concerning size and nature of entities likely to be affected, I certify that this amendment

will not, as promulgated, have a significant economic impact on a substantial number of small entities primarily because this amendment contains a relatively few corrections to a rulemaking issued January 20, 1983.

**II. Final Rule Without Notice and Without Usual Delay in Effective Date.**

Since this rule change consists of minor editorial changes or minor corrections and it does not impose additional requirements, notice and procedures thereon are considered unnecessary. For the same reasons it is considered unnecessary to delay the effective date for the usual period of time.

*Thesaurus of Indexing Terms.* The following list of Federal Register Thesaurus of Indexing Terms apply to this rulemaking:

**List of Subjects**

*49 CFR Part 107*

Hazardous materials program procedures.

*49 CFR Part 173*

Hazardous materials transportation, Regulations and definitions.

*49 CFR Part 177*

Carriage by public highway.

In consideration of the foregoing, **Federal Register** Doc. 83-1241 appearing at page 48 FR 2646 in the issue of January 20, 1983, is corrected as follows, and additional amendments under Docket HM-138A are made to Parts 107, 173, and 177:

## PART 107—HAZARDOUS MATERIALS PROGRAM PROCEDURES

**§ 107.205 [Amended]**

1. In § 107.205(b), the words "or OOE" are removed.

2. In § 107.319, the period at the end of paragraph (b)(3) is removed and replaced with a semicolon and the word "and"; and a new paragraph (4) is added to paragraph (b) to read as follows:

**§ 107.319 Request for a hearing.**

* * * * *

(b) * * *

(4) Be addressed to the official who issued the notice.

* * * * *

## PART 173—SHIPPERS—GENERAL REQUIREMENTS FOR SHIPMENTS AND PACKAGINGS

3. In § 173.22, paragraph (a)(2)(i) is revised, and paragraph (a)(3), appearing at page 48 FR 2655 is corrected, as follows:

**§ 173.22 Shipper's responsibility.**

(a) * * *

(2) * * *

(i) Section 173.7(a) and Parts 173, 178, or 179 of this subchapter;

* * * * *

(3) In making the determination under paragraph (a)(2) of this section, the person may accept—

* * * * *

## PART 177—CARRIAGE BY PUBLIC HIGHWAY

**§ 177.825 [Amended]**

4. § 177.825(e), the reference to "§ 173.22(b)" is changed to read "§ 173.22(c)."

**§ 172.22 [Amended]**

5. In paragraph VI.A. of Appendix A to Part 177, the reference to "§ 177.22(b)" is changed to read "§ 173.22(c)."

(49 U.S.C. 1803, 1804, 1808, and 1809; 49 CFR 1.53, App. A. to Part 1)

Issued in Washington, D.C. on April 15, 1983.

**L. D. Santman,**

*Director, Materials Transportation Bureau.*

[FR Doc. 83-10630 Filed 4-20-83; 8:45 am]

BILLING CODE 4910-60-M

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**49 CFR Parts 171, 172 and 173**

**[Docket No. HM-166L; Amdt. Nos. 171-72, 172-79, 173-163]**

## Regulation of Consumer Commodities; Paint and Paint Related Material Adhesive

**AGENCY:** Research and Special Programs Administration, DOT.

**ACTION:** Final rule.

**SUMMARY:** This action is being taken to reduce the shipping names associated with paint and paint related products from 28 to 7. This action will eliminate confusion over shipping names used by DOT and those used in the freight classification system. This action will result in a reduced burden in the shipment of these commodities without compromising safety. The proposal to expand the coverage of the consumer commodity category for flammable liquids by lowering the flash point limitation for one gallon inside containers is not adopted.

**DATE:** This amendment is effective April 1, 1984. However, compliance with the regulations as amended herein, is authorized April 21, 1983.

**FOR FURTHER INFORMATION CONTACT:** Darrell L. Raines, Chief, Exemptions and Regulations Termination Branch, Office of Hazardous Materials Regulation, Materials Transportation Bureau, 400 7th Street, SW., Washington, D.C. 20590 (202-472-2726).

**SUPPLEMENTARY INFORMATION:** On Monday, February 1, 1982, the Materials Transportation Bureau (MTB) published a Notice of Proposed Rulemaking (NPRM) Docket Number HM-166L (47 FR 4538) which addressed paints and paint related materials. The NPRM proposed to reduce the number of shipping names associated with paint in the Hazardous Materials Table (49 CFR 172.101) from approximately 28 to 7. In addition, the NPRM proposed to relax certain shipping requirements for paint and paint related material by allowing a flammable liquid with a flash point higher than 20°F. to be shipped as "Consumer commodity," ORM-D when in inside packagings of one gallon or less. At present, the Hazardous Materials Regulations (HMR) restrict the volume of flammable liquids having flash points below 73°F. being shipped as "Consumer commodity" to one quart. The effect of such change would be to allow four one gallon metal cans of paint in fiberboard boxes to be shipped without requiring that they be labeled or accompanied by shipping papers except when carried aboard aircraft.

MTB received a total of 37 comments in response to the NPRM. While the paint manufacturing industry and carriers generally favored the proposal, persons interested in fire protection strongly opposed those portions of the notice which would have allowed the increased quantity of paint with a flash point below 73°F. to be shipped as "Consumer commodity, ORM-D". There was little opposition to consolidation of shipping names and much support for it. Fourteen comments received from industrial firms that manufacture or ship paints and adhesives support the NPRM without exception. One manufacturer did want the shipping names "varnish" and "enamel" retained because products with these names are used to coat electrical wires, a use which most people do not associate with "paint." The purpose of shipping names in the hazardous materials table is not to pinpoint the ultimate use of a product with great exactitude, but rather to provide a standardized format which succeeds in communicating the basic properties, or kinds of hazardous materials in transportation.

In addition to industrial firms, seven trade associations, representing paint producers, carriers, and shippers supported the NPRM.

MTB received comments from four carriers. Two supported the NPRM. One air carrier expressed concern that the

relaxed requirements would exclude shipments by air and would cause confusion and inadvertent violation of the regulations because shippers may not know that one portion of a journey might be accomplished by air, requiring shipping papers. Since the package would not be labeled and marked so the contents could be identified, a violation might ensue if the package was shipped by air with no shipping papers. A rail carrier expressed concern that the proposed shipping names would not identify whether the hazardous material was a hazardous substance identified under the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA or "Superfund"). The identification of CERCLA hazardous substances is addressed at length in a previous MTB publication (see Docket No. HM-145C, 46 FR 17738, March 19, 1981). It is extremely unlikely that a hazardous substance, as presently defined in the HMR, in packagings addressed in this NPRM would be a constituent of paint in sufficient quantity to constitute a reportable quantity (RQ). If a hazardous substance were present in sufficient quantity, the marking provisions of § 172.324 would apply and the package would have to be marked with the name of the hazardous substance and the letters "RQ".

If a package contains a material which is listed in the CERCLA List (§ 172.101) but which is not a hazardous material or "hazardous substance" as presently defined in § 171.8, that material is not subject to the requirements of the HMR regardless of whether it is a "Consumer commodity" or not. This issue is discussed at length in Docket HM-145C and this final rule has no effect on it.

The Air Transport Association (ATA) expressed concern that the NPRM did not include all paint related items that appear in the ICAO Technical Instructions, specifically paint driers and thinners. One purpose of the NPRM was to reduce the number of shipping names associated with paint, including thinners, driers, removers and reducers. MTB feels that these materials can all be safely shipped under the shipping names "Paint" or "Paint related material" with separate entries for the flammable liquid, combustible liquid and corrosive material hazard classes.

MTB received comments from the fire departments of 7 municipalities, two from Members of the International Associations of Fire Chiefs, one from a fire protection engineer, and one from the National Fire Protection Association, all opposing the relaxation of shipping requirements (the use of the Consumer commodity, ORM-D hazard class) for flammable liquids as proposed in the NPRM. Comments from the fire departments and fire chiefs opposed relaxation of the communications requirements (labels and shipping papers) associated with shipments under the ORM-D hazard class. They expressed the opinion that the absence of labels and shipping papers would increase the danger to fire service personnel, or the general public, or both. The fire protection engineer expressed the view that the present regulations are consistent with National Fire Protection Association (NFPA) requirements and OSHA regulations and if the NPRM became final, the HMR would no longer be consistent. He also thought that there would be precedence for opening up the Consumer commodity, ORM-D hazard class to other flammable liquids which are not paints.

Comments received from the NFPA expressed the view that hazards at warehouses storing paints would be greatly increased. The comments stated that DOT labels and markings on outside containers are used for purposes of material classification of flammable liquids into various NFPA subclasses based on flash point and that this classification system is vital to the nationally recognized and widely used Flammable and Combustible Liquids Code, NFPA 30-1981, and without it the NFPA maintained there could be severe "fire overloading" of storage and warehousing facilities.

An evaluation of the merits of the comments reveals some concern for relaxation of shipping requirements, as proposed in the NPRM, is justified. It is true that accident data compiled from incident reports do not reveal a serious fire problem with paint as it is now shipped, however, an argument can be raised that this condition exists because of the adequacy of the present regulations and that relaxation of requirements would produce more problems than benefits. Prior to issuing the notice, MTB did not fully consider the problems that could arise if paints were inadvertently shipped by air as pointed out by the air carrier, or the non-transportation impacts of the proposals, such as the storage classification problem pointed out by the NFPA. In addition, while the comments from fire service personnel did not provide any factual data to support their concerns for increased risk to fire fighters and the public, the opinions of fire protection professionals should be given further consideration before action is taken. Because of these factors MTB has decided to withdraw those portions of the NPRM which would allow paints with flash points between 20°F. and 73°F. to be shipped as "Consumer commodity, ORM-D".

The NPRM explained the reasons why a change was needed for the entry "Adhesive, n.o.s. *See* Cement, liquid, n.o.s." However, it has been noted that "liquid, n.o.s." is not a part of the proper shipping name for the entry "Adhesives" in the United Nations Recommendations for the Transportation of Dangerous Goods and "liquid, n.o.s." is not a part of the proper shipping name for the entry "Cement" in the IMDG Code. For these reasons, "liquid, n.o.s." has been deleted from both shipping names in the § 172.101 Table. Also, § 173.132 has been changed accordingly.

**List of Subjects**

*49 CFR Part 171*

Hazardous materials transportation, Regulations and definitions.

*49 CFR Part 172*

Hazardous materials transportation, Labeling, Packaging and containers.

*49 CFR Part 173*

Hazardous materials transportation, Packaging and containers.

In consideration of the foregoing, Parts 171, 172, and 173 of 49 CFR are amended to read as follows:

## PART 171—GENERAL INFORMATION, REGULATIONS, AND DEFINITIONS

1. In § 171.16, paragraph (c)(3) is revised to read as follows:

**§ 171.16 Detailed hazardous materials incident reports.**

* * * * *

(c)* * *

(3) Paint and paint related material when shipped in packagings of five gallons or less.

* * * * *

## PART 172—HAZARDOUS MATERIALS TABLES AND HAZARDOUS MATERIALS COMMUNICATIONS REGULATIONS

2. In § 172.101 the Hazardous Materials Table is amended by adding and removing the following named entries to read as follows:

## § 172.101 Hazardous Materials Table

| (1) | (2) | (3) | (3A) | (4) | (5) | | (6) | | (7) | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | Packaging | | Maximum net quantity in one package | | Water shipments | | |
| +EAW | Hazardous materials descriptions and proper shipping names | Hazard class | Identification number | Label(s) required (if not excepted) | (a) Exceptions | (b) Specific requirements | (a) Passenger carrying aircraft or railcar | (b) Cargo only aircraft | (a) Cargo vessel | (b) Passenger vessel | (c) Other requirements |
| | * | * | * | * | * | | * | * | | | |
| | (Remove) | | | | | | | | | | |
| | * | * | * | * | * | | * | * | | | |
| | Adhesive, *See* Cement, liquid, n.o.s. | | | | | | | | | | |
| | Aluminum, liquid. *See* Paint, Enamel, Lacquer, Stain, Shellac, Varnish, *etc.* | | | | | | | | | | |
| Cement, liquid, n.o.s | Combustible liquid | NA1133 | None | 173.118a | None | No limit | No limit | 1,2 | 1,2 | | |
| | Cement, liquid, n.o.s. | Flammable liquid | NA1133 | Flammable liquid | 173.118 | 173.132 | 1 quart | 10 gallons | 1,2 | 1 | |
| | Compound, enamel. | do | NA1263 | do | 173.118 | 173.128 | do | 55 gallons | 1,2 | 1 | |
| | Compound, lacquer, paint, *or* varnish, removing, reducing, *or* thinning, liquid. | Combustible liquid | NA1142 | None | 173.118a | | | | 1,2 | 1,2 | |
| | Compound, lacquer, paint, *or* varnish, removing, liquid. | Corrosive material | NA1760 | Corrosive | 173.244 | 173.245 | do | 1 gallon | 1,2 | 1,2 | |
| | Compound, lacquer, paint, *or* varnish, removing, reducing, *or* thinning, liquid. | Flammable liquid | NA1142 | Flammable liquid | 173.118 | 173.128 | do | 55 gallons | 1,2 | 1 | |
| | *Drier. See* Paint drier, liquid. | | | | | | | | | | |
| | Enamel. *See* Paint, Enamel, Lacquer, *etc.* | | | | | | | | | | |
| | Lacquer. *See* Paint, Enamel, Lacquer, Stain, *etc.* | | | | | | | | | | |
| | Lacquer base, liquid. *See* Paint, Enamel, Lacquer, Stain, *etc.* | | | | | | | | | | |
| | Lacquer removing, reducing, *or* thinning, compound. *See* Compound, lacquer, paint, *or* varnish, removing, reducing *or* thinning liquid. | | | | | | | | | | |
| | Mortar stain, liquid | Combustible liquid | UN1263 | None | 173.118a | None | No limit | No limit | 1,2 | 1,2 | |
| | do | Flammable liquid | UN1263 | Flammable liquid | 173.118 | 173.128 | 1 quart | 55 gallons | 1,2 | 1 | |
| | Paint drier, liquid | Combustible liquid | UN1168 | None | 173.118a | None | No limit | No limit | 1,2 | 1,2 | |
| | do | Flammable liquid | UN1168 | Flammable liquid | 173.118 | 173.128 | 1 quart | 55 gallons | 1,2 | 1 | |
| | Paint, Enamel, Lacquer, Stain, Shellac, *or* Varnish, Aluminum, Bronze, Gold, Wood filler, liquid *or* Lacquer base, liquid. | Combustible liquid | UN1263 | None | 173.118a | None | No limit | No limit | 1,2 | 1,2 | |
| | Paint, Enamel, Lacquer, Stain, Shellac, *or* Varnish; Aluminum, Bronze, Gold, Wood filler, liquid *or* Lacquer base, liquid. | Flammable liquid | UN1263 | Flammable liquid | 173.118 | 173.128 | 1 quart | 55 gallons | 1,2 | 1 | |

| (1) | (2) | (3) | (3A) | (4) | (5) | | (6) | | (7) | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | Packaging | | Maximum net quantity in one package | | Water shipments | | |
| +EAW | Hazardous materials descriptions and proper shipping names | Hazard class | Identification number | Label(s) required (if not excepted) | (a) Exceptions | (b) Specific requirements | (a) Passenger carrying aircraft or railcar | (b) Cargo only aircraft | (a) Cargo vessel | (b) Passenger vessel | (c) Other requirements |
| | *Paint, reducing or thinning compound. See* Compound, lacquer, paint, *or* varnish, removing, reducing *or* thinning, liquid. | | | | | | | | | | |
| | *Reducing compound, paint, varnish, lacquer, etc. See* Compound, lacquer, paint *or* varnish, removing, reducing, *or* thinning, liquid. | | | | | | | | | | |
| | *Removing compound, paint, varnish, lacquer, etc. See* Compound, lacquer, paint *or* varnish, removing, reducing, *or* thinning, liquid. | | | | | | | | | | |
| | Shellac, *See* Paint, Enamel, Lacquer, Stain, Shellac, Varnish; *etc.* | | | | | | | | | | |
| | ....do | | | | | | | | | | |
| | *Thinning compound, paint, varnish, lacquer, etc. See* Compound, lacquer, paint *or* varnish, removing, reducing *or* thinning, liquid. | | | | | | | | | | |
| | Varnish. *See* Paint, Enamel, Lacquer, Stain, Shellac, Varnish; *etc.* | | | | | | | | | | |
| | *Varnish drier. See* Paint drier, liquid. | | | | | | | | | | |
| | *Varnish remover or reducer. See* Compound, lacquer, paint *or* varnish, removing, reducing, *or* thinning, liquid. | | | | | | | | | | |
| | *Varnish thinning compound. See* Compound, lacquer, paint *or* varnish, removing, reducing, *or* thinning, liquid. | | | | | | | | | | |
| | Wood filler, liquid. *See* Paint, Enamel, Lacquer, Stain, Shellac, Varnish; *etc.* | | | | | | | | | | |
| | * * * | * * * | * * * | * * * | * * * | | * * * | * * * | | | |
| | (Add) | | | | | | | | | | |
| | * | * | * | * | * | | * | * | | | |
| | Adhesive | Combustible liquid | UN1133 | None | 173.118a | None | No limit[1] | No limit | 1,2 | 1,2 | |
| | ....do | Flammable liquid | UN1133 | Flammable liquid | 173.118 | 173.132 | 1 quart | 10 gallons | 1,2 | 1 | |
| | Cement | Combustible liquid | NA1133 | None | 173.118a | None | No limit | No limit | 1,2 | 1,2 | |
| | ....do | Flammable liquid | NA1133 | Flammable liquid | 173.118 | 173.132 | 1 quart | 10 gallons | 1,2 | 1 | |
| | Driers, paint *or* varnish, liquid, n.o.s. | Combustible liquid | UN1168 | None | 173.118a | None | No limit | No limit | 1,2 | 1,2 | |

| (1) | (2) | (3) | (3A) | (4) | (5) | | (6) | | (7) | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | Packaging | | Maximum net quantity in one package | | Water shipments | | |
| +EAW | Hazardous materials descriptions and proper shipping names | Hazard class | Identification number | Label(s) required (if not excepted) | (a) Exceptions | (b) Specific requirements | (a) Passenger carrying aircraft or railcar | (b) Cargo only aircraft | (a) Cargo vessel | (b) Passenger vessel | (c) Other requirements |
| | do | Flammable liquid | UN1168 | Flammable liquid | 173.118<br>173.128 | 173.128 | 1 quart | 55 gallons | 1,2 | 1 | |
| | Paint | Combustible liquid | UN1263 | None | 173.118a | None | No limit | No limit | 1,2 | 1,2 | |
| | do | Flammable liquid | UN1263 | Flammable liquid | 173.118<br>173.128 | 173.128 | 1 quart | 55 gallons | 1,2 | 1 | |
| | Paint *or* paint related material. | Corrosive material | NA1760 | Corrosive | 173.244 | 173.245 | do | 1 gallon | 1,2 | 1,2 | |
| | Paint related material. | Combustible liquid | NA1263 | None | 173.118a | None | No limit | No limit | 1,2 | 1,2 | |
| | do | Flammable liquid | NA1263 | Flammable liquid | 173.118<br>173.128 | 173.128 | 1 quart | 55 gallons | 1,2 | 1 | |

## PART 173—SHIPPERS—GENERAL REQUIREMENTS FOR SHIPMENTS AND PACKAGINGS

3. In § 173.128, the heading and the introductory text of paragraph (a) are revised, paragraph (c) is redesignated paragraph (b), and a new paragraph (c) is added to read to follows:

**§ 173.128 Paint and paint related material (flammable liquids).**

(a) Except as otherwise provided in this part, the description "Paint" is the proper shipping name for paint, lacquer, enamel, stain, shellac, varnish, liquid aluminum, liquid bronze, liquid gold, liquid wood filler, and liquid lacquer base. The description "Paint related material" is the proper shipping name for a paint thinning, reducing or removing compound. However, if a more specific description is listed in § 172.101, that description must be used. Paint and paint related material must be packaged as follows:

* * * * *

(c) Special exceptions for shipment of paint and paint related material in the ORM–D class are provided in subpart N of this Part.

4. In § 173.132, the heading, introductory text of paragraph (a), and paragraph (b) are revised to read as follows:

**§ 173.132 Adhesive; cement; container cement; linoleum cement; pyroxylin cement; rubber cement; tile cement; wallboard cement, and coating solution.**

(a) Except as otherwise provided in this Part, a flammable liquid which is an adhesive; cement; container cement; linoleum cement; pyroxylin cement; rubber cement; tile cement; wallboard cement, or coating solution must be packaged as follows: * * *

* * * * *

(b) The adhesive and cements identified in paragraph (a) of this section, except any adhesive or cement containing carbon bisulfide (carbon disulfide), in glass or leakproof packagings consisting of a fiberboard body and metal tops and bottoms of not over 1-quart capacity each, or metal packagings of not over 5 gallons capacity each, further overpacked in a strong outside packaging are excepted from the specification packaging requirements of this Part.

* * * * *

(49 U.S.C. 1803, 1804, 1808; 49 CFR 1.53, App. A to Part 1)

**Note.**—The Materials Transportation Bureau has determined that this document will not result in a "major rule" under the terms of Executive Order 12291 or a significant regulation under DOT's regulatory policy and procedures (44 FR 11034), nor require an environmental impact statement under the National Environmental Policy Act (49 U.S.C. 4321 et seq.). Based on information available concerning size and nature of entities likely to be affected by this amendment, I certify that this amendment will not have a significant economic impact on a substantial number of small entities because the overall economic impact of this amendment will be minimal. A regulatory evaluation and environmental assessment are available for review in the docket.

Issued in Washington, D.C. on April 14, 1983.

**L. D. Santman,**

*Director, Materials Transportation Bureau.*

[FR Doc. 83–10031 Filed 4–20–83; 8:45 am]

BILLING CODE 4910–60–M

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

### 50 CFR Part 658

**[Docket No. 30316–39]**

### Shrimp Fishery of the Gulf of Mexico

**AGENCY:** National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Final rule.

**SUMMARY:** NOAA issues a final rule amending the regulations for the Fishery Management Plan for the Shrimp Fishery of the Gulf of Mexico. NOAA is modifying, temporarily, the boundary of the Tortugas Shrimp Sanctuary to reduce the area closed to trawl fishing. This action will enable fishermen to harvest marketable-sized shrimp from a small area that was previously closed. NOAA also corrects a definition for the phrase "fishery conservation zone".

**EFFECTIVE DATES:** April 15, 1983.

**ADDRESS:** A copy of the regulatory impact review may be obtained from Jack T. Brawner, Regional Director, Southeast Region, National Marine Fisheries Service, 9450 Koger Boulevard, St. Petersburg, Florida 33702.

**FOR FURTHER INFORMATION CONTACT:** Jack T. Brawner, 813–893–3141.

**SUPPLEMENTARY INFORMATION:**

#### Background

The Fishery Management Plan for the Shrimp Fishery of the Gulf of Mexico (FMP) was prepared by the Gulf of Mexico Fishery Management Council (Council) and was approved by the Assistant Administrator for Fisheries, NOAA, on November 7, 1980, under the authority of the Magnuson Fishery Conservation and Management Act (Magnuson Act). Final regulations implementing the FMP were effective May 20, 1981 (46 FR 27489). The Council prepared an FMP amendment that provides for modification of the closed area, identified in 50 CFR 658.22 as the Tortugas Shrimp Sanctuary (Sanctuary). The FMP amendment was approved on December 28, 1981. A notice of availability and a request for comments on the amendment was published on January 28, 1982 (47 FR 4104). No written comments were received on the FMP amendment during the public comment period which ended on March 15, 1982. A proposed rule which would amend the regulations under the provisions of the

FMP amendment was published for public comment on November 26, 1982 (47 FR 53427).

The proposed rulemaking discussed in detail the reason for the management measure (i.e., temporary geographic modification of the Sanctuary through August 14, 1983, and correction of the definition of the fishery conservation zone). This information is not repeated here.

**Response to Comments**

The Council was the only commenter on the proposed regulations during the 45-day public comment period which ended Janauary 10, 1983. The Council requested that the proposed termination date for the temporary geographic modification of the Sanctuary be extended from August 14, 1983, to August 14, 1984. NOAA has complied with this request because there would not be sufficient time to evaluate the modification if the termination date remained August 14, 1983.

**Classification**

The Assistant Administrator for Fisheries, NOAA, has determined that this amendment to the regulations complies with the national standards, other provisions of the Magnuson Act, and other applicable law.

The Administrator, NOAA, has determined that this amendment is not a major rule requiring the preparation of a regulatory impact analysis under Executive Order 12291. The regulatory impact review indicated that potential benefits are significantly greater than expected costs. The rule reduces a restriction on fishermen, slightly reduces enforcement requirements and costs, and is expected to increase shrimp landings.

The Assistant Administrator has determined that there is good cause to waive the 30-day period of delayed effectiveness required under the Administrative Procedure Act (APA). The regulations re-define the geographic scope of the Sanctuary and permit fishing within a portion of the Sanctuary as it is currently defined. The primary purpose of this modification is to obtain data on the migration patterns of shrimp as they move out of the Sanctuary. It is necessary to implement this geographic modification as quickly as possible for fishing to take place during the peak spring season this year. Since the modification to the geographic scope of the Sanctuary will be in effect only through August 14, 1984, information collected this spring will significantly increase the effectiveness of this action.

The Coastal Zone Office for the State of Florida, which is the only State adjacent to the management area, was provided a copy of coastal zone consistency statement for review as to consistency with its approved Coastal Zone Management Program. NOAA concluded that, to the maximum extent practicable, implementation of these rules is consistent with the Coastal Zone Management Program of Florida.

**List of Subjects in 50 CFR Part 658**

Fish, fisheries, Fishing.

Dated: April 14, 1983.

**Roland Finch,**

*Director, Office of Fisheries Management, National Marine Fisheries Service.*

## PART 658—[AMENDED]

For the reasons set forth in the preamble, 50 CFR Part 658 is amended as follows:

1. The authority citation for Part 658 reads as follows:

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

2. The definition of fishery conservation zone in § 658.2 is revised to read as follows:

**§ 658.2 Definitions.**

* * * * *

*Fishery conservation zone* (FCZ) means that area adjacent to the United States which, except where modified to accommodate international boundaries, encompasses all waters from the seaward boundary of each of the coastal States to a line on which each point is 200 nautical miles from the baseline from which the territorial sea of the United States is measured.

* * * * *

3. Section 658.22 and Figure 1 are revised to read and appear as follows:

**§ 658.22 Tortugas shrimp sanctuary.**

(a) The area commonly known as the "Tortugas Shrimp Sanctuary," off the State of Florida, is closed to all trawl fishing. The area is that part of the fishery conservation zone shoreward of a line connecting the following points (see Figure 1):

| Point | Latitude | Longitude | Common name |
|---|---|---|---|
| N | 25°52.9'N. | 81°37.95'W. | Coon Key Light. |
| F | 24°50.7'N. | 81°51. 3'W. | |
| G | 24°40.1'N. | 82°26. 7'W. | New Grounds Shoals Light. |
| H | 24°34.7'N. | 82°35. 1'W. | Rebecca Shoals Light. |
| P | 24°35 'N. | 82°08 'W.. | Marquessas Keys. |

(b) Notwithstanding the provisions of paragraph (a), effective through August 14, 1984, trawl fishing is allowed within that portion of the Sanctuary circumscribed by lines connecting the following points:

| Point | Latitude | Longitude |
|---|---|---|
| F | 24°50.7'N. | 81°51.3'W. |
| Q | 24°48.0'N. | 81°52.4'W. |
| R | 24°44.6'N. | 82°11.3'W. |
| F | 24°50.7'N. | 81°51.3'W. |

BILLING CODE 3510-22-M

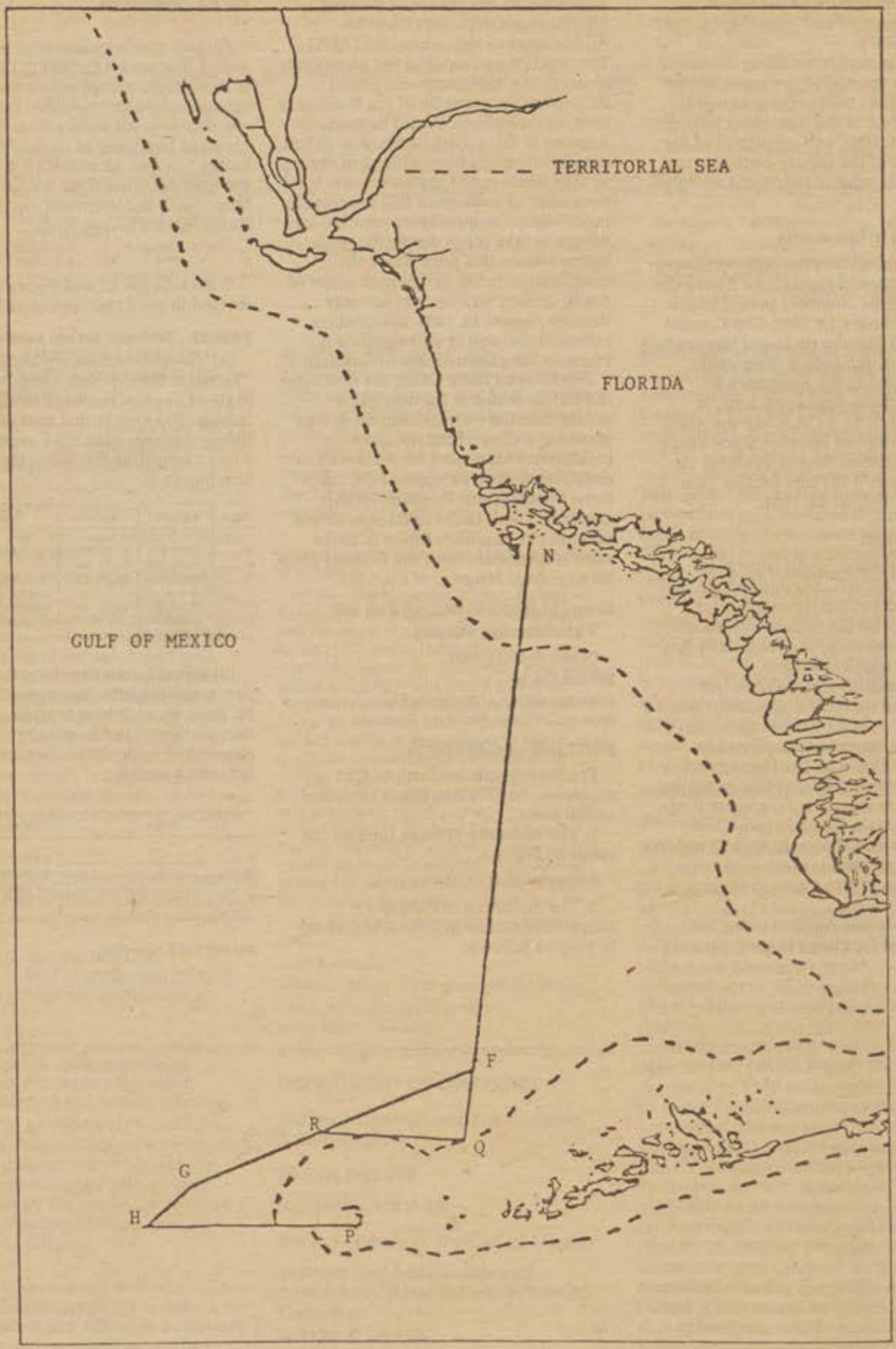


FIGURE 1. LOCATION OF TORTUGAS SHRIMP SANCTUARY.

[FR Doc. 83-10397 Filed 4-15-83; 10:02 am]
BILLING CODE 3510-22-C

# Proposed Rules

Federal Register
Vol. 48, No. 78
Thursday, April 21, 1983

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.

## OFFICE OF MANAGEMENT AND BUDGET

### Implementation of Executive Order 12372, Intergovernmental Review of Federal Programs; Public Meeting and Reopening of Comment Period

**AGENCY:** Office of Management and Budget; in conjunction with the following Departments: Agriculture, Commerce, Defense (including the Corps of Engineers), Education, Energy, Health and Human Services, Housing and Urban Development, Interior, Justice, Labor, State, Transportation, and Treasury; and in conjunction with the following agencies: ACTION, Environmental Protection Agency, Equal Employment Opportunity Commission, Federal Emergency Management Agency, General Services Administration, National Aeronautics and Space Administration, National Endowment for the Arts, National Endowment for the Humanities, National Science Foundation, Office of Personnel Management, Postal Service, Small Bussiness Administration, Tennessee Valley Authority, and the Veterans Administration.

**ACTION:** Notice of public meeting and reopening of public comment period.

**SUMMARY:** This document announces reopening of the public comment period for 28 documents previously published concerning the implementation of Executive Order 12372, "Intergovernmental Review of Federal Programs." A second public meeting has been scheduled.

The comment period is being reopened to allow the public greater time to review the various policies set forth in the proposed rules and to consider several areas of proposed change to the rules resulting from the amending of the Executive Order to include an additional statutory reference.

**DATES:** The public meeting will be held beginning at 9:30 A.M. on May 5, 1983. The reopened comment period on the notices of proposed rulemaking and the notices of proposed program exclusions will close on May 19, 1983.

**ADDRESSES:** The public meeting will be held at the GSA Auditorium, 18th and F Streets, N.W., Washington, D.C. Comments on the proposed rules during the reopened period should be sent to the addresses which agencies listed for receipt of comments in their previously published notices.

**FOR FURTHER INFORMATION CONTACT:** Walter S. Groszyk Jr., Office of the Deputy Associate Director for Management Reform, Office of Management and Budget, Room 10208, 726 Jackson Place N.W., Washington, D.C. 20503. Telephone (202) 395–3050. (Note: The Office of the Deputy Associate Director was recently reorganized and retitled from the Office of the Deputy Associate Director for Intergovernmental Affairs that appeared in earlier notices.)

The individual department and agency notices previously published also contain the names and addresses of individuals who can be contacted for further information on the notices.

**SUPPLEMENTARY INFORMATION:** Executive Order 12372, "Intergovernmental Review of Federal Programs," was signed by President Reagan on July 14, 1982. On January 24, 1983, all but two of the federal departments and agencies listed above published in the **Federal Register** either a notice of proposed rulemaking or a notice proposing their programs not be subject to the provisions of the Executive Order.The Department of Housing and Urban Development published a notice of proposed rulemaking on February 23, 1983 and the Tennessee Valley Authority published its notice of proposed rulemaking on March 4, 1983. A public meeting on the proposed rules was held on March 2, 1983. The Executive Order established a date of April 30, 1983 for implementing the policies of the Order. This effective date was extended by the President to September 30, 1983; 48 FR 15587, April 11, 1983.

#### Reopening of the Comment Period

While the public comment period of most agencies ended on March 10, 1983, the public comment periods for the Department of Housing and Urban Development and the Tennessee Valley Authority ended on April; 11, and April 4, 1983, respectively. The Department of the Interior on March 24, 1983 extended the public comment period on part of its notice until April 1, 1983. The federal departments and agencies listed above are reopening the comment period for all notices effective immediately. The comment period will now end on May 19, 1983. Any comments that were received subsequent to the end of the comment period and prior to this reopening of the comment period will be included in the agency dockets and considered.

#### Date, Time, and Location of Public Meeting

A public meeting will be held on May 5, 1983 to discuss possible changes to the proposed policies presented in the notices of proposed rulemaking. The meeting will be held in the Auditorium of the General Services Administration Building, 18th and F Streets, N.W., Washington, D.C., beginning at 9:30 A.M. The public meeting will be structured to allow federal officials to outline proposed changes, to discuss these changes with parties attending the public meeting, and to receive the views of the public on the proposed rules and changes contemplated to the proposed rules. If any additional federally-prepared material on proposed changes is given to those attending the public meeting, that material will also be provided to all parties previously submitting comments on the content of the proposed rules. Any additional material can also be obtained by requesting such from Walter Groszyk whose address appears above.

#### Areas of Change to the Proposed Rules

These changes to the proposed rules are intended to reflect the April 8, 1983, amendment of the Executive Order that cites additional statutory authority for the policies of the Order. These changes also respond to numerous commenters who sought clarification of whether and how the proposed rules would implement the provisions of Section 401 of the Intergovernmental Cooperation Act of 1968, 42 U.S.C. 4231, and Section 204 of the Demonstration Cities and Metropolitan Development Act of 1966, 42 U.S.C. 3334. The changes would encompass the entirety of Section 401. These changes do not represent final decisions on how best to carry out the amended Executive Order or to respond

to the public comments, but are possible solutions to concerns raised by the commenters and to the citation of additional statutory authority. Further public comment is sought. Alternatives to these possible solutions are also welcome. The section of the proposed rules affected by these possible solutions is identified in parentheses.

A number of other changes to the proposed rules are contemplated based on the many public comments received to date. These contemplated changes are not discussed in this notice. Public comment continues to be solicited on all of the previously published notices. Specific suggestions on the most effective means for linking assistance applications with comments by state, local, regional, or areawide entities would be particularly helpful.

*Federal Agency Programs and Activities to be Covered:* Agencies proposed program exclusions for public comment based on a set of government-wide criteria. Although some commenters were satisfied with the proposed exclusions and inclusions, many commenters wanted all programs included or fewer exclusions. —The scope of programs and activities covered by th Executive Order would be broadened to reflect the provisions of section 401 of the Intergovernmental Cooperation Act and Section 204 of the Demonstration Cities and Metropolitan Development Act. (—.3)

*Federal Agency Responsibilities for Programs or Activities not Selected for Review:* A few commenters wanted local governments to be able to select programs not included in the state process. —The manner of selecting programs or activities would be clarified, including an indication of federal responsibilities to local, regional, or areawide entities where programs or activities are not selected for inclusion under the state process. (—.5)

*The Role of Areawide Agencies in Intergovernmental Review:* Several commenters sought clarification on whether the proposed rules implemented all of Title IV of the Intergovernmental Cooperation Act and Section 204 of the Demonstration Cities and Metropolitan Development Act. —The rules would be changed to implement the applicable provisions of these two Acts. Section 204 allows areawide agencies established by state or local law to review and comment on applications for federal assistance for planning or construction of certain type facilities or utilities. For those programs or activities subject to areawide review which the state has included under its process, the state process would be required to pass through all comments from areawide agencies that differed from the state process recommendation. In the absence of a state process and for those programs and activities not included within a state process, applicants must provide a 60 day period for areawide agency review and comment, with comments then considered and taken into account by the appropriate federal agency. The federal agency would "accommodate or explain" any consensus comments from an areawide agency that were sent through the state single point of contact, even for programs and activities not included under the state process. (—.6)

*Role of the Single Point of Contact:* Many commenters did not understand the proposed role of the single point of contact or wanted it changed. —The role and responsibility of the single point of contact would be clarified. The single point of contact would transmit official, priority state process views. (The concept of priority views is being proposed as a means of highlighting for federal agency attention those recommendations involving areas of importance to state and local elected officials.) In addition, to assure federal agency awareness of views differing from a state process recommendation, the single point of contact would pass through to the federal agency all differing views, of state, local, regional, or areawide entities and officials. The single point of contact could also transmit a consensus of state, local, areawide, or regional views, as appropriate. (—.6)

*Consensus Building between State and Local Officials:* Comments were received suggesting that the state process foster consensus building between state and local officials. —A federal department or agency would be required to accommodate or explain (in cases of nonaccommodation) only those views transmitted by a single point of contact that represent either a state process recommendation or a consensus of state, local, areawide, or regional views, as appropriate, in the absence of a state process recommendation. Differing views passed through by the single point of contact would be considered, but the "accommodate or explain" obligation would not apply. (—.7)

**Office of Management and Budget**

Notices published on January 24, 1983, 48 FR 3074 and 48 FR 3079.

Dated: April 15, 1983.

**Harold I. Steinberg,**

*Associate Director for Management.*

## DEPARTMENT OF AGRICULTURE

**Office of the Secretary**

7 CFR Parts 3015, 1901, 1942, 1944, 1948, and 1980, 36 CFR 219, 7 CFR Parts 225, 227, 246, 247, 250, 253, and 282.

Notice of Proposed Rulemaking published on January 24, 1983, 48 FR 3082; proposed rule related notice published on January 25, 1983, 48 FR 3375.

Dated: April 15, 1983.

**Richard E. Lyng,**

*Deputy Secretary, Department of Agriculture.*

## DEPARTMENT OF COMMERCE

**Office of the Secretary**

13 CFR Parts 303, 307, and 309, 15 CFR Parts 13, 905, 920, 921, 923, 930, 931, and 2301, 50 CFR Part 401.

Notice of Proposed Rulemaking published on January 24, 1983, 48 FR 3096.

Dated: April 15, 1983.

**Malcolm Baldrige,**

*Secretary of Commerce.*

## DEPARTMENT OF DEFENSE

32 CFR Part 243.

Notice of Proposed Rulemaking published on January 24, 1983, 48 FR 3106.

Dated: April 13, 1983.

**M. S. Healy,**

*OSD Federal Register Liaison Officer, Department of Defense.*

**Department of the Army;**

**Corps of Engineers**

33 CFR Part 384.

Notice of Proposed Rulemaking published on January 24, 1983, 48 FR 3111.

Dated: April 14, 1983.

**Paul F. Kavanaugh,**

*Colonel, Corps of Engineers, Executive Director of Civil Works.*

## DEPARTMENT OF EDUCATION

34 CFR Parts 75, 76, and 79.

Notice of Proposed Rulemaking published on January 24, 1983, 48 FR 3120.

Dated: April 15, 1983.

**T. H. Bell,**

*Secretary of Education.*

## DEPARTMENT OF ENERGY

10 CFR Parts 600 and 1005.

Notice of Proposed Rulemaking published on January 24, 1983, 48 FR 3130.

Dated: April 15, 1983.
**Eric J. Fygi,**
*Deputy General Counsel.*

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of the Secretary

42 CFR Parts 51c, 52b, 55a, 56, and 122, 45 CFR parts 100, 224, and 1351.
Notice of Proposed Rulemaking published on January 24, 1983, 48 FR 3140.

Dated: April 15, 1983.
**Margaret M. Heckler,**
*Secretary of Health and Human Services.*

## DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

### Office of the Secretary

24 CFR Parts 50, 52, 570, 590, 590, 720, 841, 870, 881, 883, 883, 885, and 891.
Notice of Proposed Rulemaking published on February 23, 1983, 48 FR 7688.

Dated: April 14, 1983.
**Donald I. Hovde,**
*Under Secretary.*

## DEPARTMENT OF THE INTERIOR

43 CFR Part 9.
Notice of Proposed Rulemaking published on January 24, 1983, 48 FR 3152; extension of comment period published on March 24, 1983, 48 FR 12409.

Dated: April 14, 1983.
**Richard R. Hite,**
*Principal Deputy Assistant Secretary.*

## DEPARTMENT OF JUSTICE

### Office of the Attorney General

28 CFR Part 30.
Notice of Proposed Rulemaking published on January 24, 1983, 48 FR 3162.

Dated: April 14, 1983.
**Edward C. Schmults,**
*Acting Attorney General.*

## DEPARTMENT OF LABOR

29 CFR Part 17, 30 CFR Part 46.
Notice of Proposed Rulemaking published on January 24, 1983, 48 FR 3172.

Dated: April 15, 1983.
**Raymond J. Donovan,**
*Secretary of Labor.*

## DEPARTMENT OF STATE

Notice published on January 24, 1983, 48 FR 3183.

Dated: April 14, 1983.
**Davis R. Robinson,**
*Legal Adviser.*

## DEPARTMENT OF TRANSPORTATION

### Office of the Secretary

14 CFR Part 152, 23 CFR Parts 420, 650, and 740, 49 CFR Parts 17, 25, 266, and 450.
Notice of Proposed Rulemaking published on January 24, 1983, 48 FR 3186.

Dated: April 15, 1983.
**Rosalind A. Knapp,**
*Deputy General Counsel.*

## DEPARTMENT OF THE TREASURY

### Office of the Secretary

Notice published on January 24, 1983, 48 FR 3197.

Dated: April 14, 1983.
**Peter J. Wallison,**
*General Counsel.*

## ACTION

45 CFR Part 1233.
Notice of Proposed Rulemaking published on January 24, 1983, 48 FR 3200.

Dated: April 15, 1983.
**Thomas W. Pauken,**
*Director, ACTION.*

## ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 29, 30, 35, 40, 51, and 255.
Notice of Proposed Rulemaking published on January 24, 1983, 48 FR 3208.

Dated: April 13, 1983.
**Lee M. Thomas,**
*Acting Deputy Administrator.*

## EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

Notice published on January 24, 1983, 48 FR 3219.

Dated: April 15, 1983.
**Clarence Thomas,**
*Chairman.*

## FEDERAL EMERGENCY MANAGEMENT AGENCY

44 CFR Parts 4, 9, 59, 60, 76, 300, and 302.
Notice of Proposed Rulemaking published on January 24, 1983, 48 FR 3222.

Dated: April 11, 1983.
**George W. Jett,**
*General Counsel.*

## GENERAL SERVICES ADMINISTRATION

41 CFR Part 101–6.
Notice of Proposed Rulemaking published on January 24, 1983, 48 FR 3232.

Dated: April 14, 1983.
**Charles S. Davis III,**
*Acting Administrator.*

## NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

14 CFR Part 1204.
Notice of Proposed Rulemaking published on January 24, 1983, 48 FR 3240.

Dated: April 15, 1983.
**James M. Beggs,**
*Administrator.*

## NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

### National Endowment for the Arts

45 CFR 1152
Notice of Proposed Rulemaking published on January 24, 1983, 48 FR 3248.

Dated: April 15, 1983.
**Francis S. M. Hodsoll,**
*Chairman.*

### National Endowment for the Humanities

Notice published on January 24, 1983, 48 FR 3258.

Dated: April 14, 1983.
**William J. Bennett,**
*Chairman.*

## NATIONAL SCIENCE FOUNDATION

45 CFR Part 660.
Notice of Proposed Rulemaking published on January 24, 1983, 48 FR 3262.

Dated: April 12, 1983.
**Charles H. Herz,**
*General Counsel.*

## OFFICE OF PERSONNEL MANAGEMENT

Notice published on January 24, 1983, 48 FR 3270.

Dated: April 14, 1983.
**Loretta Cornelius,**
*Deputy Director, Office of Personnel Management.*

## POSTAL SERVICE

39 CFR Parts 775, 776, 778.
Notice of Proposed Rulemaking published on January 24, 1983, 48 FR 3274.

Dated: April 13, 1983.
**Fred Eggleston,**
*Assistant General Counsel, Legislative Division.*

## SMALL BUSINESS ADMINISTRATION

13 CFR Part 135.

Notice of Proposed Rulemaking published on January 24, 1983, 48 FR 3282.

Dated: April 15, 1983.

**Heriberto Herrera,**

*Deputy Administrator.*

## TENNESSEE VALLEY AUTHORITY

18 CFR Part 1311

Notice of Proposed Rulemaking published on March 4, 1983, 48 FR 9496.

Dated: April 14, 1983.

**W. F. Willis,**

*General Manager.*

## VETERANS ADMINISTRATION

38 CFR Part 40

Notice of Proposed Rulemaking published on January 24, 1983, 48 FR 3290.

Dated: April 13, 1983.

**Everett Alvarez, Jr.,**

*Deputy Administrator.*

[FR Doc. 83-10615 Filed 4-20-83; 8:45 am]

BILLING CODE 3110-01-M

## DEPARTMENT OF AGRICULTURE

### Agricultural Marketing Service

### 7 CFR Parts 1120, 1126, 1132, and 1138

**[Docket Nos. AO-231-A50, et al.]**

### Milk in Texas and Certain Other Marketing Areas; Rescheduling of Hearing on Proposed Amendments to Tentative Marketing Agreements and Orders

| 7 CFR Parts | Marketing area | AO Numbers |
|---|---|---|
| 1126 | Texas | AO-231-A50. |
| 1120 | Lubbock-Plainview, Texas | AO-328-A24. |
| 1132 | Texas Panhandle | AO-262-A34. |
| 1138 | Rio Grande Valley | AO-335-A29. |

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

**ACTION:** Rescheduling of public hearing on proposed rulemaking.

**SUMMARY:** This notice reschedules for June 27, 1983, a public hearing to consider industry proposals relative to the orders regulating the handling of milk in the marketing areas listed above. One of the proposals would merge the marketing areas under one order and expand the merged area to include additional territory in the States of Texas, New Mexico, and Arkansas. The hearing was initially scheduled to begin on April 26, 1983. A cooperative association and proprietary handlers requested the rescheduling, indicating that they need additional time to prepare for the hearing.

**DATE:** The hearing will convene at 1:30 p.m. on June 27, 1983.

**ADDRESS:** The hearing will be held at the Sheraton Grand Hotel, Dallas-Ft. Worth Airport, Highway 114 and Esters Boulevard, Dallas, Texas 75261.

**FOR FURTHER INFORMATION CONTACT:** Robert F. Groene, Marketing Specialist, Dairy Division, Agricultural Marketing Service, U.S. Department of Agriculture, Washington, D.C. 20250, 202-447-4824.

**SUPPLEMENTARY INFORMATION:** Prior document in this proceeding: Notice of Hearing—Issued March 30, 1983, published April 5, 1983 (48 FR 14613).

A notice was issued on March 30, 1983, giving notice of a public hearing to be held April 26, 1983, with respect to proposed amendments to the tentative marketing agreements and to the orders regulating the handling of milk in the aforesaid specified marketing areas.

Notice is hereby given, pursuant to the rules of practice applicable to these proceedings (7 CFR Part 900), that the said hearing is rescheduled to be held at the Sheraton Grand Hotel, Dallas-Ft. Worth Airport, Highway 114 and Esters Boulevard, Dallas, Texas 75261, beginning at 1:30 p.m., local time, on June 27, 1983.

### List of Subjects in 7 CFR Parts 1120, 1126, 1132, and 1138

Milk marketing orders, Milk, Dairy products.

Signed at Washington, D.C., on April 15, 1983.

**William T. Manley,**

*Deputy Administrator, Marketing Program Operations.*

[FR Doc. 83-10634 Filed 4-20-83; 8:45 am]

BILLING CODE 3410-02-M

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

### 14 CFR Part 33

**[Docket No. 82-ANE-49, Notice No. SC-83-1-NE]**

### Special Conditions; General Electric Company CT7 Series Turboprop Engines

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

**ACTION:** Notice of proposed special conditions.

**SUMMARY:** This notice proposes special conditions for type certification of the General Electric Company CR7 series turboprop engines. These engines will have novel or unique design features associated with a propeller brake for which the applicable airworthiness regulations do not contain adequate or appropriate safety standards. This notice proposes the safety standards which the Administrator finds necessary to establish a level of safety equivalent to that established in the regulations.

**DATE:** Comments must be received by June 1, 1983.

**ADDRESSES:** Comments on this proposal may be mailed in duplicate to Federal Aviation Administration, Office of the Regional Counsel, Attn: Rules Docket No. 82-ANE-49, 12 New England Executive Park, Burlington, Massachusetts 01803. Comments in the Rules Docket may be examined weekdays, except Federal holidays, between 8:00 a.m. and 4:30 p.m.

**FOR FURTHER INFORMATION CONTACT:** Donald F. Perrault, Engine and Propeller Standards Staff, ANE-110, Federal Aviation Administration, New England Region, 12 New England Executive Park, Burlington, Massachusetts 01803; telephone (617) 273-7330.

**SUPPLEMENTARY INFORMATION:**

### Comments Invited

Interested persons are invited to comment on these special conditions by submitting such written data, views, or arguments as they may desire. Communications should identify the regulatory docket or notice number and be submitted in duplicate to the address specified above. All communciations received on or before the closing date for comments specified above will be considered by the Administrator before taking action on this proposal. The proposals contained in this notice may be changed in the light of comments received. All comments submitted will be available both before and after the closing date in the Rules Docket for examination by interested persons.

The applicable airworthiness standards for the General Electric Company CT7 series turboprop engines are those regulations designated in accordance with § 21.21 and are known as the "Type Certification Basis" for the engine design. Special conditions may be issued and amended, as necessary, as part of the type certification basis if the Administrator finds that the airworthiness standards designated in accordance with § 21.17(a)(1) do not contain adequate or appropriate safety standards because of novel or unusual design features of the engine. Special Conditions are now being proposed in accordance with § 21.16, to become part

of the type certification basis in accordance with § 21.17(a)(2).

On August 6 and 14, 1981, General Electric Company, 1000 Western Avenue, Lynn, Massachusetts 01907, filed applications for type certification of its CT7–5A and –7 model turboprop engines, respectively, under Part 33 of the Federal Aviation Regulations (FAR). The CT7–5A and –7 engines are takeoff-rated at 1630 and 1700 shaft horsepower, respectively. Since these engines are turboprop derivatives of the existing type certificated CT7 turboshaft series engines, the Special Conditions proposed herein will be made applicable to the CT7 series turboprop engines to also cover future models within this engine series. The type certification basis for the CT7–5A and –7 engines is proposed to be Part 33, effective February 1, 1965, as amended by Amendments 33–1 through 33–5, Special Condition No. 33–76NE–2 (to be amended), and the Special Condition proposed herein.

The CT7–5A and –7 turboprop engines incorporate a propeller brake which will allow the propeller to be brought to a stop, while the gas generator portion of the engine remains in operation, and remain stopped during operation of the engine as an auxiliary power unit ("APU Mode").

The applicable airworthiness requirements do not contain adequate or appropriate safety standards for the type certfication of this unusual design feature.

**Proposed Special Conditions**

Accordingly, the FAA proposes the following Special Conditions for the General Electric Company CT7 series turboprop engines equipped with a propeller brake:

In addition to the requirement of FAR 33.87, the applicant must conduct the folowing runs:

1. Ground locking. A total of at least 45 hours with the propeller brake engaged in a manner which clearly demonstrates its ability to function without adverse effects, while the engine is operating in the "APU Mode" under the maximum conditions of engine speed, torque, temperature, air bleed, and power extraction as specified by the applicant.

2. Dynamic braking. A total of at least 400 application-release cycles of brake engagements must be made in a manner which clearly demonstrates its ability to function, without adverse effects, under the maximum conditions of engine acceleration/deceleration rate, speed, torque, and temperature. The propeller must be stopped prior to brake release.

3. Conduct at least 100 engine starts and stops with the propeller brake engaged.

This testing may be performed in conjunction with the endurance test schedule of FAR 33.87(b) if system parameter conditions permit.

**List of Subjects in 14 CFR Part 33**

Engines, Propellers, Aircraft safety.

(Secs. 313(a), 601, and 603, Federal Aviation Act of 1958, as amended, (49 U.S.C. 1354(a), 1421, and 1423); Sec. 6(c), Department of Transportation Act (49 U.S.C. 1655(c); and 14 CFR 11.28, 11.29(b), 11.45)

**Note.**—This action is not a proposed rule of general applicability and is therefore not covered under Executive Order 12291 or the Regulatory Flexibility Act. The FAA has determined that this document is not considered to be significant as defined in Department of Transportation Regulatory Policies and Procedures (44 FR 11034; February 26, 1979). A copy of the regulatory evaluation prepared for this action is contained in the docket. A copy of it may be obtained by contacting the person identified as the information contact.

Issued in Burlington, Massachusetts, on April 7, 1983.

**Robert E. Whittington,**

*Director, New England Region.*

[FR Doc. 83–10166 Filed 4–20–83; 8:45 am]

BILLING CODE 4910–13–M

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**14 CFR Ch. I**

**[Summary Notice No. PR–83–3]**

## Petitions for Rulemaking; Summary of Petitions Received and Dispositions of Petitions Denied or Withdrawn

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

**ACTION:** Notice of petitions for rulemaking and of dispositions of petitions denied or withdrawn.

**SUMMARY:** Pursuant to FAA's rulemaking proivisions governing the applications, processing, and disposition of petitions for rulemaking (14 CFR Part 11), this notice contains a summary of certain petitions requesting the initiation of rulemaking procedures for the amendment of specified provisions of the Federal Aviation Regulations and of denials or withdrawals of certain petitions previously received. The purpose of this notice is to improve the public's awareness of this aspect of FAA's regulatory activities. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of any petition or its final disposition.

**DATE:** Comments on petitions received must identify the petition docket number involved and be received on or before, June 21, 1983.

**ADDRESSES:** Send comments on the petition in triplicate to: Federal Aviation Administration, Office of the Chief Counsel, Attn: Rules Docket (AGC–204), Petition Docket No. ———, 800 Independence Avenue, SW., Washington, D.C. 20591.

**FOR FURTHER INFORMATION CONTACT:** The petition, any comments received, and a copy of any final disposition are filed in the assigned regulatory docket and are available for examination in the Rules Docket (AGC–204), Room 916, FAA Headquarters Building (FOB–10A), Federal Aviation Administration, 800 Independence Avenue, SW., Washington, D.C. 20591; telephone (202) 426–3644.

This notice is published pursuant to paragraphs (b) and (f) of § 11.27 of Part 11 of the Federal Aviation Regulations (14 CFR Part 11).

Issued in Washington, D.C. on April 15, 1983.

**Richard C. Beitel,**

*Acting Assistant Chief Counsel, Regulations and Enforcement Division.*

PETITIONS FOR RULEMAKING

| Docket No. | Petitioner | Description of the petition |
|---|---|---|
| 23525 | Leonard E. Wolff | *Description of petition:* Amendment of § 21.191 to allow operation of an aircraft of which 41% has been fabricated and assembled by persons who have constructed the aircraft solely for the purpose of their own education or recreation.<br>*Regulations affected:* 14 CFR 21.191(g). |

PETITIONS FOR RULEMAKING—Continued

| Docket No. | Petitioner | Description of the petition |
|---|---|---|
| 23544 | Raisbeck-Western | *Petitioner's reason for rule:* The existing rule penalizes and discriminates against those aircraft designers whose aircraft designs meet the overall tone and purpose of § 21.191(g) but do not meet the "over 50%" condition of the rule. Changing the rule would result in an increased activity in amateur-built aircraft, which in turn will stimulate the economy by creating additional demands for engines, parts, accessories, etc. This in turn will result in a stronger aircraft industry. The rules applying to this part are 20 to 30 years old. The rules were developed at a time when the methods of construction entailed primary usage of wood, fabric, steel tubing and aluminum. Today's composite structure (reinforced plastics) are evident in a number of new designs. The methods of construction differ with each design, and eliminates some of the actual fabrication. Therefore, the present 51" requirement is not consistent with present day composite structure (Kits) technology.<br>*Description of petition:* To amend § 21.195 to permit aircraft modifiers to use those aircraft for market survey purposes in the same manner as airfram manufacturers.<br>*Regulations affected:* 14 CFR 21.195(a).<br>*Petitioner's reason for rule:* The existing rule penalizes and discriminates against those aircraft modifiers who should be allowed to use their aircraft for Market Survey the same as aircraft manufacturers. |

PETITIONS FOR RULEMAKING: WITHDRAWN OR DENIED

| Docket No. | Petitioner | Description and disposition of the rule requested |
|---|---|---|
| None this period | | |

[FR Doc. 83-10559 Filed 4-20-83; 8:45 am]
BILLING CODE 4910-13-M

## CIVIL AERONAUTICS BOARD

### 14 CFR Part 212

**[EDR-457; Docket 41415]**

### Charter Trips by Foreign Air Carriers

**AGENCY:** Civil Aeronautics Board.

**ACTION:** Notice of Proposed Rulemaking.

**SUMMARY:** The CAB proposes to prohibit some foreign air carriers from advertising and selling charters until they receive permission to perform those charters. This action is taken to protect potential passengers and U.S. international aviation interests.

**DATES:** Comments by: May 23, 1983.

Comments and relevant information received after this date will be considered by the Board only to the extent practicable.

Requests to be put on Service List by: May 6, 1983.

The Docket Section prepares the Service List and sends it to each person listed on it, who then serves comments on others on the list.

**ADDRESSES:** Twenty copies of comments should be sent to Docket 41415, Civil Aeronautics Board, 1825 Connecticut Avenue, NW., Washington, D.C. 20428. Individuals may submit their views as consumers without filing multiple copies. Comments may be examined in Room 711, Civil Aeronautics Board, 1825 Connecticut Avenue, NW., Washington, D.C., as soon as they are received.

**FOR FURTHER INFORMATION CONTACT:** David Schaffer, Office of the General Counsel, Civil Aeronautics Board, 1825 Connecticut Avenue, NW., Washington, D.C. 20428 (202) 673-5442.

**SUPPLEMENTARY INFORMATION:** Section 212.4 of the Board's rules (14 CFR 212.4) prohibits a foreign air carrier from performing certain charters until it receives approval from the Board. The charters subject to this prior approval requirement are fifth freedom charters (charters that originate and terminate in countries other than the foreign carrier's home country), long-term wet leases (leases for more than 60 days where the lessor provides both aircraft and crew), part charters (flights carrying both charter and scheduled passenger traffic), and other charters for which the Board requires prior approval under § 212.4 (e) or (f). A foreign carrier's application for approval must be filed between 5 and 45 days before the proposed flight depending on the type of charter or the reasons that the Board has imposed the prior approval requirement on it.

Recently, the Board has become concerned that foreign carriers may undermine the prior approval system by advertising and selling passenger charter flights before receiving the required approval. This presents both international aviation and consumer protection problems.

The Board adopted the prior approval system to monitor and control charter activity by foreign air carriers and thereby ensure that there was charter flight reciprocity between the United States and foreign countries. It is now based on the Congressional directives in sections 102(a)(12) and 1102(b) of the Federal Aviation Act (49 U.S.C. 1302(a)(12) and 1502(b)) and section 2(a) of the Fair Competitive Practices Act (49 U.S.C. 1159b(a)) to ensure equal competitive opportunities for U.S. carriers.

The prior approval requirement gives the Board the opportunity to review aviation relations with the foreign country involved and decide whether there are problems that would warrant denial of the charter request. If the charter in question has already been marketed and sold to prospective passengers, however, those persons' plans would be disrupted if the Board took the strong action that might be necessary to protect U.S. aviation interests. Advertising and selling may therefore place pressure on the Board to grant approval even where reciprocity problems might call for a denial. The rule proposed here, by making advertising and selling contingent on prior Board approval, would relieve some of that pressure.

An additional benefit of the proposed rule is that it would tend to prevent travelers from being deceived about the status of their charter flight. Section 411 of the Act (49 U.S.C. 1381) prohibits foreign air carriers from engaging in unfair and deceptive practices. The Board tentatively concludes that advertising and selling transportation on a flight that is unlikely to be performed is a violation of that section. Most prospective passengers are not aware that a flight is subject to government approval, or if they are, assume that approval is merely a formality. They make plans based on the reasonable assumption that, barring some unexpected event such as bad weather, the flight will run more or less on schedule. If the Board must disapprove the charter for foreign policy reasons, however, their travel plans will be disrupted. Section 411 and this rule are designed to avoid such disruptions.

Of course, not all charters subject to prior approval are likely to be disapproved by the Board. Where there are no reciprocity problems, the Board grants the necessary approval as a

matter of course. Therefore, to apply this advance marketing prohibition to all foreign air carrier charters would be an unwarranted departure from our general policy of allowing the charter industry the greatest degree of freedom consistent with the public interest. The proposed prohibition is needed only where the Board has found reciprocity defective and has imposed extraordinary prior approval requirements under § 212.4(e) of the Board's rules. Currently only ten nations' carriers are subject to these procedures.

Since the basis for this rule is in part passenger protection, its restrictions would not apply to cargo charters. In the case of cargo charters, the carrier normally does not seek Board approval under Part 212 until the flight has been chartered by the shipper.

### Regulatory Flexibility Act

In accordance with 5 U.S.C. 605(b), as added by the Regulatory Flexibility Act, Pub. L. 96-354, the Board certifies that this rule would not, if adopted, have a significant economic impact on a substantial number of small entities. The change proposed here will affect only foreign airlines providing international air service. These are typically not small airlines.

Because of the important U.S. aviation and consumer protection interests that remain unprotected in the absence of this rule, the Board finds that it is in the public interest to allow only 30 days for comments. In addition, the increasing popularity of charters and the fact that the high season for charters is almost upon us justify a shorter than normal comment period. For the same reasons, if adopted the Board expects to make the rule effective less than 30 days after it is published in the **Federal Register**. Carriers subject to this rule would have to stop advertising and selling unapproved passenger charters after the effective date.

### List of Subjects in 14 CFR Part 212

Air transportation—foreign, Charter flights, Reporting requirements, Surety bonds, Travel agents.

## PART 212—[AMENDED]

Accordingly, the Board proposes to amend paragraph (a) of § 212.4 of 14 CFR Part 212, *Charter Trips by Foreign Air Carriers*, by adding another sentence at the end thereof so that it would read as follows:

**§ 212.4 Prior authorization requirements.**

(a) A foreign air carrier shall not perform any charter trip for which a statement of authorization is required until one has been granted by the Board. In addition, if the carrier is one that is required to obtain a statement of authorization under paragraph (e) of this section, it shall not advertise or sell any passenger charter services except those that have been specifically authorized by the Board.

* * * * *

(Secs. 204, 402, 407, 411, 416, 1102, Pub. L. 85-726, as amended, 72 Stat. 743, 757, 766, 769, 771, 94 Stat. 42, 49 U.S.C. 1324, 1372, 1377, 1381, 1386, 1502)

Dated: April 7, 1983.

By the Civil Aeronautics Board.

**Phyllis T. Kaylor,**

*Secretary.*

[FR Doc. 83-10647 Filed 4-20-83; 8:45 am]

BILLING CODE 6320-01-M

## SECURITIES AND EXCHANGE COMMISSION

### 17 CFR Parts 210 and 239

**[Release Nos. 33-6461; 34-19674; File No. S7-968]**

### Accounting for Internal Costs of Developing Computer Software for Sale or Lease to Others

**AGENCY:** Securities and Exchange Commission.

**ACTION:** Proposed rules.

**SUMMARY:** The Commission is proposing to prohibit the capitalization of internal costs of developing computer software for sale or lease to others by registrants that have not previously disclosed the adoption of such a practice. This action is proposed in order to prevent further divergence in practice in accounting for such costs. The proposed rules would also require registrants that have previously disclosed the adoption of such a practice to disclose the effect on net income of not expensing all such costs as incurred. When the authoritative accounting literature provides better guidance for determining (1) which activities associated with developing such computer software are not research and development activities, and (2) the appropriate accounting for costs of those activities, if any, which are not research and development activities, the Commission will reconsider any rules adopted by it in this area.

**DATE:** Comments should be received by the Commission on or before May 31, 1983.

**ADDRESS:** Comment letters should refer to File No. S7-968 and should be submitted in triplicate to George A. Fitzsimmons, Secretary, Securities and Exchange Commission, 450 5th Street, NW., Washington, D.C. 20549. All comments received will be available for public inspection and copying in the Commission's Public Reference Room, 450 5th Street, NW., Washington, D.C. 20549.

**FOR FURTHER INFORMATION CONTACT:** Marc D. Oken or Robert K. Herdman (202/272-2130), Office of the Chief Accountant, or Howard P. Hodges 272-2553), Division of Corporation Finance, Securities and Exchange Commission, Washington, D.C. 20549.

**SUPPLEMENTARY INFORMATION:**

### Background

The Commission believes that most registrants engaged in the business of selling, leasing or otherwise marketing computer software to others expense all internal software development costs as incurred. However, the Commission is concerned about the increasing number of registrants that are capitalizing internal costs of developing computer software. Since these costs can constitute a significant percentage of operating costs incurred by registrants in the computer software industry, the method of accounting for them can have a material impact on financial position and results of operations. Furthermore, the existence of differing accounting practices has created a source of incomparability between the financial statements of those registrants that are capitalizing such costs and others in the industry that are expensing them.

As discussed further below, two separate pronouncements of the Financial Accounting Standards Board ("FASB") and an FASB staff technical bulletin have addressed the accounting for internal software development costs in the context of the relationship of computer software development activities to research and development activities.[1] Nonetheless, the existing literature has not prevented the diversity of practice which is developing. Because of the increasing diversity of practice in this area, the Commission believes that the existing accounting literature should be clarified to provide more explicit guidance for determining which computer software development activities do not constitute research and development activities and to specify the appropriate accounting for the costs of any such activities that are

[1] In Statement of Financial Accounting Standards No. 2, "Accounting for Research and Development Costs" ("SFAS No. 2"), the FASB required that the costs of research and development activities be charged to expense as incurred.

determined not to be research and development activities.

In recognition of this need for clarification, the Accounting Standards Executive Committee ("AcSEC") of the AICPA and the Association of Data Processing Service Organizations ("ADAPSO") have formed a joint task force to develop issues papers for consideration by the FASB. The Commission understands that the objectives of the proposed issues papers are to clarify the requirements for accounting for software development costs, as well as to address other financial reporting issues of importance to the computer software industry (such as principles governing revenue recognition and guidance concerning amortization periods for purchased and any internally developed software that is capitalized). The Commission is concerned that until such time as the accounting literature is clarified for software development activities, the present diversity in practice will lead to increased use of the capitalization method without adequate guidance as to either its propriety or the proper subsequent accounting of costs that have been capitalized. Therefore, the Commission is issuing this release to propose a prohibition on the capitalization of such costs by any registrant that has not previously followed that practice. When adequate guidance has been developed, the Commission will reconsider any rules adopted by it in this area.

**Existing Accounting Literature**

The FASB's conclusion in SFAS No. 2 (October 1974) that the costs of all research and development activities should be expensed as incurred was stated to be based on both the uncertainty of future benefits derived from such activities and the lack of causal relationship between expenditures made and any future benefits.[2] SFAS No. 2 provides general examples, applicable to companies in all industries, of activities that typically would be included in or excluded from the definition of research and development. In paragraph 31, it also provides the following example specifically applicable to computer software development:

> [E]fforts to develop a new or higher level of computer software capability intended for sale (but not under a contractual arrangement) would be a research and development activity encompassed by this Statement.

[2] SFAS No. 2, paragraphs 39–41. The concept of future benefits discussed by the FASB includes commercial success in the marketplace.

Soon thereafter, in February 1975, the FASB issued FASB Interpretation No. 6, "Applicability of FASB Statement No. 2 to Computer Software" ("Interpretation No. 6"), in an effort to explain further the relationship of costs incurred to develop computer software to the general examples used in SFAS No. 2 for the identification of research and development costs. Paragraph 7 of Interpretation No. 6 addresses development of software as a product or process to be sold, leased, or otherwise marketed. It provides that:

> [I]f the development of software is undertaken to create a new or significantly improved product or process without any contractual arrangement, costs incurred for *conceptual formulation or the translation of knowledge into a design* would be research and development costs. Other costs, including those incurred for programming and testing software, are research and development costs when incurred in the search for or the evaluation of product or process alternatives or in the design of a pre-production model. On the other hand, costs for programming and testing are *not* research and development costs when incurred, for example, in routine or other on-going efforts to improve an existing product or adapt a product to a particular requirement or customer's need. (Emphasis in original.)

This language basically tracks the general examples of SFAS No. 2 in an equally broad manner and, until recently, has generally been interpreted in practice as requiring that all internal computer software development costs, other than those incurred for relatively minor modifications of existing products, be expensed.

Finally, in December 1979 the FASB staff issued Technical Bulletin No. 79–2, "Computer Software Costs" (TB 79–2"), in response to a request by the software industry for clarification of SFAS No. 2 and Interpretation No. 6. In TB 79–2, by reference to the criteria of SAFS No. 2, the FASB staff stated that not all computer software *production* costs must necessarily be considered research and development costs.[3] However, neither a specific definition of production nor any other guidance as to the activities which are not research and development activities was provided.

[3] "Production" is a term generally used by the industry to denote programming and testing activities. In this regard, the Commission staff has learned that some believe that the nature of production activities is such that they should never be considered to be research and development activities. They base this conclusion on their opinion that these activities represent routine implementation of a program's design, and point out that a working pre-production model does not exist in the conventional sense. Thus, they would consider production activities associated with both new products and routine enhancements of existing products to be other than research and development activities.

TB 79–2 did, however, add the warning that "a determination that software production costs are not research and development costs does not necessarily mean that they would be inventoriable or deferrable to future operations. Those decisions can only be made in light of all of the facts and circumstances surrounding the particular situation."

**Recent Developments**

The Commission's staff has recently noted that an increasing number of registrants in the computer software sales and service industry are capitalizing material amounts of internal software development costs. Through the comment process, the staff has learned that these registrants believe that the existing accounting literature permits such capitalization because they have expensed costs that they consider to be related to research and development activities (essentially those incurred through the "conceptual formulation and design" phase), and have capitalized only what they consider to be "production" costs. In some instances these registrants have limited capitalization to projects which contend are intended to result in "routine improvements of existing products."[4] Other registrants have also capitalized production costs associated with new products.

The Commission is concerned about the propriety of capitalization of costs of all production activities in the absence of more definitive guidance. The nature of the attendant programming and testing functions may continually require revisions to the original plans such that the "conceptual formulation or the translation of knowledge into a design" phase may continue throughout the length of the project. Further, even

[4] Following are two examples of the types of products characterized as routine improvements by these registrants. The first involves adaptation of a previously developed software application to a higher level of computer hardware capability. The second involves integration of a new processing application into a previously developed package of applications. In some cases, the package of applications can be marketed either with or without the new application; in others, only the upgraded package can be marketed. In both situations, as well as in the development of new products, these activities have often required that significant costs be expended over an extensive period of time. In order to distinguish their activities from the development of new products, the registrants have contended that, since their basic "product" has already been developed, the current activities are "routine or other on-going efforts to improve an existing product" which are assured of successful completion. The Commission believes, however, that because of the nature of these activities, the amounts expended, and the extended development period, these efforts might also be viewed as the "creation of a new or significantly improved product or process."

though the companies may engage in these activities only after studying market needs, there typically is uncertainty whether any products ultimately produced will effectively meet those needs, or that the needs will still exist when the development project is completed. For example, others may develop programs that perform the application more efficiently or may create the same capability with a reduced expenditure of cost, thus creating a competitive advantage. Also, rapid changes in industry technology may result in some product obsolescence by the time the product is introduced. These latter considerations were among the factors inherent in the FASB's conclusions on accounting for research and development costs in general. They should also be important facts and circumstances to be evaluated in connection with a descision to capitalize production costs.

### Conclusion

The above matters are expected to be addressed by the joint task force AcSEC, and ultimately by the FASB so that registrants in the computer software development industry will have sufficient guidance in accounting for the various costs involved to ensure comparable financial reporting for similar situations. In view of these anticipated private sector actions, the Commission has concluded that it should not seek to develop definitive accounting guidelines in this area at the present time. However, the Commission is concerned that the current trend toward capitalization will continue until such time as appropriate clarification of the existing standards is accomplished. This would increase the incomparability of financial information among registrants in the computer software industry and also may result in inappropriate capitalization of costs by some registrants.

Accordingly, the Commission has determined to propose a new Rule 3–21 of Regulation S–X [17 CFR Part 210]. This rule would provide that companies which had not disclosed the practice of capitalizing internal computer software development costs [3] either in audited financial statements issued prior to the date of this release or in a report or registration statement filed with the Commission prior to the date of this release, shall not follow such a practice in financial statements filed with the Commission after that date.[4] Companies which have so disclosed such a practice prior to that date may continue to apply it on a consistent basis to the extent the methods of applying the practice are not inconsistent with the accounting literature that does exist. In view of the Commission's understanding as to the predominant accounting practice of the industry, the proposed rules would also require disclosure by registrants that are permitted to continue to capitalize such costs, of the effect on net income (and earnings per share) of following such a practice as opposed to charging to expense all such costs as incurred.

The Commission also reminds registrants that have capitalized such costs that their financial statements should include disclosure of the policies being followed, together with the amounts of such costs and related amortization. The method and period of amortization, as well as the bases therefor, should also be disclosed in the notes to the financial statements.

In reviewing specific registrant cases, the Commission staff has noted that the period over which capitalized costs of purchased and internally developed software are currently being amortized has ranged from three years to as many as seven years. In determining an appropriate amortization period based on the relevant facts and circumstances, registrants should carefully consider the rapid pace of technological development and the increased competition and growth in this industry. The Commission believes that such factors dictate the use of very short amortization periods.

### List of Subjects in 17 CFR Parts 210 and 239

Accounting, Reporting and recordkeeping requirements, Securities.

### Text of Proposed Rules

Chapter II Title 17 of the Code of Federal Regulations is proposed to be amended as follows:

## PART 210—FORM AND CONTENT OF AND REQUIREMENTS FOR FINANCIAL STATEMENTS, SECURITIES ACT OF 1933, SECURITIES EXCHANGE ACT OF 1934, PUBLIC UTILITY HOLDING COMPANY ACT OF 1935, INVESTMENT COMPANY ACT OF 1940, AND ENERGY POLICY AND CONSERVATION ACT OF 1975

1. By adding § 210.3–21 to read as follows:

**§ 210.3–21 Special provisions as to financial statements of companies engaged in marketing computer software.**

(a) Companies which had not disclosed the practice of capitalizing internal costs of developing computer software as a product or process to be sold, leased, or otherwise marketed to others in either: (1) Audited financial statements issued prior to April 14, 1983; or (2) a report or registration statement filed with the Commission prior to April 14, 1983; shall not follow such a practice in financial statements filed with the Commission after April 14, 1983.

(b) Because the term product also encompasses services that are sold, leased, or otherwise marketed to others, the prohibition in paragraph (a) of this section applies, for example, to a data processing service bureau or a computer time-sharing company.

(c) A company which, pursuant to paragraph (a) of this section continues to follow the practice of capitalizing internal costs of developing computer software as a product or process to be sold, leased, or otherwise marketed to others, shall disclose for each period for which an income statement is required to be presented, the effect on net income (and earnings per share) of not charging all such costs to expense as incurred.

## PART 239—FORMS PRESCRIBED UNDER THE SECURITIES ACT OF 1933

2. By adding Item 21(j) in Form S–18 in § 239.28 to read as follows (Form S–18 does not appear in the Code of Federal Regulations):

**§ 239.28 [Form S–18, amended]**

* * * * *

*Item 21(j) Special instructions for companies engaged in marketing computer software*

(1) Companies which had not disclosed the practice of capitalizing internal costs of developing computer software as a product or process to be sold, leased, or otherwise marketed to others in either: (1) Audited financial statements issued prior to April 14, 1983; or (2) a report or registration statement filed with the Commission prior to April 14, 1983; shall not follow such a practice in financial statements filed with the Commission after April 14, 1983.

(2) Because the term product also encompasses services that are sold, leased, or otherwise marketed to others, the prohibition in (1) above applies, for example, to a data processing service bureau or a computer time-sharing company; or

(3) A company which, pursuant to (1) above, continues to follow the practice of capitalizing internal costs of developing computer software as a product or process to be sold, leased, or otherwise marketed to others, shall disclose for each period for which an income statement is required to be

[3] This conclusion applies to all development of software as a product or process to be sold, leased, or otherwise marketed. For the reasons set forth in paragraph 7 of Interpretation No. 6, it also applies to internal costs incurred in developing software to be used by a data processing service bureau or a computer time-sharing company.

[4] A revision to form S–18 is also proposed since financial statements included in registration statements on that form are not prepared pursuant to all of the provisions of Regulation S–X.

presented, the effect on net income (and earnings per share) of not charging all such costs to expense as incurred.

* * * * *

**Authority:** These rules are being proposed pursuant to the authority in Sections 5, 6, 7, 10, 19a and Schedule A(25) and (26) of the Securities Act of 1933, 15 U.S.C. 77e, 77f, 77g, 77j, 77s(a), 7nn(25) and (26); and Sections 12, 13, 14, 15(d), and 23(a) of the Securities Exchange Act of 1934, 15 U.S.C. 78l, 78m, 78n, 78o(d), 78w(a).

Pursuant to Section 23(a)(2) of the Securities Exchange Act, the Commission has considered the impact of these proposals on competition and it is not aware at this time of any burden that such rules, if adopted, would impose on competition. However, the Commission specifically invites comments as to the competitive impact of these proposals, if adopted.

In addition, the Commission is mindful of the cost to registrants and others of its proposals and recognizes its responsibilities to weigh with care the costs and benefits which result from its rules. Accordingly, the Commission specifically invites comments on the costs to registrants and others of the adoption of the proposals published herein.

By the Commission.

**George A. Fitzsimmons,**

*Secretary.*

April 14, 1983.

**Initial Regulatory Flexibility Analysis**

This initial regulatory flexibility analysis, which relates to proposed rules for financial statements of companies engaged in marketing computer software, has been prepared in accordance with 5 U.S.C. 603.

1. *Reasons for Proposed Action*—The Commission is proposing amendments to Regulation S–X and Form S–18 to prohibit the capitalization of internal costs of developing computer software for sale or lease to others by registrants that had not previously adopted such a practice.

As discussed in the section of the release entitled, "Recent Developments," the Commission staff has recently noted that an increasing number of registrants in the computer software sales and service industry are capitalizing material amounts of internal software development costs. Because cost registrants in the industry continue to expense all such costs as incurred, the trend towards capitalization has created a source of incomparability between the financial statements of those registrants that are capitalizing such costs and those registrants that are expensing them.

While the private sector has initiated activities intended ultimately to result in clarification of the requirements for accounting for such costs, the Commission is concerned that, until such time as appropriate clarification occurs, the present diversity in practice will lead to increased use of the capitalization method without adequate guidance as to either its propriety or the proper accounting for costs that have been capitalized. Should this occur, incomparability of financial information among registrants in the computer software industry would increase. Also, inappropriate capitalization of costs by some registrants might occur.

2. *Objectives*—As stated in the "Summary" to the release, the primary objective of the proposed rules is to prevent further divergence in practice in accounting for internal computer software development costs. To that end, the proposed rules would prohibit the capitalization of internal costs of developing computer software for sale or lease to others by registrants that had not previously adopted such a practice. When the accounting literature provides better guidance for determining (1) which activities associated with developing such computer software are not research and development activities, and (2) the appropriate accounting for costs of those activities, if any, which are not research and development activities, the Commission will reconsider any rules adopted by it in this area.

Further, in order to facilitate comparison of financial information of registrants engaged in such activities, and in view of the Commission's understanding as to the predominant accounting practice of the industry, the proposed rules would also require disclosure by registrants that have capitalized such costs of the effect on net income of following such a practice as opposed to charging to expense all such costs as incurred.

3. *Legal Basis*—The Commission is proposing the rules for financial statements of companies engaged in marketing computer software pursuant to the authority in Sections 5, 6, 7, 10, 19a and Schedule A(25) and (26) of the Securities Act of 1933, 15 U.S.C. 77e, 77f, 77g, 77j, 77s(a), 77nn(25) and (26); and Sections 12, 13, 14, 15(d), and 23(a) of the Securities Exchange Act of 1934, 15 U.S.C. 78l, 78m, 78n, 78o(d), 78w(a).

4. *Small Entities Subject to Rule*—For purposes of this analysis, the Commission is using the definition of "small business" as adopted in Securities Act Release No. 6380.[7] That release provides that when used in reference to the Securities Act, small business means any issuer whose total assets on the last day of its most recent fiscal year were $3 million or less and is engaged or proposes to engage in "small business financing." [8] When used with reference to an issuer or a person other than an investment company under the Securities Exchange Act, small business means an issuer or person that, on the last day of its most recent fiscal year, had total assets of $3 million or less. Accordingly, the amendments would affect all entities engaged in marketing computer software which fall within the Commission's definition of a "small entity." Since Form S–18 is available to non-reporting entities seeking to raise $5 million through the sale of their securities, a substantial portion of the registrants using the form would be "small businesses" as described above. It is not possible to estimate the number of small businesses that would be affected by the proposal, since issuers may use Form S–18 when they elect to make a public offering based on, among other things, general economic and market conditions and trends within the particular industry.

5. *Reporting, Recordkeeping, and Other Compliance Requirements*—The proposed rules would introduce no new data collection or recordkeeping requirements for any companies which are engaged in marketing computer software. Information about internal costs of developing such software is already generally available as an integral part of existing accounting records and the proposed rules would only affect whether such costs are expensed as incurred or capitalized and amortized over future periods. For companies for which the latter accounting practice is permitted, the proposed requirement to disclose the effect on net income of not charging all internal software development costs to expense as incurred can be satisfied by a relatively simple calculation based on data already generally available as an integral part of existing accounting records.

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[7] Securities Act Release No. 6380 (January 28, 1982) [47 FR 5215].

[8] Small business financing is defined to mean conducting or proposing to conduct an offering of securities which does not exceed the dollar limitation prescribed by Section 3(b) of the Securities Act. The Section 3(b) limitation is presently $5 million.

Because the proposed rules would prohibit registrants from capitalizing internal software development costs if they had not disclosed such practice in the past, the proposed rules could have a significant impact on an individual registrant's reported net income. (There will be no effect on actual cash flows.) However, in view of the Commission's understanding that the predominant practice in the industry is to charge all such costs to expense as incurred, the Commission does not believe that this potential book income impact will have an effect on competitive position or the ability to sell securities in the capital markets.

6. *Overlapping or Conflicting Federal Rules*—The Commission believes that no present Federal rules duplicate or conflict with the proposals.

7. *Significant Alternatives*—Because the proposed rules are intended to prevent further incomparability of financial information among registrants in the computer software industry, the Commission believes that an exemption or an alternative approach designed particularly for small entities would not be appropriate. With respect to the reporting requirements of the proposed rules, the consideration of differing reporting or compliance requirements is not necessary since the proposed rules would not change the recordkeeping requirements or other compliance burdens.

In the Commission's view, the use of performance rather than design standards was not applicable since the proposals are not related to either performance or design standards.

8. *Solicitation of Comments*—The Commission encourages the submission of comments with respect to any aspect of this initial regulatory flexibility analysis and such comments will be considered in the preparation of the final regulatory flexibility analysis if the proposed amendments are adopted. The Commission is especially interested in any empirical data on the costs and/or benefits of the proposed amendments. Persons wishing to submit written comments should file four copies thereof with George A. Fitzsimmons, Secretary, Securities and Exchange Commission, 450 5th Street, N.W., Washington, D.C. 20549. All submissions should refer to File No. S7–968 and will be available for public inspection at the Commission's Public Reference Room, 450 5th Street, N.W., Washington, D.C. 20549.

[FR Doc. 83-10623 Filed 4-20-83; 8:45 am]

BILLING CODE 8010-01-M

## 17 CFR Part 240

[Release No. 34-19673; File No. S7-967]

## Initiation or Resumption of Quotations Without Specified Information

**AGENCY:** Securities and Exchange Commission.

**ACTION:** Proposed rulemaking.

**SUMMARY:** The Commission is reevaluating whether there is a continuing need to regulate the publication by broker-dealers of quotations for certain over-the-counter securities. In connection with this examination, it is proposing for comment amendments to an existing rule that regulates the submission and publication of such quotations. The amendments would require those broker-dealers to maintain information concerning certain issuers of securities, including foreign issuers. The Commission is considering whether these actions are necessary to protect investors against fraudulent, deceptive and manipulative practices. Alternatively, the Commission is considering whether to rescind the Rule.

**DATE:** Comments must be received on or before June 14, 1983.

**ADDRESSES:** Interested persons should submit three copies of their written data, views and arguments to George A. Fitzsimmons, Secretary, Securities and Exchange Commission, Washington, D.C. 20549 and should refer to File No. S7–967. All submissions will be made available for public inspection at the Commission's Public Reference Section, Room 1024, 450 Fifth Street, N.W., Washington, D.C.

**FOR FURTHER INFORMATION CONTACT:** Kenneth B. Orenbach at (202) 272–7391; Office of Legal Policy and Trading Practices, Division of Market Regulation, Securities and Exchange Commission, 450 Fifth Street, N.W., Washington, D.C. 20549.

**SUPPLEMENTARY INFORMATION:** The Securities and Exchange Commission is today proposing for comment amendments to Rule 15c2–11 (the "Rule") [1] under the Securities Exchange Act of 1934 (the "Act").[2] Rule 15c2–11 generally requires a broker-dealer to have information concerning an issuer before the broker-dealer may publish quotations in the issuer's securities. As more fully discussed in this release, the Commission has decided to review whether Rule 15c2–11 achieves its intended purposes and whether there is a continuing need for it. In connection with that review, the Commission is proposing amendments that would strengthen the Rule, particularly as it applies to foreign securities and certain other securities traded over-the-counter.

One of the proposed amendments would modify paragraph (f)(2), which currently excepts quotations regarding securities issued by certain foreign non-reporting issuers.

The proposal would require broker-dealers to maintain in their files the information that such issuers have furnished to the Commission during the preceding fiscal year pursuant to Rule 12g3–2(b). The proposal also requires broker-dealers that initiate quotations in American Depositary Receipts to maintain certain information concerning the issuer of the deposited foreign shares.

The Commission is also proposing an amendment which would extend the information maintenance and other requirements of the Rule to brokers and dealers who submit unpriced entries to inter-dealer quotation media. Unpriced entries based on unsolicited customer orders or indications of interest would continue to be excepted. Another amendment would prohibit the initiation of quotations for the securities of reporting companies that are delinquent in meeting their filing obligations under the Act.

In addition, the Commission is announcing that it is undertaking a review of paragraph (f)(3) of the Rule. Paragraph (f)(3), commonly known as the "piggyback" provision, excepts quotations from the substantive requirements of the Rule if the security being quoted has been the subject of two-way priced quotations on a certain number of days within the last thirty calendar days. This review will determine whether current compliance practices under the piggyback provision are consistent with the purposes of the Rule.

Finally, the Commission is soliciting comment on the compliance burdens associated with the information requirements of the Rule, and whether these burdens are warranted in view of the regulatory purposes of the Rule.

### I. Background

Adopted in 1971,[3] Rule 15c2–11 was designed primarily to prevent certain manipulative and fraudulent trading schemes that had arisen in connection with the distribution and trading of unregistered securities issued by companies that had little or no assets.

[1] 17 CFR 240.15c2–11.

[2] 15 U.S.C. 78a-jj.

[3] Securities Exchange Act Release No. 9310 (Sept. 13, 1971).

earnings, or operations ("shell companies") [4] or other companies having outstanding but infrequently traded securities. The Rule was intended to prevent brokers and dealers from furnishing arbitrary initial quotations, and activity that was critical to the success of many of the unlawful schemes.

The Rule prohibits a broker or dealer from entering a quotation for a security in a quotation medium at a price unless it has specified information concerning the quoted security and the issuer [5] and, with respect to certain quotations, it furnishes certain information to the appropriate quotation medium two days prior to the publication of such quotation.[6] The Rule does not, however, apply to the publication of any entry in a quotation medium that is not a specified price ("name only entries").[7] It also excepts from its coverage the publication of quotations in securities that are quoted regularly (*i.e.*, that are the subject of both bid and asked quotations for a specified number of days during the preceding 30 day period) ("piggyback provision") as well as quotations for most exchange-traded and all municipal securities.

Today, most entries of quotations or indications of interest in inter-dealer quotation systems are not subject to the Rule. There are several reasons for this. In 1971 the NASD inaugurated an automated inter-dealer quotation system—NASDAQ—in which market-makers enter quotations for securities on a "real-time" basis and generally quote securities continuously. Those quotations therefore are eligible for an exception from Rule 15c2–11. The enhanced efficiency of the NASDAQ system over pre-existing inter-dealer quotation systems, such as The National Daily Quotation Service (the "pink sheets"), has caused most eligible securities to be quoted in that system. As a result, NASDAQ has become the principal quotation system for many over-the-counter securities while other inter-dealer quotation systems, such as the pink sheets, are now used as the principal quotation medium for the generally less frequently traded securities of lesser-known issuers or as a supplement to the typically more active securities in NASDAQ.

In fact, most securities that are quoted in the pink sheets relate to the thousands of lesser-known securities that are traded in what might be called the "residual" over-the-counter market.[8] Compared with "third market" stocks and the majority of over-the-counter stocks quoted in the NASDAQ system, those pink sheet securities are, in general, characterized by low levels of trading activity and dealer competition. Information concerning such stocks is often not readily available to the market place, few professional analysts regularly follow these stocks, and there is no tape or electronic display system designed to disseminate widely current quotations and other market information about these securities. Moreover, pink sheet stocks generally do not enjoy substantial liquidity, owing in large part to a lack of broad-based investor interest and dealer competition and the absence of any rules requiring the maintenance of continuous markets or firm priced quotes for such securities. Because the residual over-the-counter stocks are not quoted in NASDAQ, the pink sheets are critical to the dissemination of quotations by broker-dealers that wish to make a market in such securities. Rule 15c2–11 is the Commission's only oversight mechanism secifically designed to ensure that such quotations (and any upward movement in such quotations) are not clearly inconsistent with available information about the security being quoted.

In addition, perhaps because of the availability of priced quotations on a real-time basis in the NASDAQ system, broker-dealers using other inter-dealer quotation media, particularly the pink sheets, have increasingly elected to advertise their interest in a particular security by publishing name only entries, which are not subject to the Rule, rather than priced quotations, which may in those systems be stale when published.

Finally, as discussed more fully in this release, other practices appear to have developed under the piggyback provision that have decreased the efficacy of the Rule.

As a result of these developments, the Commission has determined to review all aspects of the Rule, including whether the self-regulatory surveillance mechanisms play, or can play, an important role in assuring compliance with the Rule. In that connection, the Commission is publishing for comment a number of proposed amendments to the Rule. The proposed amendments are discussed below.

## II. Proposed Amendments

### *A. Rescission of Exemption for Foreign Issuers Granted by Paragraph (f)(2) of the Rule*

Rule 15c2–11 does not apply, by reason of paragraph (f)(2), to securities of foreign issuers that are exempt from Section 12(g) of the Act pursuant to Rule 12g3–2(b). Although Section 12(g) applies to many foreign issuers, Rule 12g3–2(b) represents the Commission's resolution of the problem associated with imposing the burdens and obligations of Section 12(g) on foreign issuers that have not taken any initiative to introduce those securities into, or to promote, U.S. markets for those securities.[9]

Most securities of foreign issuers that are not listed on an exchange but otherwise would be required to be registered under, and subject to the reporting provisions of, Section 12(g) of the Act are exempted from those requirements by Rule 12g3–2(b).[10]

The Commission is concerned, however, about the increasing frequency with which unregistered foreign securities are quoted in inter-dealer quotations systems, including NASDAQ, often under circumstances where little or no current information about the issuer of the securities is available to the market place. For non-reporting foregin securities that satisfy the information-supplying exemption of

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[4] *See* Securities Exchange Act Release Nos. 9310 (Sept. 13, 1971) and 8909 (June 24, 1970).

There were several typical practices. One, for example, involved the acquisition of publicly-held shell companies by promoters who then engaged in various activities designed to raise the market price of the securities and, along with other insiders, took advantage of the subsequent price rise by selling their shares to the public at an inflated price. Securities Exchange Act Release No. 4982 (July 2, 1969).

[5] The information requirements of the Rule are set forth in paragraph (a). They generally require a broker or dealer that wishes to enter a quotation for the securities of an issuer to maintain (i) in the case of an issuer that has conducted a recent public offering that was registered under the Securities Act of 1933 or effected pursuant to Regulation A, a copy of the prospectus or offering circular or (ii) in the case of a company that is required to file certain reports pursuant to Sections 13 or 15(d) of the Act or is an insurance company of the kind specified in Section 12(g)(2)(G), the issuer's most recent annual report and interim reports that have been filed thereafter. In the alternative, or where the issuer falls into none of the categories described above, the broker or dealer may acquire and maintain the information specified in paragraph (a)(4), including certain financial information.

[6] 17 CFR 240.15c2–11(d).

[7] Rule 15c2–11(e)(3) defines "quotation" as "any bid or offer at a specified price with respect to a security." Consequently, if a broker or dealer furnishes an entry in name only, offer wanted ("OW") or bid wanted ("BW"), it is not subject to the Rule. See text at n. 14, *infra*.

[8] In this regard, *see* Rogoff, *Legal Regulation of Over-the-Counter Market Manipulation: Critique and Proposal*, 28 Maine L. Rev. 149, 198 (1976).

[9] *See* generally H.R. Rep. No. 1418, 88th Cong., 2d Sess. 11 (1964).

[10] The Rule 12g3–2(b) exemption is conditioned upon, among other things, a requirement that the issuer (or an appropriate government agency in its domicile) furnish to the Commission copies of certain information required to be made public pursuant to the law of its domicile (or which is otherwise made available to its shareholders).

Rule 12g3–2(b), the Commission is proposing to amend Rule 15c2–11 to add a new paragraph (a)(4) that would require a broker or dealer quoting securities of a foregin private issuer that furnishes information to the Commission pursuant to Rule 12g3–2(b) to maintain in its records (and make available to investors upon request) the information furnished to the Commission since the beginning of the issuer's last fiscal year.[11] The broker or dealer would be permitted to rely on such information if it had no reasonable basis for believing that the materials so furnished and in its records were not true and correct. Such a proposal is consistent with the requirements and purpose of Rule 12g–3–2(b), but would also enhance investor protection without imposing undue burdens on broker-dealers or issuers.

The Commission also has certain concerns that arise when brokers or dealers make a market in American Depositary Receipts ("ADRs") that represent shares of a foreign issuer deposited with a depositary. In many instances, the information provided in Form F–6 under the Securities Act of 1933 will not relate to the issuer of the deposited security, notwithstanding that the ADR is the functional equivalent of shares of such issuer's securities.[12] Accordingly, in order to ensure that market-makers in ADRs maintain information concerning the issuer of the deposited foreign shares represented by the ADRs, the Commission is proposing for comment certain additional modifications to Rule 15c2–11.

First, the Commission is proposing to amend paragraph (a)(1) of the Rule, which permits quotations if the broker or dealer has in its records the prospectus relating to a registration statement under the Securities Act of 1933 which became effective within 90 days, to exclude specifically Form F–6 from the registration statements as to which paragraph (a)(1) is available, since a registration statement on that form relates to the ADRs and not to the issuer of the deposited foreign shares.

In addition, the Commission is proposing a new paragraph (e)(4) that will specifically provide that, for purposes of Rule 15c2–11, the issuer of the deposited foreign shares shall be deemed to be the issuer of any ADR proposed to be quoted under the Rule. The effect of this amendment would be to require brokers and dealers that wish to publish quotations for ADRs to maintain the information required by the Rule concerning the issuer of the deposited shares.

These amendments should not, as a practical matter, impose an undue burden on brokers and dealers. Form F–6 requires that the foreign private issuer of foreign shares represented by ADRs registered on that form be in compliance with the periodic reporting requirements of the Act or Rule 12g3–2(b).[13] Consequently, the information required by Rule 15c2–11 will be publicly available. At the same time, the amendments would ensure that a market-maker in an ADR maintains information regarding the issuer of the foreign shares as if it were quoting the foreign shares directly.

*B. Amendment to Paragraph (e): Unpriced Entries Subject to the Rule*

The Commission is also proposing an amendment to the Rule that would require a broker or dealer to comply with its provisions when such broker-dealer publishes an entry without stating a price at which it would be willing to effect a transaction in the security.[14]

As originally published for comment in 1970, the Rule would have covered all unpriced entries.[15] At that time, however, commentators argued that the publication by a broker or dealer of an unpriced entry should not be made subject to the Rule's requirements because such a requirement would impose a substantial burden on brokers and dealers who effect isolated transactions in a security but do not have any interest in making a market in the security.[16] It was noted that a firm may publish an unpriced entry on behalf of a customer solely for the purpose of executing an unsolicited buy or sell order or when it is interested only in acquiring an investment position in a security. In adopting the Rule, the Commission decided to exclude all unpriced entries from its requirements.

As previously noted, since the adoption of the Rule, the practice of publishing unpriced entries, instead of priced quotations, has become increasingly common in quotation media that permit such entries. The result has been that dealers interested in making a market in a security on a continuous basis can and frequently do so without having to comply with the Rule. Specifically, such dealers can publish unpriced entries daily in quotation media and, when contacted regarding their trading interest, furnish quotations in the security. Those quotations may be the primary indications of trading interest in a security and the broker or dealer may influence the development of an active trading market that would not otherwise have existed. As a result of the increased use of this practice, the Rule may no longer reach activities that it was intended to cover. Accordingly, the Commission has determined to publish for comment an amendment that would require a broker or dealer to comply fully with the Rule if it publishes an unpriced entry. Another amendment proposed today would, however, exclude from the Rule all entries that represent unsolicited customer orders and thus should largely resolve the concerns that lay behind the original exclusion of unpriced entries.

*C. Amendment to Paragraph (f): Exception for Quotations Representing Unsolicited Customer Orders*

When an order is unsolicited, the trading interest is not initiated by the broker, and the broker generally would not have a motive to affect the market price for the security involved. If a quotation or indication of interest represents such an order, there appears to be little potential for manipulative abuse. Accordingly, the Commission is

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[11] Existing paragraph (a)(4) would be redesignated paragraph (a)(5). The Commission has also proposed amendments to Rule 12g3–2 that would require issuers to become reporting companies if their securities are to be quoted in NASDAQ. *See* Securities Act Release No. 6433 (October 28, 1982)

[12] The Commission recently adopted Form F–6, which replaces Form S–12. The new F–6 is a form for the registration of ADRs under the Securities Act of 1933. *See* Securities Act Release No. 6459 (March 18, 1983). Form F–6, among other things, requires that the foreign private issuer of securities represented by the ADR become a reporting company or comply with the information supplying exemption of Rule 12g3–2(b).

[13] In contrast, Form S–12 contained an undertaking pursuant to which the depositary agreed, among other things, to furnish to the Commission any information that it actually received from the issuer of the underlying securities.

[14] Brokers and dealers may indicate their trading interest in an inter-dealer quotation system in several ways. In certain systems, such as the pink sheets, a broker or dealer may enter a priced quotation on both the buy and sell sides or on one side only. As an alternative, a broker or dealer may advertise that it is interested in buying or selling a particular security without entering a bid or offer price. Specifically, it may insert (i) "OW" (offer wanted), indicating that the firm is interested in receiving quotations from persons who want to sell the security; (ii) "BW" (bid wanted), indicating that it is interested in receiving quotations from persons who want to buy the security; or (iii) the firm's name only, indicating that the firm wants to advertise its general interest in both purchasing and selling the security. In the NASDAQ system, however, a firm may insert only two-sided quotations, *i.e.*, entries at a price on both the buy and sell sides of the market.

[15] Securities Exchange Act Release No. 8909 (June 24, 1970).

[16] *See* letter from Gordon S. Macklin, President, National Association of Securities Dealers, Inc., to Orval L. DuBois, Secretary, SEC, dated July 27, 1970, and letter from Carl W. Schneider, Esq., to Orval L. DuBois, Secretary, SEC, dated August 12, 1970, which are contained in the Commission's public file relating to the original rulemaking proceeding for the Rule.

proposing an amendment to the Rule that would except from its provisions the publication or submission of any quotation on behalf of a customer whose order was unsolicited.[17] The exception would not be available if the quotation represented an unsolicited order from another registered broker or dealer.

*D. Review of the "Piggyback" Provision and Existing Compliance Practices*

Paragraph (f)(3) excepts from the Rule's provisions any quotation with respect to a security that has been the subject of both bid and asked quotations on at least twelve of the preceding thirty days and for which no more than four consecutive business days during that period have elapsed since such a two-way quotation has been published. This provision, which is commonly referred to as the "piggyback" provision, is designed to limit the application of the Rule to securities that have not been actively quoted in the recent past.[18] Because of certain procedures in the National Quotation Bureau's application process, however, brokers and dealers may be able to enter quotations in the pink sheets for a security in purported reliance on the piggyback provision during the thirty days after the publication of any other quotation or unpriced entry for the same security, although it is not clear to what extent this practice has become prevalent.[19]

The practice described above is not permissible under the current piggyback provision and may undermine the original purpose of the provision.[20] It raises particular concerns in the context of trading suspensions, many of which are associated with an issuer's failure to satisfy its statutory disclosure obligations. If, after a trading suspension expires, brokers and dealers resume quoting securities before a disclosure deficiency has been cured in reliance on quotations that were entered before the trading suspension began, those quotations may be made on the basis of inadequate information about the issuer. Strict compliance with the piggyback provision would normally prevent broker-dealers from entering quotations in reliance on it if at any time during the previous thirty days there had been a trading suspension in the security.[21]

The Commission intends to review current compliance practices under the provision and specifically solicits the views of interested persons on current compliance practices under it. The review is designed to determine whether current practices by broker-dealers are satisfactory and whether any modification of the provision by the Commission would be appropriate, and specifically, whether there are other formulations that would achieve the same result while at the same time imposing fewer constraints on brokers and dealers.

*E. Amendment to Present Paragraph (a)(4): Information Requirement Concerning Reporting Companies and Exempt Insurance Companies*

Present paragraph (a)(4) of the Rule (to be redesignated paragraph (a)(5)) permits a broker or dealer to publish or submit quotations for a security if it maintains in its records certain specified financial and other information relating to the issuer and the security. The paragraph does not specify the type of issuer with respect to which, or the circumstances under which, brokers and dealers may rely upon paragraph (a)(4). Consequently, although the provision was intended primarily to regulate quotations for the securities of small non-reporting companies that have not conducted recent public offerings, in its current form, it would permit a broker or dealer to rely on paragraph (a)(4) in other circumstances.

When a reporting company is delinquent in complying with its periodic reporting requirements under the Act, or an exempt insurance company has not filed its required annual statement with the appropriate state regulatory agency, brokers and dealers may not rely on paragraph (a)(3) to quote the company's securities. As currently drafted, however, paragraph (a)(4) would permit a broker or dealer to publish quotations for the company's securities if it had the requisite information specified in that paragraph. That result would obtain under the Rule even though the information called for under paragraph (a)(4) frequently would fall short of the information the company is required to make public under the Act.

The Commission believes that brokers and dealers should not be permitted to enter quotations for the securities of a company that is delinquent in meeting its statutory disclosure obligations. In the Act, the Congress established a system of continuous disclosure by issuers that (i) have a class of equity securities traded on a national securities exchange, (ii) meet certain minimum criteria relating to assets and number of shareholders, or (iii) have sold securities to the public pursuant to an effective registration statement.[22] In enacting this framework, the Congress determined that such issuers have a special obligation to their shareholders to makes certain information available to investors and the market place.

In view of the congressional policy concerning disclosure by issuers, it seems inappropriate to permit brokers and dealers to enter quotations concerning the securities issued by companies that have not met their reporting obligations. Consequently, the Commission is proposing an amendment that would prohibit a broker or dealer from relying on paragraph (a)(4) (new paragraph (a)(5)) when it enters quotations for the securities of a reporting company or an exempt insurance company.

**III. Deregulatory Alternative**

As noted above, the Commission believes that the purposes of Rule 15c2-11 cannot be fully achieved unless certain changes are made. At the same time, however, the Commission recognizes that such changes may be accompanied by certain additional

[17] If the amendment that subjects all unpriced entries to the Rule is adopted, this amendment would except all unpriced entries, as well as priced quotations, on behalf of customers whose orders are unsolicited.

[18] As a practical matter, subsequent to the initiation of quotations, securities quoted in NASDAQ today are excepted from the operation of the Rule by the piggyback provision, since these securities are the subject of two-sided quotations for at least 12 days during the preceding 30 day period without a four day interruption. Because securities quoted on NASDAQ generally raise none of the concerns on which the Rule is based, the Commission invites comment on whether the Rule should be amended to except NASDAQ securities. Commentators are also requested to address the question whether such an exception, if appropriate, should exclude securities in the system that have been summarily suspended from trading for ten days by the Commission on the basis of a disclosure deficiency by the issuer, since such securities would no longer qualify for the piggyback provision and information relating to the security would not be current until the deficiency is cured.

[19] This practice, if permitted, would allow piggybacked quotations to be made without requiring current information to be maintained about an issuer and under circumstances in which significant market activity for the security may not exist.

[20] In this connection, the Commission seeks comment as to whether market-makers generally maintain, apart from the requirements of the Rule, "due diligence" files containing current information on some or all over-the-counter stocks in which they make markets.

[21] Summary trading suspensions under Section 12(k) of the Act typically last ten days. Such a cessation in trading and in activities designed "* * * to induce the purchase or sale of, any security in which trading is so suspended," would preclude brokers and dealers from complying with the strict terms of the piggyback provision because they would be unable to show that there has been "* * * no more than four business days in succession without * * * a two-way quotation * * *" during the previous thirty days, as required by the piggyback provision.

[22] *See* Sections 12(b), 12(g) 13(a), 13(b) and 15(d) of the Act; 15 U.S.C. 78*l*(b), 78*l*(g) 78m(a), 78m(b), and 78*o*(d).

regulatory restraints on some broker-dealers and the markets which they serve.

The proposed revisions to the Rule would require some broker-dealers to obtain and maintain information that they otherwise might not acquire. Also, tighter enforcement of the piggyback provision might cause some broker-dealers to discontinue placing quotations in the pink sheets for some thinly traded securities. This might decrease market liquidity. Similar arguments might be made against application of the Rule to quotations not at a price or the proposed requirement that certain information be maintained respecting securities of foreign issuers exempt from Section 12(g) of the Act.

In this regard, the Commission intends to reevaluate Rule 15c2-11 in its entirety and determine whether there is a continuing need for some or all of its provisions. In this connection, the Commission invites comments on the following questions:

1. What are the burdens on issuers of preparing the information required by the Rule and providing it to requesting broker-dealers and how should these costs be weighed against the purposes of the Rule?

Can some portion of the information requirement of the Rule be rescinded with little additional risk to investors but substantial savings to issuers?

2. What are the burdens to broker-dealers associated with obtaining the information required by the Rule and are these burdens significant in light of the regulatory purposes of the Rule?

3. Will a significant number of broker-dealers cease market-making in securities subject to the Rule rather than comply with its provisions as proposed to be amended?

4. To what extent do market-makers that publish quotations currently excepted from the Rule nevertheless maintain the information required by the Rule?

## IV. Summary of Initial Regulatory Flexibility Analysis

The Commission has prepared an Initial Regulatory Flexibility Analysis in accordance with 5 U.S.C. 603 regarding the proposed amendments to Rule 15c2-11. The Analysis notes that the objective of requiring the Rule to apply to ADRs as well as foreign issuers that furnish information to the Commission pursuant to Rule 12g3-2(b) is to ensure that brokers and dealers have adequate information upon which to evaluate initial quotations for foreign securities and ADRs. The Analysis further states that the proposal to subject unpriced entries to the Rule lessens the possibility that brokers and dealers can engage in manipulative conduct by publishing unpriced entries on a regular basis without being subject to the Rule. Finally, the Analysis notes the inappropriateness of allowing broker-dealers to rely on present paragraph (a)(4) to quote securities of reporting companies that are delinquent in their statutory reporting obligations.

A copy of the Initial Regulatory Flexibility Analysis may be obtained by contacting Kenneth B. Orenbach, Division of Market Regulation, Securities and Exchange Commission, Washington, D.C. 20549 (202-272-7391).

### List of Subjects in 17 CFR Part 240

Reporting requirements, Securities.

## V. Statutory Basis and Text of Proposed Rule

Pursuant to sections 3, 10, 15, 17 and 23, 15 U.S.C. 78c, 78j, 78o, 78q and 78w, the Commission proposes to amend § 240.15c2-11 in Chapter II of Title 17 of the Code of Federal Regulations by revising paragraphs (a)(1), (e)(3) and (f)(2); redesignating paragraph (a)(4) as (a)(5) and inserting a new introductory clause in paragraph (a)(5); and adding new paragraphs (a)(4) and (e)(4) to read as follows:

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

### § 240.15c2-11 Initiation or resumption of quotations without specified information.

(a) * * *

(1) The issuer has filed a registration statement under the Securities Act of 1933, other than a registration statement on Form F-6, which became effective less than 90 calendar days prior to the day on which such broker or dealer publishes or submits the quotation to the quotation medium, *Provided* That such registration statement has not thereafter been the subject of a stop order which is still in effect when the quotation is published or submitted, and such broker or dealer has in his records a copy of the prospectus specified by Section 10(a) of the Securities Act of 1933;

* * * * *

(4) (i) The issuer is exempt from Section 12(g) of the Act by reason of compliance with the provisions of § 240.12g3-2(b), and

(ii) The broker or dealer wishing to submit for publication a quotation for such security has in its records, and makes reasonably available upon request to any person expressing an interest in a proposed transaction in the security with such broker or dealer, the information furnished to the commission pursuant to § 240.12g3-2(b) since the beginning of the issuer's last fiscal year, which the broker or dealer has no reasonable basis for believing is not true and correct; or

* * * * *

(5) The issuer of the security is not required to file reports pursuant to Section 13 or 15(d) of the Act, and is not an issuer exempted from Section 12(g) of the Act by Section 12(g)(2)(B) or (G) of the Act, and * * *

* * * * *

(e) * * *

(3) Except as otherwise specified in this rule, "quotation" shall mean any bid or offer at a specified price with respect to a security, or any indication of interest by a broker or dealer in receiving bids or offers from others for a security, or any indication by a broker or dealer that it wishes to advertise its general interest in buying or selling a particular security.

(4) "Issuer," in the case of quotations represented by American Depositary Receipts, shall mean the issuer of the deposited shares represented by such American Depositary Receipts.

(f) * * *

(2) The publication or submission by a broker or dealer, on behalf of a customer (other than a broker or dealer), of a quotation that represents the customer's indication of interest and a transaction not involving the solicitation of the customer's order.

* * * * *

## VI. Solicitation of Comments

All interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons desiring to make written submissions should submit three copies thereof to George A. Fitzsimmons, Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, D.C. 20549, not later than June 14, 1983.

By the Commission.

George A. Fitzsimmons,

*Secretary.*

[FR Doc. 83-10646 Filed 4-20-83; 8:45 am]

BILLING CODE 8010-01-M

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## DEPARTMENT OF DEFENSE

## Office of the Secretary

## 32 CFR Part 64

**[DOD Directive 1352.xx]**

## Management and Mobilization of Regular and Retired Military Members

**AGENCY:** Defense Department.

**ACTION:** Proposed rule.

**SUMMARY:** This proposed rule is being issued to implement the provisions of the Defense Officer Personnel Management Act and to implement Section 672(a) (as amended December 23, 1980), Pub. L. 96–584. This proposed rule provides specific DOD guidance on the peacetime management of retired military personnel, both regular and reserve, in preparation for their use during a mobilization or other emergency.

**DATE:** Written comments must be received by May 23, 1983.

**ADDRESS:** Office of the Deputy Assistant Secretary of Defense (Reserve Affairs), the Pentagon, Room 3C980, Washington, D.C. 20301.

**FOR FURTHER INFORMATION CONTACT:** Major Robert F. Norton, USAR, 202–697–0624.

**SUPPLEMENTARY INFORMATION:** This proposed rule is being submitted to the **Federal Register** under 5 U.S.C. 552(a)(1)(D) and 1 CFR 305.76–2.B.

**List of Subjects in 32 CFR Part 64**

Retired regular and reserve military personnel, Mobilization of retired military personnel.

Accordingly, it is proposed to amend Chapter I, 32 CFR by adding a new Part 64, reading as follows:

## PART 64—MANAGEMENT AND MOBILIZATION OF REGULAR AND RETIRED MILITARY MEMBERS

Sec.



**Authority:** 10 U.S.C. 688 and 672(a).

### § 64.1 Purpose.

This Part implements sections 688 and 672(a) of Title 10, United States Code by prescribing uniform policy and procedures governing the peacetime management of retired military personnel, both regular and reserve, in preparation for this use during a mobilization.

### § 64.2 Applicability.

This Part applies to the Office of the Secretary of Defense, the Military Departments (including their National Guard and reserve components), the Organization of the Joint Chiefs of Staff, and the Defense Agencies (hereafter referred to collectively as "DoD Components"). The term "Military Services," as used herein, refers to the Army, Navy, Air Force, Marine Corps, and Coast Guard (by agreement with the Department of Transportation).

### § 64.3 Definitions.

(a) *Key Employee.* A civilian employee who is vital to the defense of the United States in his or her civilian capacity and cannot be mobilized with the Military Services in the event of an emergency (see Part 44 of this title).

(b) *Retired Military Members* (hereafter called "military retirees"). All regular and reserve officers and enlisted members who retire from the Military Services under Chapters 61, 63, 65, 67, 367, 571, 573, or 867 of Title 10, United States Code and Chapters 11 and 21 of Title 14, United States Code; all reserve officers and enlisted members who are otherwise eligible for retirement under one of the above provisions of law but who have not reached age 60 and who have not elected discharge or are not members of the Ready Reserve or Standby Reserve (including members of the inactive Standby Reserve who meet the above criteria); and all members of the Fleet Reserve and the Fleet Marine Corps Reserve under section 6330 of Title 10, United States Code.

(c) *Military Retiree Categories.* (1) *Category I.* Nondisability military retirees under age 60 who have been retired less than 5 years.

(2) *Category II.* Nondisability military retirees under age 60 who have been retired 5 years or more.

(3) *Category III.* Military retirees, including those retired for disability, other than category I or II retirees.

### § 64.4 Policy.

It is the policy of the Department of Defense to use military retirees to meet the demands of mobilization or other emergencies. The Secretaries of the Military Departments are authorized to order any retired regular member to active duty at any time to perform duties deemed necessary in the interests of national defense in accordance with section 688 of Title 10, United States Code. Military retirees, both regular and reserve, may be ordered to active duty by the Secretaries of the Military Departments to satisfy mobilization requirements.

### § 64.5 Procedures.

(a) *Premobilization.* (1) *Preassignment of Categories I and II Military Retirees.* Generally, military retirees who are physically qualified shall be preassigned in peacetime, either voluntarily or involuntarily, to installations or to mobilization positions that must be filled within 30 days after mobilization and that are determined appropriate for retirees by the Secretary of the Military Department concerned. Key employees and category III retirees will not be preassigned. Severe hostilities may prevent the transmittal of mobilization orders to military retirees. Therefore, all military retirees preassigned to mobilization positions or installations, either voluntarily or involuntarily, shall be issued preassignment or contingent preassignment orders.

(2) *Category III Military Retirees.* The nature and extent of the mobilization of category III retirees shall be determined by each Military Service based on the retiree's military skill and the nature and degree of the retiree's disability. Age or disability alone may not be basis for excluding a retiree from service during mobilization.

(3) *Military Retirees Living Overseas.* Military retirees who live overseas shall be preassigned in peacetime to the maximum extent possible, as determined by the Military Service concerned, to meet mobilization augmentation requirements at overseas U.S. or an Allied military installations or activities that are near their places of residence. Preassignment orders shall be sufficiently complete so that written confirmation after the start of a mobilization is not necessary. Military retirees who do not reside within reasonable distances from U.S. military installations or activities shall have included in their preassignment orders a statement ordering them to report to the nearest U.S. military activity with follow-on reporting to their unit of assignment.

(4) *Military Retiree Information.* The development and maintenance of current information pertaining to the mobilization availability of military retirees shall be the responsibility of the Military Services. Such information shall include, but not be limited to, date of retirement, date of birth, current address, and military qualifications. In addition, the Military Services shall maintain information on categories I and II military retirees concerning availability for mobilization and physical condition. Indication of physical condition may be from certification by the individual military retiree. Moreover, each Military Service shall develop procedures for identifying categories I and II retirees and shall conduct screening of retirees using Part 44 of this title as guidance in formulating screening criteria.

(5) *Refresher Training.* Each Military Service shall determine the necessity for and the frequency of refresher training of military retirees, based on the needs of the Military Service and the specific military skill of the military retiree.

(b) *Mobilization.* (1) *General.* The Military Services shall establish plans and procedures to use, during a

mobilization, military retirees who meet specific skill and experience requirements.

(2) *Involuntary Order to Active Duty.*

(i) *Regular.* The Secretary of a Military Department may order any retired regular member to active duty at any time to perform duties deemed necessary in the interests of national defense in accordance with section 688 of 10 U.S.C.

(ii) *Reserve.* The Secretary of a Military Department may order a retired member of a reserve component of a Military Service to active duty for the duration of a war or emergency and for 6 months thereafter on the basis of required skills, provided:

(A) War or national emergency has been declared by the Congress.

(B) The Secretary of the Military Department concerned, with the approval of the Secretary of Defense, determines there are not enough qualified reserves in an active status or in the Inactive National Guard, pursuant to 10 U.S.C. 672(a).

(3) *Time-Phased Mobilization.* The Military Services shall develop plans and procedures for ordering military retirees to active duty in accordance with a schedule that includes pre- and post-M-day requirements. These procedures shall consider mobilization manpower requirements and the incremental mobilization of National Guard and reserve components.

(4) *Partial Mobilization.* The Military Services shall develop plans and procedures for ordering to active duty only the number of military retirees required during partial mobilizations.

**§ 64.6 Responsibilities.**

(a) The *Assistant Secretary of Defense (Manpower, Reserve Affairs, and Logistics)* shall establish policy for the management and mobilization of military retirees.

(b) The *Secretaries of the Military Departments* shall ensure that plans for the management and mobilization of military retirees are consistent with this Directive.

(c) The *Heads of the Military Services* shall:

(1) Prepare plans and establish procedures for mobilization of military retirees in conformance with this Directive.

(2) Determine the extent of military retiree mobilization requirements based on existing inventories and inventory projections for mobilization of qualified reservists in an active status in the Ready Reserve, the Inactive National Guard, or the Standby Reserve.

(3) Develop procedures for identifying category I and II retirees and conduct screening of retirees using Part 44 of this title for guidance.

(4) Maintain personnel records for military retirees and other necessary records, including date of birth, date of retirement, current address, documentation of military technical skills, and, for categories I and II military retirees and key employees, availability for mobilization, civilian employment as necessary, and physical condition. Data shall be maintained on retired reserve members in accordance with Part 114 of this title.

(5) Advise military retirees of their duty to provide the Military Services with accurate mailing addresses and any changes in civilian employment, military qualifications, availability for service, and physical condition.

(6) Preassign retired members, as necessary.

(7) Determine refresher training requirements.

**M. S. Healy,**

*OSD Federal Register Liaison Officer, Department of Defense.*

April 18, 1983.

[FR Doc. 83-10655 Filed 4-20-83; 8:45 am]

BILLING CODE 3810-01-M

## DEPARTMENT OF TRANSPORTATION

### Coast Guard

### 33 CFR Part 117

**[CGD3 82-034]**

## Drawbridge Operation Regulations; South River, New Jersey

**AGENCY:** Coast Guard, DOT.

**ACTION:** Proposed rule.

**SUMMARY:** At the request of Consolidated Railroad Corporation, the Coast Guard is considering a change to the regulations governing the South River railroad drawbridge at South River, New Jersey. It is being proposed that the bridge be left in the open position from June 1 through October 31 except for the transit of a train. From November 1 through May 31 the draw would be opened upon 12 hours notice Monday through Friday, while openings on Saturdays and Sundays would require that notice be given prior to 6 p.m. on the preceeding Friday. This proposal is being made because there have been few requests to open the draw from November through May. This action should relieve the bridge owner of the burden of having a person constantly available to open the draw, and should still provide for the reasonable needs of navigation.

**DATE:** Comments must be received on or before June 6, 1983.

**ADDRESS:** Comments should be submitted to and are available for examination from 9 a.m. to 3 p.m., Monday, through Friday, except holdays, at the office of the Commander (oan-br), Third Coast Guard District, Bldg. 135A, Governors Island, New York 10004. Comments may also be hand-delivered to this address.

**FOR FURTHER INFORMATION CONTACT:** William C. Heming (212) 668-7994.

**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 name and address, identify the bridge, and give reasons for concurrence with or for any recommended change in the proposal. Persons desiring acknowledgment that their comments have been received should enclose a stamped, self-addressed postcard or envelope.

The Commander, Third Coast Guard District, will evaluate all communications received and will determine a final course of action on this proposal. The proposed regulations may be changed in light of comments received.

*Drafting Information:* The drafters of this notice are Richard A. Gomez, project manager and LCDR Frank E. Couper, project attorney.

*Discussion of Proposed Regulations:* The South River drawbridge provides access across South River for rail freight traffic traveling between East Brunswick and South River, New Jersey. This drawbridge provides a vertical clearance of four feet above mean high water when in the closed position. The waterway is used principally by recreational boaters, so it is being proposed that the bridge remain in the open postion from June 1 until October 31 except for closure for passage of about four trains per day. The bridge would require 12 hours notice from November 1 through May 31 except that notice would have to be given prior to 6 p.m. on Friday to obtain openings on Saturday and Sunday, or on the last working day to obtain openings before a holiday. A draft economic evalution has not been prepared since the bridge will remain in the open position (except for passage of a train) during the prime boating season.

*Economic Assessment and Certification:* These proposed regulations have been reviewed under the provisions of Executive Order 12291

and have been determined not to be a major rule. In addition, these proposed regulations are considered to be nonsignificant in accordance with guidelines set our in the Policies and Procedures for Simplification, Analysis, and Review of Regulations (DOT Order 2100.5 of 5–22–80). As explained above, an economic evaluation has not been conducted since its impact is expected to be minimal. In accordance with section 605(b) of the Regulatory Flexibility Act (5 U.S.C. 605(b)), it is certified that these rules, if promulgated, would not have a significant economic impact on a substantial number of small entities because there are none above the drawbridge that will be impacted as a result of this rule.

**List of Subjects in 33 CFR Part 117**

Bridges.

## PART 117—DRAWBRIDGE OPERATION REGULATIONS

*Proposed Regulations:* In consideration of the foregoing, the Coast Guard proposes to amend Part 117 of Title 33, Code of Federal Regulations by adding a new § 117.210(h) immediately after § 117.210(g) to read as follows:

**§ 117.210 Raritan River and Arthur Kill and their navigable tributaries; bridges.**

* * * * *

(h) South River, mile 2.8, (CONRAIL bridge) at South River, NJ. From June 1 through October 31, the draw shall remain in the open position except for passage of a train. From November 1 through May 31, the draw shall open on signal upon 12 hours notice during weekdays, and the draw shall open on signal on Saturday, Sunday, and holidays upon notice given prior to 6 p.m. on Friday or the last workday before a holiday.

(33 U.S.C. 499; 49 U.S.C. 1655(g)(2); 49 (CFR 1.46(c)(5); 33 CFR 1.05–1(g)(3))

Dated: April 4, 1983.

**W. E. Caldwell,**

*Vice Admiral, U.S. Coast Guard Commander, Third Coast Guard District.*

[FR Doc. 83–10649 Filed 4–20–83; 8:45 am]

BILLING CODE 4910–14–M

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**33 CFR Part 165**

**[Reg. 83–03]**

## COTP Wilmington, NC, Safety Zone Regulations; Upper Cape Fear River, North Carolina

**AGENCY:** Coast Guard, DOT.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Coast Guard is considering a proposal to close the Cape Fear River to all traffic from the Hilton Bascule Bridge down river to the Cape Fear Lighted Daymark #57 during the period of the annual Riverfest raft race on Sunday, 2 October 1983. The regulations are intended to reduce river congestion and ensure the safety of the participants in the Riverfest raft race.

**DATE:** Comments must be received on or before June 6, 1983.

**ADDRESSES:** Comments should be mailed to Commanding Officer, Marine Safety Office, 201 N. Front St., Suite 20, Wilmington, NC 28401. The comments will be available for inspection and copying at the Marine Safety Office, 201 N. Front St., Suite 20, Wilmington, NC. Normal office hours are between 7:30 a.m. and 4:00 p.m., Monday through Friday except holidays. Comments may also be hand delivered to this address.

**FOR FURTHER INFORMATION CONTACT:** Lieutenant K. C. Olds, Chief, Operations Department, Coast Guard Marine Safety Office, Wilmington, North Carolina, Phone: (919) 343–4892.

**SUPPLEMENTARY INFORMATION:** Interested persons are invited to participate in this rule making by submitting written views, data, or arguments. Persons submitting comments should include their names and addresses, identify this notice COTP Regulation 83–03 and the specific section of the proposal to which their comments apply, and give reasons for each comment. Receipt for comments will be acknowledged if a stamped self-addressed post card or envelope is enclosed. The rules may be changed in light of the comments received. All comments received before the expiration of the comment period will be considered before final action is taken on this proposal. No public hearing is planned, but one may be held if written requests for a hearing are received and it is determined that the opportunity to make oral presentations will aid the rulemaking process.

*Drafting Information:* The drafters of this notice are Lieutenant K. C. Olds, project officer for the Captain of the Port and Commander D. J. Kanter, project attorney, Fifth Coast Guard District Legal Office.

*Discussion of Proposed Regulations:* The Coast Guard received a proposal for a safety zone from Captain F. S. Conlon, USN (Ret) on behalf of Old Wilmington Riverfront, Inc., requesting that traffic on the Cape Fear River from the Hilton Bascule Bridge to the Cape Fear Lighted Daymark #57 be halted during the period of the annual Riverfest raft race on Sunday, October 2, 1983. More specifically, the proposed safety zone would prohibit any vessel (sailboat, pleasure craft, commercial vessel) other than designated safety boats and raft race participants, from movement within or through the safety zone. This will eliminate the extreme safety hazard created by moving vessels throwing large wakes, thereby upsetting raft race participants. The tenative duration of this safety zone will be from 1100 to 1500 on Sunday, October 2, 1983.

*Economic Assessment and Certification:* This proposed regulation is considered to be non-significant in accordance with DOT Policies and Procedures for Simplification, Analysis and Review of Regulations (DOT Order 2100.5). Its economic impact is expected to be minimal since the period of closure to river traffic will only be four hours. Vessel movement records indicate that commercial river traffic in this area of the Cape Fear River would be minimal during the period of closure and scheduling of commercial vessel movements can be adjusted if necessary to avoid the area during the closure times. The most impact, though non-economic, will be to the pleasure boat operators who have in past years lined the riverbanks during past raft races. They have in the past created safety hazards and much congestion in this area of the river during the raft race. Based upon this assessment, it is certified in accordance with Section 805(b) of the Regulatory Flexibility Act (5 U.S.C. 605(b)), that this regulation, if promulgated, will not have a significant economic impact on a substantial number of small entities. Also, the regulation has been reviewed in accordance with Executive Order 12291 of February 17, 1981, on Federal Regulation and has been determined not to be a major rule under the terms of that order.

**List of Subjects in 33 CFR Part 165**

Harbors, Marine safety, Navigation (water), Security measures, Vessels, Waterways.

## PART 165—[AMENDED]

In consideration of the foregoing, Part 165 of Title 33, Code of Federal Regulations is amended by adding a new § 165.T503 to read as follows:

**§ 165.T503 Safety Zone.**

(a) *Location.* The following area is a safety zone: The Northeast Cape Fear River from the Hilton Bascule Bridge down river to Point Peter and the Cape Fear River from Point Peter down river to Cape Fear Lighted Daymark #57.

(b) *Regulations.* (1) In accordance with General Regulation in § 165.23 of this part entry into or remaining in this

zone is prohibited unless authorized by the Captain of the Port.

(33 U.S.C. 1225 and 1231; 49 CFR Part 146; 33 CFR 165.3)

Dated: April 18, 1983.

C. M. Holland,

*Captain, USCG, Executive Secretary, Marine Safety Council.*

[FR Doc. 83-10653 Filed 4-20-83; 8:45 am]

BILLING CODE 4910-14-M

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 86

[AMS-FRL-2351-1]

### Control of Air Pollution From New Motor Vehicles and New Motor Vehicle Engines; Gaseous Emission Regulations for 1985 and Later Model Year Heavy-Duty Engines

**AGENCY:** Environmental Protection Agency.

**ACTION:** Notice of availability of information and extension of comment period.

**SUMMARY:** This Notice announces the availability of an EPA staff paper on certain issues related to emission standards and test procedures for 1985 and later model year heavy-duty engines (HDEs) and an extension of the comment period available for written comment on these issues. These actions are being taken as a continuation of EPA's rulemaking process to establish final regulations for 1985 and later HDEs.

**DATES:** The comment period on those issues covered in the staff paper will remain open until May 6, 1983.

**ADDRESSES:** The staff paper has been placed in Public Docket No. A-81-11, located at the Environmental Protection Agency, Central Docket Section, West Tower Lobby, Gallery 1, 401 M Street SW., Washington, D.C. 20460. The docket is open for inspection weekdays between 8:00 a.m. and 4:00 p.m. A reasonable fee may be charged for copying.

In addition, single copies of the staff paper may be obtained by contacting: Mrs. Jennifer A. Criss, Emission Control Technology Division, U.S. Environmental Protection Agency, 2565 Plymouth Road, Ann Arbor, MI 48105, (313) 668-4272.

Those persons desiring to provide written comment on the Staff paper should submit those comments to Docket No. A-81-11 at the Central Docket Section address given earlier.

Commenters desiring to submit proprietary information should clearly distinguish such information from other comments to the greatest extent possible, and label it "Confidential Business Information." Submissions containing such proprietary information should be sent directly to the EPA contact person indicated below, and not to the Public Docket, to ensure that proprietary information is not inadvertently placed in the docket.

Information covered by such a proprietary claim will be disclosed by EPA only to the extent, and by means of the procedures, set forth in 40 CFR Part 2. If no claim of confidentiality accompanies the information when it is received by EPA, it may be made available to the public without further notice to the commenter.

**FOR FURTHER INFORMATION CONTACT:** Mr. Glenn W. Passavant, Emission Control Technology Division, U.S. Environmental Protection Agency, 2565 Plymouth Road, Ann Arbor, MI 48105, (313) 668-4408.

**SUPPLEMENTARY INFORMATION:**

#### Background

EPA published a proposal in 1982 (47 FR 1642, January 13, 1982) to revise certain portions of the emission regulations for 1984 and later model year light-duty trucks and HDEs. In January 1983, the Agency finalized provisions for the 1984 model year (48 FR 1406, January 12, 1983) and proposed revised useful-life provisions for 1985 and later model years (48 FR 1472, January 12, 1983).

Today's Notice provides commenters further opportunity to comment on issues dealing with intermediate and long-term standards for HDEs and implementation of transient test procedures. These issues are discussed in depth in the EPA staff paper.

#### II. Review of EPA Staff Paper

The following discussion provides a brief overview of the staff paper's contents.

In approaching the issue of emission standards, the paper develops five options beginning with a baseline case and progressing in stringency to the implementation of the statutory 90 percent reduction levels on all HDEs. After considering the factors of cost, technical feasibility, and environmental impact, the analysis in the paper indicates that an intermediate strategy is the most desirable. That strategy involves heavy-duty diesel engines meeting the statutory standards of 1.3 grams per brake horsepower-hour (g/BPH-hr) hydrocarbon (HC) and 15.5 g/BHP-hr carbon monoxide (CO) in 1985, while heavy-duty gasoline engines would meet non-catalyst standards of 2.5 g/BHP-hr HC and 35 g/BHP-hr CO beginning in 1985. Beginning in either 1987 or 1988, (the choice of model year is discussed in the staff paper, but not resolved) emissions from heavy-duty gasoline engines would be further reduced by requiring those engines used in gasoline-engine powered trucks sold in Gross Vehicle Weight (GVW) categories IIB and III (less than 14,000 lbs. GVW) to meet the statutory levels of 1.3 g/BHP-hr HC and 15.5 g/BHP-hr CO.

Turning to test procedures, the staff paper analyzes questions surrounding alternative test procedures to the EPA transient test. The analysis suggests that, if alternative test procedures are allowed, they should be accompanied by adjustments in the emission standards to maintain equivalent emission rates to the statutory standards under the EPA test.

#### III. Public Participation

The Agency held a public workshop on April 6, 1983 to provide interested parties an opportunity to ask EPA questions regarding the contents of the staff paper, as well as to provide an opportunity for public reaction to the paper. No formal transcript of the workshop was taken, but it was recorded and a summary of the proceedings will be prepared and placed in the docket.

All previous commenters on this rulemaking were notified of the workshop by advance mail and given copies of the staff paper for review. In addition, it was EPA's intent to publish this Notice in advance of the public workshop. However, due to an inadvertent oversight this was not accomplished. The workshop was still held as scheduled, since all know parties to the rulemaking had been notified by mail. It is EPA's belief that this approach has not denied any party adequate opportunity to participate in the rulemaking. Any party questioning whether they have been afforded adequate opportunity should contact EPA through the person identified earlier under the heading **"For Further Information Contact:."**

Written comments on EPA's staff paper are invited. The record will remain open until May 6, 1983 and comments should be submitted to the EPA docket identified above. It is also requested, but not required, that a copy of any submittal be sent directly to the contact person indicated above.

Dated: April 11, 1983.

**Kathleen M. Bennett,**

*Assistant Administrator for Air, Noise and Radiation.*

[FR Doc. 83-10617 Filed 4-20-83; 8:45 am]

BILLING CODE 6560-50-M

## DEPARTMENT OF TRANSPORTATION

### Maritime Administration

### 46 CFR Part 298

### Vessel Obligation Guarantees; Waivers for Foreign Built Main Diesel Engines

**AGENCY:** Maritime Administration, DOT.

**ACTION:** Advance Notice of Proposed Rulemaking.

**SUMMARY:** One of the requirements for eligibility to receive vessel obligation guarantees under Title XI of the Merchant Marine Act, 1936 (46 U.S.C. 1271–1279) is that the vessel be of United States construction. The applicable Maritime Administration (MARAD) regulation implementing this requirement is at 46 CFR 298.11. MARAD proposes to issue an amendment to this regulation that would adopt a policy to allow all applications for waiver of the "Buy American" requirement with respect to foreign-built high and medium speed diesel engines that are not built in the United States and which afford a specified energy savings.

**DATE:** All written comments by interested persons received on or before June 20, 1983, will be considered. Anyone submitting comments who wishes acknowledgment of its receipt by MARAD should include a stamped, self-addressed post card.

**ADDRESS:** Send the original and five copies of comments to the Secretary, Maritime Administration, Room 7300, Department of Transportation, 400 Seventh Street, SW., Washington, D.C. 20590.

All comments will be made available for inspection during normal business hours in Room 7300 at this address.

**FOR FURTHER INFORMATION CONTACT:** Mr. John Walter, Office of Ship Construction, Room 2103, Department of Transportation, 400 Seventh Street, SW., Washington, D.C. 20590, (202) 426–5727.

**SUPPLEMENTARY INFORMATION:** The Maritime Administration recognizes that there is an increased interest in the use of ship propulsion diesel engines that are capable of burning residual blended fuel. The availability of such engines from U.S. manufacturers, in certain power levels, is severely limited. The utilization of blended fuels in these diesel engines can result in substantial savings in vessel operating costs and will also conserve valuable distillate fuels. Accordingly, MARAD is giving consideration to a change in the Title XI regulations (§ 298.11 "Vessel requirements"). This amendment would adopt a policy to allow all applications for waivers to use foreign-built high and medium speed diesel engines, where the use of foreign engines would: (1) Result in a 10 percent energy savings (on a thermal basis); or (2) allow vessel operation using a lower quality fuel such that the magnitude of the distillate fuel consumed by the engine would be reduced by 50 percent over the best comparable U.S. built engine. Waiver procedures would follow current practice. Slow speed diesels would be covered by the existing MARAD Slow Speed Diesel Policy.[1] The cost of these foreign-built engines would be included in the total "actual cost" of the vessel, which is the basis for determining the limit for vessel obligation guarantees.

After reviewing the comments, MARAD will determine whether to proceed by publishing a Notice of Proposed Rulemaking, proposing specific changes to the regulations in 46 CFR Part 298. Pursuant to DOT Order 2100.5, this would be considered to be a nonsignificant regulation.

### List of Subjects in 46 CFR Part 298

Banks, Banking, Loan programs—transportation, Mortgages, Mortgage insurance, Maritime carriers, and Uniform system of accounts.

Dated: April 15, 1983.

By Order of the Maritime Administrator.

**Georgia P. Stamas,**

*Secretary.*

[FR Doc. 83-10004 Filed 4-20-83; 8:45 am]

BILLING CODE 4910-81-M

[1] **Federal Register** Notice Vol. 41, No. 90 of May 7, 1976 (41 FR 18896) announced that: The Maritime Administration (MarAd) has determined that an exclusively domestic capability for the manufacturer of slow speed diesel engines for ship propulsion would be a valuable asset towards the national goal of having a modern and efficient U.S. Merchant Marine * * *, that such a capability does not presently exist, * * * that a substantial time period as well as a significant capital expenditure will be required for its development * * * [and] that domestic manufacturers could produce slow speed diesel engines in a much shorter time period if certain foreign components may temporarily be incorporated therein. In view of the foregoing considerations, MarAd has determined that, as a matter of policy and under the authority provided by the "so far as practicable" exception of Section 505 * * * it, for a period of time reasonably required for the development of domestic sources for such components, will not withhold approval, for purposes of Title V [CDS], of vessel designs incorporating slow speed diesels solely on the basis of the presence of foreign components therein.

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

### 50 CFR Part 649

### American Lobster Fishery; Availability of Fishery Management Plan and Request for Comments

**AGENCY:** National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Notice of availability of a fishery management plan and request for comments.

**SUMMARY:** NOAA issues this notice that the New England Fishery Management Council has submitted a fishery management plan for the American lobster for Secretarial review and is requesting comments from the public. The plan proposes measures for managing the American lobster fishery in the Northwest Atlantic. Copies of the plan may be obtained from the address below.

**DATE:** Comments on the plan should be submitted on or before July 1, 1983.

**ADDRESS:** All comments should be sent to Mr. Allen E. Peterson, Jr., Regional Director, National Marine Fisheries Service, Northeast Regional Office, 14 Elm Street, Gloucester, MA 01930. Clearly mark, "Comments on Lobster Plan", on the envelop.

Copies of the plan are available upon request from Mr. Douglas G. Marshall, Executive Director, New England Fishery Management Council, Suntaug Office Park, 5 Broadway (route 1), Saugus, MA 01906.

**FOR FURTHER INFORMATION CONTACT:** Bruce Nicholls, Lobster Management Coordinator, 617–281–3600, ext. 324.

**SUPPLEMENTARY INFORMATION:** The Magnuson Fishery Conservation and Management Act (16 U.S.C. 1801 *et seq.*) requires that each regional fishery management council submit any fishery management plan or plan amendment it prepares to the Secretary of Commerce (Secretary) for review and approval or disapproval. The act also requires that the Secretary, upon receiving the plan or amendment, must immediately publish a notice that the plan or amendment is available for public review and comment. The Secretary will consider the public comments in determining whether to approve the plan or plan amendment.

The plan proposes measures for managing the American lobster fishery in the Northwest Atlantic. On September 24, 1982, the Environmental

Protection Agency published a notice of availability of a draft environmental impact statement for this plan (47 FR 42157).

Regulations proposed by the Council and based on this plan are scheduled to be published within 30 days.

(16 U.S.C. 1801 *et seq.*)

Dated: April 18, 1983.

**Joe P. Clem,**

*Acting Chief, Plan Review Division, National Marine Fisheries Service.*

[FR Doc. 83-10645 Filed 4-20-83; 8:45 am]

BILLING CODE 3510-22-M

# Notices

Federal Register
Vol. 48, No. 78
Thursday, April 21, 1983

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.

## ADMINISTRATIVE CONFERENCE OF THE UNITED STATES

### Committee on Judicial Review; Public Meeting

Pursuant to the Federal Advisory Committee Act (Pub. L. No. 92–463), notice is hereby given of a meeting of the Committee on Judicial Review of the Administrative Conference of the United States, to be held at 10 a.m. Tuesday, May 3, 1983, in the seventh floor conference room at Cadwalader, Wickersham & Taft, 1333 New Hampshire Avenue, NW., Washington, D.C. The Committee will meet to discuss a draft recommendation on certification of claims under the Contract Disputes Act, based on a study by Thomas Madden and a study by Professor Colin Diver on articulation of agency policies.

Attendance is open to the interested public, but limited to the space available. Persons wishing to attend should notify the Office of the Chairman of the Administrative Conference at least two days in advance. The Committee chairman, if he deems it appropriate, may permit members of the public to present oral statements at the meeting; any member of the public may file a written statement with the Committee before, during or after the meeting.

For further information concerning this meeting contact Mary Candace Fowler, Office of the Chairman, Adminsitrative Conference of the United States, 2120 L Street, NW., Suite 500, Washington, D.C. [Telephone: 202–254–7065.] Minutes of the meeting will be available on request.

Dated: April 18, 1983.

Richard K. Berg,

*General Counsel.*

[FR Doc. 83–10661 Filed 4–20–83; 8:45 am]

BILLING CODE 6110-01-M

## DEPARTMENT OF AGRICULTURE

### Commodity Credit Corporation

### 1983 Crop Upland Cotton; Determinations Regarding 1983 Upland Cotton Loan Rate, Established (Target) Price, Advance Deficiency Payment Rate, Acreage Reduction Program, Paid Diversion Program, and Seed Cotton Loan Program

**AGENCY:** Commodity Credit Corporation, USDA.

**ACTION:** Notice of determinations of the 1983 upland cotton loan rate, established (target) price, advance deficiency payment rate, acreage reduction program, paid diversion program, and seed cotton loan program.

**SUMMARY:** This notice affirms the following determinations made by the Secretary of Agriculture September 27, 1982 with respect to the 1983 crop of upland cotton: (1) A loan rate for Strict Low Middling one-and-one-sixteenth-inch upland cotton (micronaire 3.5 through 4.9) of 55.00 cents per pound; (2) an established (target) price of 76 cents per pound; (3) an advance deficiency payment rate of 6.4 cents per pound; (4) an acreage reduction program of 20 percent; (5) a paid land diversion program of up to 5 percent; and (6) the availability of a seed cotton loan program. These determinations are required to be made in accordance with sections 103 (g) and 107C of the Agricultural Act of 1949, as amended (hereinafter referred to as the "Act").

**EFFECTIVE DATE:** September 27, 1982.

**ADDRESS:** Director, Analysis Division, ASCS, USDA, Room 3741 South Building, P.O. Box 2415, Washington, D.C. 20013.

**FOR FURTHER INFORMATION CONTACT:** Charles V. Cunningham, Deputy Director, Analysis Division, USDA–ASCS, P.O. Box 2415, Washington, D.C. 20013, (202) 447–7954. The Final Regulatory Impact Analysis describing the options considered in developing these determinations is available on request from the above named individual.

**SUPPLEMENTARY INFORMATION:** These determinations have been reviewed in accordance with the provisions of Executive Order 12291 and Secretary's Memorandum No. 1512–1 and have been designated as "major." These determinations have been designated as "major" because they are expected to affect the supply and price of upland cotton during the 1983–84 marketing year, which will in turn impact upon producers, processors, exporters and consumers of cotton and cotton products.

The titles and numbers of the federal assistance programs that this notice applies to are: Title—Commodity Loans and Purchases, number 10.051, and Title—Cotton Production Stabilization, number 10.052, as found in the Catalog of Federal Domestic Assistance.

It has been determined that the Regulatory Flexibility Act is not applicable to this notice since there is no requirement that a notice of proposed rulemaking be published in accordance with 5 U.S.C. 553 or anyi other provisions of law with respect to the subject matter of these determinations.

1. *Loan Rate for Upland Cotton.* Section 103(g)(1) of the Act provides that the loan level for 1983-crop upland cotton must reflect for Strict Low Middling one-and-one-sixteenth-inch upland cotton (micronaire 3.5 through 4.9) at average location in the United States, the smaller of: (1) 85 percent of the average price (weighted by market and month) of Strict Low Middling one-and-one-sixteenth-inch cotton as quoted in the designated United States spot markets during three years of the five-year period ending July 31, 1982, excluding the years of the highest and lowest average prices, or (2) 90 percent of the average, for the fifteen week period beginning July 1, 1982, of the five lowest priced growths of the growths quoted for Middling one-and-three-thirty-seconds-inch cotton, C.I.F. northern Europe (adjusted downward by the average difference during the period April 15, 1982 through October 15, 1982 between such average northern European quotation and quotations in the designated United States spot markets for Strict Low Middling one-and-one-sixteenth-inch cotton (micronaire 3.5 through 4.9)). The loan level cannot be less than 55 cents per pound. If the northern European calculation is less than the spot market calculation, the Secretary may adjust the loan level upward, not to exceed the spot market calculation. The 1983 loan rate must be announced not later than

November 1, 1982 and cannot thereafter be changed.

2. *Established (Target) Price.* Section 103(g)(3)(B) of the Act provides that the established price for 1983-crop upland cotton shall not be less than the higher of: (a) 76 cents per pound plus any adjustments for changes in production costs or (b) 120 percent of the loan level determined in accordance with section 103 (g)(3)(1). Section 103(g)(3)(c) provides that the price of 76 cents per pound quoted in the preceding sentence may be adjusted as the Secretary determines to be appropriate to reflect any change in (a) the average adjusted cost of production per acre for the two crop years immediately preceding the year for which the determination is made (1981 and 1982) from (b) the average adjusted cost of production per acre for the two crop years immediately preceding the year previous to the one for which the determination is made (1980 and 1981). The adjusted cost of production for each of such years may be determined by the Secretary on the basis of such information as the Secretary finds necessary and appropriate and may include variable costs, machinery ownership costs, and general farm overhead costs, allocated to the crops involved on the basis of the proportion of the value of the total production derived from each crop.

3. *Advance deficiency payments.* Section 107C(b)(1) of the Act provides that if the Secretary establishes an acreage reduction program for the 1983 crop of upland cotton and determines that deficiency payments will likely be made, the Secretary shall make available advance deficiency payments to producers who agree to participate in such program. Section 107C(b)(2) further provides that advance deficiency payments shall be made as soon as practicable after the producer files a notice of intention to participate in such program, but in no case prior to October 1, 1982. The advance deficiency payments shall be in such amounts as the Secretary determines to be appropriate to encourage adequate participation in the program, except that any such amounts may not exceed an amount determined by multiplying the estimated farm program acreage for the crop times the farm program payment yield for the crop times 50 percent of the projected payment rate, as determined by the Secretary.

4. *Acreage Reduction Program.* Section 103(g)(9)(A) of the Act provides that the Secretary may establish a limitation on planted acreage if the Secretary determines that the total supply of upland cotton, in the absence of such limitation, will be excessive taking into account the need for an adequate carryover to maintain reasonable and stable supplies and prices and to meet a national emergency. Such limitation shall be achieved by applying a uniform percentage reduction to the acreage base for each cotton-producing farm. Producers who knowingly produce cotton in excess of the permitted acreage determined for a farm shall be ineligible for cotton loans and payments with respect to that farm. The acreage base for any farm for the purpose of determining any reduction required to be made for any year shall be the acreage planted on the farm to upland cotton for harvest in the immediately preceding year or, at the discretion of the Secretary, the average acreage planted to upland cotton for harvest in the two crop years immediately preceding the year for which the determination is made. For the purpose of determinng the acreage base, the acreage planted to upland cotton for harvest shall include any acreage which producers were prevented from planting to cotton or other nonconserving crop in lieu of cotton because of a natural disaster or other condition beyond the control of the producers. The Secretary may make adjustments to reflect established crop-rotation practices and such other factors as the Secretary determines necessary to establish a fair and equitable base. A number of acres on the farm determined by dividing (a) the product obtained by multiplying the number of acres required to be withdrawn from the production of upland cotton times the number of acres actually planted to upland cotton, by (b) the number of acres authorized to be planted to upland cotton in accordance with the acreage limitation established by the Secretary shall be devoted to approved conservation uses in accordance with regulations issued by the Secretary. If an acreage limitation is in effect for any crop, the national program acreage, program allocation factor, and voluntary reduction provisions of section 103(g) of the Act are not applicable to such crop. The individual farm program acreage shall be the acreage planted on the farm to upland cotton for harvest within the permitted upland cotton acreage established for the farm under the acreage reduction program.

5. *Land Diversion Program.* Section 103(g)(9)(B) of the Act provides that the Secretary may make land diversion payments, whether or not an acreage limitation is in effect, if the Secretary determines that such payments are necessary to assist in adjusting the total national acreage of upland cotton to desirable goals. Such land diversion payments shall be made to producers who, to the extent prescribed by the Secretary, devote to approved conservation uses an acreage of cropland on the farm in accordance with land diversion contracts entered into by the Secretary with such producers.

6. *Seed Cotton Loan Program.* Section (103)(g)(18) of the Act provides that in order to assist producers in the orderly ginning and marketing of their cotton production, the Secretary shall make recourse loans available to such producers on seed cotton in accordance with authority vested in the Secretary under the Commodity Credit Corporation Charter Act (15 U.S.C. 714 *et seq.*).

Production of upland cotton in 1982 is projected to be approximately 10.9 million bales. With estimated beginning stocks of 6.4 million bales, the total 1982 supply of upland cotton is projected to be 17.4 million bales. Total disappearance of upland cotton during the marketing year that began on August 1, 1982 is estimated to be 11.8 million bales. If these estimates are accurate, then carryover stocks on August 1, 1982 will equal about 5.7 million bales, which is deemed an excessive level.

Because of the large projected beginning stock level, it is likely that the supply of cotton in the 1983–84 marketing year again will be excessive. Therefore, options for an acreage reduction program ranging from 0 to 20 percent and options for a paid diversion program ranging from 0 to 10 percent were considered to reduce the production of upland cotton in 1983. A 20 percent acreage reduction program in combination with a 5 percent voluntary paid diversion program was selected because it was deemed the most cost-effective option to reduce supplies, raise market prices, and improve farm income.

A notice that the Secretary was preparing to make determinations with respect to these provisions was published in the **Federal Register** on July 16, 1982 (47 FR 31025). A total of forty-one comments was received, seventeen from producer associations and marketing cooperatives, twenty-three from individual producers, and one from a member of Congress. A summary of responses with respect to the 1983 crop of upland cotton is as follows:

1. *Loan rate:* Twenty-three respondents commented on the 1983 upland cotton loan rate. Five favored the statutory minimum of 55 cents; three suggested that the loan rate be

increased from 55 cents; five recommended a loan rate of between 60 and 65 cents; one requested a loan rate of 70 percent of parity; one a loan rate of 90 to 100 percent of parity; one favored a loan rate equal to production costs; one recommended establishing the loan rate at the cost of production plus a profit; two respondents suggested a loan rate equal to 90 percent of the cost of production if no acreage reduction program is implemented; one asked that production costs be considered; one recommended a loan rate of 95 cents; and two proposed that the loan program be discontinued altogether.

2. *Target price:* Fifteen respondents comment on the target price. Seven respondents favored a target price of 76 cents; one suggested a target price of 76 cents with no limitation on the amount of deficiency payments which a producer could receive; one recommended a target price of 81 cents; one recommended a target price of 86 cents; one recommended a target price of 88 cents; one respondent suggested a target of 70 cents for short staple cotton and 86 cents for longer staples; one respondent requested an increase of 30 percent in the target price; and two comments favored a target price commensurate with the cost of production.

3. *Acreage reduction program:* Nineteen comments were received with respect to the implementation of an acreage reduction program separate from a paid land diversion program. One respondent favored a 30 percent acreage reduction program with a 30 percent increase in the target price for program participants; four comments proposed a 25 percent acreage reduction program; one favored a mandatory 25 percent acreage reduction; one suggested a 15 to 20 percent acreage reduction; one recommended a mandatory 20 percent acreage reduction; two respondents favored a 15 percent acreage reduction; one suggested a reduction of at least 15 percent in combination with a cotton reserve program; one recommended a 10 percent acreage reduction; three recommended mandatory acreage reductions with no level specified; one favored an acreage reduction, if needed; one suggested an acreage reduction with no level specified; one favored an acreage reduction if 90 to 100 percent participation could be achieved; and one respondent opposed an acreage reduction program.

4. *Land diversion program.* Thirteen comments were received with respect to the implementation of a paid land diversion program separate from an acreage reduction program. Eight comments favored a paid diversion with no level specified; three comments suggested a 15 percent paid diversion; one recommended a 25 percent paid diversion; and one respondent opposed a paid diversion.

5. *Acreage reduction program in combination with a land diversion program.* Fourteen comments were received with respect to the combination of an acreage reduction program and a land diversion program. One respondent suggested a 50 percent acreage reduction with a 25 percent paid diversion; one favored a 25 percent acreage reduction with a 25 percent paid diversion; one proposed a 20 percent acreage reduction with a 15 percent paid diversion; three respondents recommended a 15 percent acreage reduction with a 10 percent paid diversion; one requested a total reduction of 25 percent; one proposed a 10 to 15 percent acreage reduction with a 10 percent paid diversion; one recommended a 15 to 20 percent acreage reduction with a 5 percent paid diversion; one favored a 15 percent acreage reduction with a 5 percent paid diversion; one comment suggested a 10 percent acreage reduction in combination with a 15 percent paid diversion; and three respondents recommended that the Secretary of Agriculture use all available resources to reduce the cotton carryover to 3.5 to 4.0 millon bales as rapidly as possible.

6. *Diversion payment rate.* Seven comments were received on the appropriate level for the diversion payment rate. Two respondents favored a diversion payment rate of 30 cents per pound; two suggested a rate of 20 cents per pound; one recommended 20 cents per pound times 75 percent of the farm program yield; one proposed that the government pay the costs of conservation practices which are required to be installed on diverted acres; and one recommended that a rate be established which would maximize program participation by producers.

7. *Seed cotton loan rate.* Seven comments were received with respect to the loan rate for seed cotton. Four respondents favored establishing a loan rate for seed cotton at the same level as the loan rate which is established for lint cotton adjusted to a lint basis. One comment suggested a rate of from 57.2 to 62.2 cents; one suggested 50 percent of the estimated yield at the lint rate; and one opposed a seed cotton loan rate.

8. *National program acreage (NPA).* Two comments were received on the national program acreage. One respondent favored an NPA level that would assure an adequate, but not excessive, supply and one suggested an NPA of 12,066,400 acres.

All comments received were duly considered by the Secretary. The purpose of this notice is to affirm determinations which were announced by the Secretary with respect to the 1983 crop of upland cotton in a press release issued on September 27, 1982. The following determinations were made by the Secretary on that date with respect to the 1983 crop of upland cotton:

**Determinations**

1. *Upland Cotton Loan Rate.* Based on the formula prescribed in Section 103(g)(1) of the Act, the loan rate for Strict Low Middling, one-and-one-sixteenth-inch upland cotton (micronaire 3.5 through 4.9) at average location in the United States is determined to be 55.00 cents per pound. This loan rate is the minimum statutory level specified by Section 103(g)(1).

The spot market calculation is as follows: (1) Weighted average spot market prices for Strict Low Middling one-and-one-sixteenth-inch upland cotton, micronaire 3.5 through 4.9:

August 1977 through July 1978—51.15 cents;
August 1978 through July 1979—61.01 cents;
August 1979 through July 1980—68.87 cents;
August 1980 through July 1981—83.77 cents;
August 1981 through July 1982—57.66 cents;

(2) Average of the five years, excluding the highest and lowest years: $61.01+68.87+57.66/3=62.51$ cents; and (3) Loan rate based on U.S. spot market calculation: $62.51\times0.85=53.13$ cents.

The northern European calculation is as follows:

| | |
|---|---|
| (1) Average northern European quotation for Middling one-and-three-thirty-seconds-inch cotton July 1 through October 13, 1982 | 75.35 |
| (2) Average difference between average northern European quotation and the U.S. spot market average for Strict Low Middling one-and-one-sixteenth-inch, (micronaire 3.5 through 4.9) April 15 through October 15, 1982 | 13.85 |
| (3) Adjusted northern European average | 61.50 |
| (4) 90 percent of adjusted average | 55.35 |

The smaller of the two calculations is the spot market calculation. Since the loan rate based on the spot market calculation is less than the statutory minimum loan rate of 55 cents per pound, the 1983 loan rate is 55 cents per pound.

2. *Established (Target) Price.* In accordance with the provisions of section 103(g)(3) of the Act, the 1983 established (target) price for upland cotton is determined to be 76 cents per pound, the statutory minimum level.

3. *Advance deficiency payments.* In accordance with the provisions of Section 107 C of the Act, it is hereby

determined that advance deficiency payments shall be made for the 1983 crop of upland cotton. The rate of payment is determined to be 6.4 cents per pound, which is 50 percent of the estimated 1983 deficiency payment rate.

4. *Acreage Reduction Program (ARP).* In accordance with the provisions of Section 103(g)(9)(A) of the Act, it is hereby determined that an acreage reduction program shall be in effect for the 1983 crop of upland cotton. The reduction shall be achieved by applying a uniform reduction of 20 percent to the acreage base for each cotton-producing farm. Acreage bases for farms which participated in the 1982-crop acreage reduction program shall be the same as the acreage bases established for the 1982 crop, in order to assure fair and equitable treatment of program participants. Acreage bases on farms that did not comply with the 1982-crop acreage reduction program shall be established using the average of the acres planted to upland cotton in 1981 and 1982. An acreage reduction program is being established because it has been determined that the total supply of upland cotton will be excessive in the absence of a program.

Producers who knowingly produce cotton in excess of the permitted acreage shall be ineligible for loans and payments under the Upland Cotton Program with respect that farm. A number of acres equal to 25.0 percent of the planted acres (not to exceed the acres permitted to be planted) must be devoted to approved conservation uses in accordance with regulations issued by the Secretary. It is hereby determined that, because an acreage reduction program has been established, the national program acreage, program allocation factor, and voluntary reduction provisions shall not be applicable to the 1983 crop of upland cotton.

5. *Land Diversion Program (LDP).* It is hereby determined that a 5 percent land diversion program shall be in effect for the 1983 crop of upland cotton in accordance with the provisions of Section 103(g)(9)(B) of the Act. Producers who comply with the acreage reduction program shall have the option of reducing an additional 0 to 5 percent of their acreage bases in order to be eligible to receive diversion payments at a rate of 25 cents per pound times the acres diverted times the farm program yield. The maximum acres eligible to receive diversion payments shall be 6.67 percent times the acres actually planted to upland cotton not to exceed the permitted acres under the combined acreage reduction and land diversion programs. Acres reduced under the land diversion program must be devoted to conservation uses approved by the Secretary in accordance with regulations issued by the Secretary. Producers who file a notice of intention to comply with the land diversion program may receive advance diversion payments at a rate of 12.5 cents per pound, which is 50 percent of the diversion payment rate.

6. *Seed Cotton Loan Program.* It is hereby determined that a recourse seed cotton loan program shall be available for upland cotton. Seed cotton shall be converted to a lint basis for loan-making purposes and loan levels with respect to such cotton will be the same as those applicable to lint cotton.

(Secs. 4, 5, 62 Stat. 1070, as amended (15 U.S.C. 714 b and c); secs. 101, 103 (g)(1), 107 C and 401, 66 Stat. 758, as amended, 95 Stat. 1234, as amended, 96 Stat. 766, 63 Stat. 1054, as amended (7 U.S.C. 1441, 1444, 1445b–2, 1421))

Signed at Washington, D.C. on April 15, 1983.

**C. Hoke Leggett,**

*Acting Executive Vice President, Commodity Credit Corporation.*

[FR Doc. 83-10659 Filed 4-20-83; 8:45 am]

BILLING CODE 3410-05-M

## CIVIL AERONAUTICS BOARD

**[Docket 41390]**

### California-Toronto/Montreal Service Case; Prehearing Conference

Notice is hereby given that a prehearing conference in the above-title proceeding will be held on May, 5, 1983, at 10:00 a.m. (local time), in Room 1027, Universal Building, 1825 Connecticut Avenue, N.W., Washington, D.C., before the undersigned.

In order to facilitate the conduct of the conference, parties, including the bureau of International Aviation, are instructed to submit one copy to each party and six copies to the Judge of: (1) Proposed statements of issues; (2) proposed stipulations; (3) proposed requests for information and evedence; (4) statements of position; and (5) proposed procedural dates. The Bureau's material shall be submitted on or before April 28, 1983, and that of the other parties on or before May 3, 1983.

Dated at Washington, D.C., April 18, 1983.

**William A. Kane, Jr.,**

*Administrative Law Judge.*

[FR Doc. 83-10681-Filed-4-20-83; 8:45 am]

BILLING CODE 6320-01-M

## CIVIL RIGHTS COMMISSION

### Kentucky Advisory Committee; Agenda and Notice of Public Meeting

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 Kentucky Advisory Committee to the Commission will convene at 1:00 p.m. and will end at 4:00 p.m., on May 17, 1983, in the White Hart Room, at the Executive Inn East, 978 Phillips Lane, Louisville, Kentucky, 40213. The purpose of this meeting is to discuss followup plans to the Community Development Block Grant study.

Persons desiring additional information or planning a presentation to the Committee, should contact the Chairperson, James M. Rosenblum, 33 Ten Broeck Way, Louisville, Kentucky, 40222; (502) 636–1411 or the Southern Regional Office, Citizens Trust Bank Building, 75 Piedmont Street, North East, Room 362, Atlanta, Georgia, 30303; (404) 221–4391.

The meeting will be conducted pursuant to the provisions of the Rules and Regulations of the Commission.

Dated at Washington, D.C., April 18, 1983.

**John I. Binkley,**

*Advisory Committee Management Officer.*

[FR Doc. 83-10627 Filed 4-20-83; 8:45 am]

BILLING CODE 6335-01-M

### Mississippi Advisory Committee; Agenda and Notice of Public Meeting

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 Mississippi Advisory Committee to the Commission will convene at 4:00 p.m. and will end at 7:30 p.m., on May 6, 1983, in the Magnolia Room, at the Sheraton Regency, 750 North State Street, Jackson, Mississippi, 39201. The purpose of this meeting is to discuss program plans for Fiscal Years 1983 and 1984.

Persons desiring additional information or planning a presentation to the Committee, should contact the Chairperson, Mary L. Ramberg, 1514 Gay Street, Jackson, Mississippi, 39211; (601) 982–2432 or the Southern Regional Office, Citizen Trust Bank Building, 75 Piedmont Avenue, North East, Room 362, Atlanta, Georgia, 30303; (404) 221–4391.

The meeting will be conducted pursuant to the provisions of the Rules and Regulations of the Commission.

Dated at Washington, D.C., April 18, 1983.

**John I. Binkley,**

*Advisory Committee Management Officer.*

[FR Doc. 83-10626 Filed 4-20-83; 8:45 am]

**BILLING CODE 6335-01-M**

### Ohio Advisory Committee; Agenda and Notice of Public Meeting

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 Ohio Advisory Committee to the Commission will convene at 10:00 a.m., and will end at 3:00 p.m., on May 14, 1983, in Room 1115, at the Holiday Inn, 404 West First, Dayton, Ohio 45402. The purppose of this meeting is to discuss the subcommittee report on Hispanic educational issues and the re-use of urban renewal land in Akron.

Persons desiring additional information or planning a presentation to the Committee, should contact the Chairperson, Marian A. Spencer, 940 Lexington Avenue, Cincinnati, Ohio 45229; (513) 221-5656 or the Midwestern Regional Office, 230 South Dearborn Street, 32nd Floor, Chicago, Illinois 60604; (312) 353-7479.

The meeting will be conducted pursuant to the provisions of the Rules and Regulations of the Commission.

Dated at Washington, D.C., April 18, 1983.

**John I. Binkley,**

*Advisory Committee Management Officer.*

[FR Doc. 83-10629 Filed 4-20-83; 8:45 am]

**BILLING CODE 6335-01-M**

### South Carolina Advisory Committee; Agenda and Notice of Public Meeting

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 1:00 p.m., and will end at 3:30 p.m., on May 11, 1983, in Room 405, at the Gressette Senate Office Building, State Capitol Complex, Columbia, South Carolina 29201. The purpose of this meeting is to review the draft report on Block Grand Education Funds, Chapter 2.

Persons desiring additional information or planning a presentation to the Committee, should contact the Chairperson, Oscar P. Butler, Jr., Post Office Box 1705, South Carolina State College, Orangeburg, South Carolina 29115; (803) 536-7040 or the Southern Regional Office, Citizens Trust Bank Building, 75 Piedmont Street, North East, Room 362, Atlanta, Georgia 30303; (404) 221-4391.

The meeting will be conducted pursuant to the provisions of the Rules and Regulations of the Commission.

Dated at Washington, D.C., April 18, 1983.

**John I. Binkley,**

*Advisory Committee Management Officer.*

[FR Doc. 83-10630 Filed 4-20-83; 8:45 am]

**BILLING CODE 6335-01-M**

### Washington Advisory Committee; Agenda and Notice Public Meeting

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 Washington Advisory Committee to the Commission will convene at 2:00 p.m. and will end at 5:00 p.m., on May 5, 1983, in the Conference Room, at the Seattle Hilton, Sixth and University, Seattle, Washington, 93101. The purpose of this meeting is to discuss plans for future Committee Activities.

Persons desiring additional information or planning a presentation to the Committee, should contact the Chairperson, Kathjarine M. Bullitt, 1125 Harvard Avenue, East, Seattle, Washington, 98102; (206) 447-9800 or the Northwestern Regional Office, 915 Second Street Room 2852, Seattle, Washington, 98174; (206) 442-1246.

The meeting will be conducted pursuant to the provisions of the Rules and Regulations of the Commission.

Dated at Washington, D.C., April 18, 1983.

**John I. Binkley,**

*Advisory Committee Management Officer.*

[FR Doc. 83-10628 Filed 4-20-83; 8:45 am]

**BILLING CODE 6335-01-M**

## DEPARTMENT OF COMMERCE

### International Trade Administration

### Termination of Countervailing Duty Investigation; Prestressed Concrete Steel Wire Strand From Brazil

**AGENCY:** International Trade Administration, Department of Commerce.

**ACTION:** Termination of countervailing duty investigation.

**SUMMARY:** Since the U.S. International Trade Commission (ITC) determined that an industry in the United States is not materially injured or threatened with material injury, nor is the establishment of an industry in the United States materially retarded, by reason of subsidized imports of prestressed concrete steel wire strand (PC strand) from Brazil, the countervailing duty investigation on that product is terminated. Further, the suspension agreement on PC strand from Brazil has no force or effect.

**EFFECTIVE DATE:** March 23, 1983.

**FOR FURTHER INFORMATION CONTACT:** Francis R. Crowe, Office of Investigations, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, D.C. 20230, telephone: (202) 377-3051.

**SUPPLEMENTARY INFORMATION:**

#### Product Description

The product covered by this notice is prestressed concrete steel wire strand manufactured in Brazil and exported, directly or indirectly, from Brazil to the United States. The term "prestressed concrete steel wire strand" covers wire strand of steel other than stainless steel for prestressed concrete, as currently provided for in item 642.1120 of the *Tariff Schedules of the United States Annotated.*

#### Case History

On the basis of a petition filed on behalf of the U.S. industry producing PC strand, we initiated a countervailing duty investigation on March 30, 1982 (47 FR 13396).

On April 19, 1982, the ITC determined that there is a reasonable indication that these imports are materially injuring, or threatening to materially injure, a U.S. industry (47 FR 18200).

On August 2, 1982, we preliminarily determined that the government of Brazil was providing its manufacturers, producers, or exporters of PC strand with benefits that constitute subsidies (47 FR 34609).

On October 15, 1982, the Department and the government of Brazil signed an agreement suspending the investigation (47 FR 47048). Under the agreement, the government of Brazil agreed to offset completely by an export tax the amount of the net subsidy determined by the Department to exist on Brazilian exports of PC strand to the United States.

By letter of November 12, 1982, counsel for the petitioners requested that the investigation be continued under 19 U.S.C. 1671c(g). Accordingly, we completed the investigation and determined that certain benefits that constitute subsidies within the meaning of the countervailing duty law are being provided to manufacturers, producers or exporters in Brazil of PC strand (48 FR 4516).

On March 23, 1983, the ITC published notice of its unanimous final determination that an industry in the

U.S. is not materially injured or threatened with material injury, nor is the establishment of an industry in the United States materially retarded by reason of subsidized imports of PC strand from Brazil (48 FR 12143).

Since the ITC made a final negative injury determination, the suspension agreement on PC strand from Brazil between the Department and the government of Brazil has no force or effect and the investigation on this product is terminated (19 U.S.C. 1671c(f)(3)).

Dated: April 15, 1983.

**Gary N. Horlick,**

*Deputy Assistant Secretary for Import Administration.*

[FR Doc. 83-10642 Filed 4-20-83; 8:45 am]

BILLING CODE 3510-25-M

## Office of the Secretary

### Advisory Committees; Availability of Report on Closed Meetings

**AGENCY:** Department of Commerce.

**ACTION:** Announcing Public Availability of Report on Closed Meetings of Advisory Committees.

**SUMMARY:** The Department of Commerce has prepared its report on the activities of closed or partially-closed meetings of advisory committees, as required by the Federal Advisory Committee Act.

**ADDRESSES:** Copies of the reports have been filed and are available for public inspection at two locations:

Library of Congress, Newspaper and Current Periodicals Reading Room, Room 1026, John Adams Building, 2nd and Independence Avenue, SE., Washington, D.C. 20540.

Department of Commerce, Central Reference and Records Inspection Facility, Room 6628, Herbert C. Hoover Building, 14th and Constitution Avenue, NW., Washington, D.C. 20230, telephone (202) 377-4217, Attention Mrs. G. LeBoo or Mr. A. Pinkney.

**SUPPLEMENTARY INFORMATION:** The reports cover the closed and partially-closed meetings held in 1982 for 25 of the Department's 36 advisory committees and several subcommittees, the names of which are listed below. The (*) indicates the committees whose reports are not included with this submission but will be submitted under separate cover. Their availability will be announced in the **Federal Register.**

Committee (Subcommittee)

Advisory Committee on East-West Trade
*Committee of Chairmen of the Industry Sector Advisory Committee (ISAC) for Trade Policy Matters (TPM)
Computer Peripherals, Components, and Related Test Equipment Technical Advisory Committee
Computer Systems Technical Advisory Committee
—Hardware Subcommittee
*Electronic Instrumentation Technical Advisory Committee
*Industry Functional Advisory Committee on Customs Matters for Trade Policy Matters
Industry Functional Advisory Committee on Standards for Trade Policy Matters
Industry Policy Advisory Committee for Trade Policy Matters
*ISAC on Aerospace Equipment for TPM
ISAC on Capital Goods for TPM
ISAC on Chemicals and Allied Products for TPM
ISAC on Consumer Goods for TPM
*ISAC on Electronics and Instrumentation for TPM
ISAC on Energy for TPM
ISAC on Ferrous Ores and Metals for TPM
ISAC on Footwear, Leather, and Leather Products for TPM
*ISAC on Industrial and Construction Materials and Supplies for TPM
ISAC on Lumber and Wood Products for TPM
*ISAC on Nonferrous Ores and Metals for TPM
ISAC on Paper and Paper Products for TPM
*ISAC on Services for TPM
*ISAC on Small and Minority Business for TPM
*ISAC on Textiles and Apparel for TPM
*ISAC on Transportation, Construction, and Agricultural Equipment for TPM
ISAC on Wholesaling and Retailing for TPM
Land Remote Sensing Advisory Commission
Marine Fisheries Advisory Committee
New England Fishery Management Council
Numerically Controlled Machine Tool Technical Advisory Committee
Pacific Fishery Management Council
President's Export Council
President's Export Council Subcommittee on Export Administration
Sea Grant Review Panel
Semiconductor Technical Advisory Committee
—Discrete Semiconductor Device Subcommittee
—Microcircuit Subcommittee
—Semiconductor Manufacturing Materials and Equipment Subcommittee
Telecommunications Equipment Technical Advisory Committee
—Fiber Optic Subcommittee
—Switching Subcommittee
Western Pacific Fishery Management Council

At the end of the year the Department of Commerce had 44 other advisory committees which did not hold any closed or partially-closed meetings during the reporting period.

**FOR FURTHER INFORMATION CONTACT:** Mrs. Yvonne Barnes, Committee Management Analyst, U.S. Department of Commerce, Washington, D.C. 20230, telephone (202) 377-4217.

Dated: March 31, 1983.

**Marilyn S. McLennan,**

*Chief, Information Policy and Management Division, Office of Information Management.*

[FR Doc. 83-10641 Filed 4-20-83; 8:45 am]

BILLING CODE 3510-CW-M

## DEPARTMENT OF DEFENSE

## Department of the Army

### Army Science Board: Closed Meeting

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (92-463), announcement is made of the following Committee Meeting:

Name of committee: Army Science Board (ASB).

Dates of meeting: Friday, 13 May 1983.

Times: 0830-1700 hours (Closed).

Place: Pentagon, Washington, D.C.

Agenda: The Army Science Board Ad Hoc Subgroup on Army Initiatives—Equipment Upgrade will meet for classified briefings and discussions on recent Army actions regarding planned combat capability upgrades to existing equipment and on the emerging need for innovative technology for application to future equipment. This meeting will be closed to the public in accordance with Section 552b(c) of Title 5 U.S.C., specifically subparagraph (1) thereof, and Title 5, U.S.C. App. 1, subsection 10(d). The classified and nonclassified matters to be discussed are so inextricably intertwined so as to preclude opening any portion of the meeting. The ASB Administrative Officer, Helen M. Bowen, may be contacted for further information at (202) 695-3039 or 697-9703.

**Helen M. Bowen,**

*Administrative Officer.*

[FR Doc. 83-10581 Filed 4-20-83; 8:45 am]

BILLING CODE 3710-08-M

### Military Traffic Management Command; Military Personal Property Symposium; Open Meeting

Announcement is made of a meeting of the Military Personal Property Symposium. This meeting will be held

on May 19, 1983 at Headquarters, Military Traffic Management Command, 5611 Columbia Pike, Falls Church, VA and will convene at 0930 hours.

Proposed agenda: The purpose of the Symposium is to provide an open discussion and free exchange of ideas with the public on procedural changes to the Personal Property Traffic Management Regulation (DOD 4500.34–R), and the handling of other matters of mutual interest relating to the movement and/or storage of household goods and unaccompanied baggage, as well as proposed changes and innovations in the Department of Defense Personal Property Movement and Storage Program.

All interested persons desiring to submit topics to be discussed should submit them in writing to the Commander, Military Traffic Management Command, ATTN: MT–PPM, Washington, DC 20315. Topics to be discussed should be received on or before May 2, 1983.

Dated: April 8, 1983.

**John O. Roach, II,**

*Army Liaison Officer with the Federal Register.*

[FR Doc. 83–10625 Filed 4–20–83; 8:45 am]

BILLING CODE 3710–92–M

## Department of the Army; Corps of Engineers

### National Dredging Study

**AGENCY:** Water Resources Support Center, U.S. Army Corps of Engineers.

**ACTION:** Announcement of study.

**SUMMARY:** The U.S. Army Corps of Engineers has asked the National Research Council of the National Academy of Sciences, through its Marine Board, to undertake a study of national needs and capabilities for dredging of ports and harbors and of navigational channels.

**DATES:** Comments must be received by May 23, 1983.

**ADDRESSES:** Send written comments to Aurora Gallagher, Staff Officer, Study of National Dredging Issues, Marine Board, National Academy of Sciences, 2101 Constitution Avenue, NW., Washington, D.C. 20418.

**SUPPLEMENTARY INFORMATION:** A committee appointed by the National Research Council will undertake an interdisciplinary assessment of national needs for improvement and maintenance dredging in coastal ports and harbors, including their navigational channels. These needs will be evaluated as a function of (1) demands for shipborne trade, (2) likely trends in the world shipping fleet to carry that trade, (3) relationship of inland and marine transportation systems, (4) design criteria for safe and efficient navigation of the projected ship types and levels of traffic, (5) identification of opportunities for improvement dredging or development or alternatives such as deepwater ports, ships of high beam-to-draft ratios, and others, as well as critically needed maintenance dredging. The period covered by the study is the near-term and mid-term future (to about the year 2000).

In making its assessment, the committee will consider the likelihood and value of trade for various channel and port configurations, appropriateness of various institutional and financial arrangements, design criteria and disposal plans for dredged materials, mutual implications of port development and the physical and biological environment, and needed research and development.

Of particular interest of the Marine Board in the conduct of this study are the judgments of those with interests in the navigational channels and other facilities of the coastal ports created or maintained by dredging. Examples of areas to be addressed include (1) the extent of the current and future national dredging needs, (2) whether existing regulatory and institutional arrangements for dredging are adequate, and (3) the implications for the marine and inland environment of dredging operations and disposal of dredged materials.

Comments may be general or directed to specific concerns: general comments should be supported by facts or examples. Interested people are invited to participate in this study by submitting written data, views, suggestions, or other statements, or by offering to make their expertise available in the course of the study. Commentators should include their affiliation and reasons for comments.

Dated: April 13, 1983.

**John O. Roach, II,**

*DA Liason Officer with the Federal Register.*

[FR Doc. 83–10624 Filed 4–20–83; 8:45 am]

BILLING CODE 3710–08–M

## DEPARTMENT OF EDUCATION

### National Advisory Council on Vocational Education

**AGENCY:** National Advisory Council on Vocational Education, Education

**ACTION:** Amendment of notice.

**SUMMARY:** This document is intended to notify the general public of the locations of coming Forums on Industry and Vocational Education, and change of date of one Forum, first published in the **Federal Register** on March 31, 1983, Pages 13479–13480. The Forums are being conducted by the National Advisory Council on Vocational Education in cooperation with the National Commission for Employment Policy, and the State Advisory Councils on Vocational Education. Notice of these meetings is required under Section 10(a)(2) of the Federal Advisory Committee Act, and is intended to notify the general public of its opportunity to attend. The schedule follows:

Dates and locations:

May 3, 1983, the Clift Hotel, Geary & Taylor Streets, San Francisco, CA;

May 17, 1983, the Standard Oil Building, 200 East Randolph Drive, Chicago, IL (Changed from the 19th);

May 24, 1983, Visiting Nurse Association of Boston, 100 Boylston Street.

**SUPPLEMENTARY INFORMATION:** These regional forums are open to the public. The purpose of the Forums is to hear from representatives of the private sector regarding their views on the condition of vocational education. The Forums will elicit business community perspectives on the effectiveness of vocational education at the secondary and postsecondary levels, the ability of vocational education to respond to changes in technology and training methods, the degree to which business works with vocational education to help upgrade program and instruction, examples of good working relationships and cooperative effort between business and education, and other education/business linkages. The panels at each Forum will be made up of Members of the National Advisory Council on Vocational Education, the National Commission for Employment Policy, and State Advisory Councils. A report with findings and recommendations drawn from the proceedings will be prepared.

Records are kept of Council proceedings and are available for public inspection at the office of the National Advisory Council on Vocational Education from 9:00 a.m. to 5:00 p.m., 425 13th Street, NW., Suite 412, Washington, DC 20004. For further information contact: Virginia Solt, NACVE Staff, at above address. Telephone (202) 376–8873.

Signed at Washington, DC on April 18, 1983.

James W. Griffith,

*Executive Director, National Advisory Council on Vocational Education.*

[FR Doc. 83-10590 Filed 4-20-83; 8:45 am]

BILLING CODE 4000-01-M

## DEPARTMENT OF ENERGY

### Office of Conservation and Renewable Energy

[Case No. F-008]

### Energy Conservation Program for Consumer Products; Petition for Waiver of Furnace Test Procedures From Duo-Matic/Olsen, Inc.

**AGENCY:** Department of Energy.

**SUMMARY:** Today's notices publishes a "Petition for Waiver" from Duo-Matic/Olsen, Inc., of Ontario, Canada, requesting a waiver from the existing Department of Energy (DOE) test procedures for furnaces. Duo-Matic/Olsen manufactures and plans to market in the U.S. a gas-fired forced air condensing furnace. The petition requests DOE to grant relief from the test procedure requirements relating to the annual fuel utilization efficiency (AFUE) improvement attributable to the condensing of flue gases. Duo-Matic/Olsen seeks to use a National Bureau of Standards (NBS) condensate test method for AFUE instead of the present DOE test procedures which base condensation calculations on the average flue gas temperature. Duo-Matic/Olsen further seeks to modify the NBS test method in order to calculate steady state efficiency improvement due to condensing of flue gases in order to determine output capacity. DOE is soliciting comments, data, and information respecting the petition.

**DATE:** DOE will accept comments, data, and information not later than May 23, 1983.

**ADDRESS:** Written comments and statements shall be sent to: Department of Energy, Office of conservation and Renewable Energy, Case No. F-008, Mail Stop CE-113.1, Forrestal Building, 1000 Independence Avenue, SW., Washington, D.C. 20585.

**FOR FURTHER INFORMATION CONTACT:**

Michael J. McCabe, U.S. Department of Energy, Office of Conservation and Renewable Energy, Mail Station CE-113.1, Forrestal Building, 1000 Independence Avenue, SW., Washington, D.C. 20585; (202) 252-9127;or

Eugene Margolis, Esq., U.S. Department of Energy, Office of General Counsel, Mail Station GC-33, Forrestal Building, 1000 Independence Avenue, SW., Washington, D.C. 20585; (202) 252-9513.

**SUPPLEMENTARY INFORMATION:**

#### Background

The energy Conservation Program for Consumer Products (other than automobiles) was established pursuant to the Energy Policy and Conservation Act (EPCA), Pub. L. 94-163, 89 Stat. 917, as amended by the National Energy Conservation Policy Act (NECPA), Pub. L. 95-619, 92 Stat. 3266, which requires DOE to prescribe standardized test procedures to masure the energy consumption of certain consumer products, including furnaces. The intent of the test procedures is to provide a comparable measure of energy consumption that will assist consumers in making purchasing decisions. These test procedures appear at 10 CFR Part 430, Subpart B.

DOE has amended the prescribed test procedures by adding 10 CFR 430.27, Petitions for Waiver, to allow the Assistant Secretary for Conservation and Renewable Energy temporarily to waive test procedures for a particular basic model. 45 FR 64108 (September 26, 1980.) Waivers may be granted when one or more design characteristics of a basic model either prevent testing of the basic model according to the prescribed test procedures or lead to results so unrepresentative of the model's true energy consumption as to provide materially inaccurate comparative data.

The Duo-Matic/Olsen petition seeks a waiver from the DOE test method basing condensation calculations on the average flue gas temperature. Instead, Duo-Matic/Olsen requestes the use of the condensate measureing method as set forth in Appendix C of National Bureau of Standards Interagency Report 80-2210, "Recommended Testing and Calculation Procedures for Estimating the Seasonal Performance of Residential Condensing Furnaces and Boilers," dated April 1980, to determine the AFUE of its condensing furnace. The firm also is requesting to use a similar condensate measurement method for determining the steady state efficiency improvement of its condensing furnace instead of using the flue loss method in the existing test procedures.

Pursuant to paragraph (b) of 10 CFR 430.27, DOE is hereby publishing the "Petition for Waiver" in its entirety including the additional request. The petition contains no confidential information. DOE solicits comments, data, and information respecting the petition.

Issued in Washington, D.C. April 18, 1983.

Howard S. Coleman,

*Principal Deputy Assistant Secretary, Conservation and Renewable Energy.*

Re: Energy Conservation Program for Consumer Products, Petition for Waiver of Furnace Test Procedures

Gentlemen: Under the provisions of 10 CFR 430.27 a petition for waiver from the test procedures in 10 CFR Part 430, Subpart B, Appendix N, dated August 12, 1980, is requested by Duo-Matic/Olsen Inc., Tilbury, Ontario.

Duo-Matic/Olsen Inc. manufactures a complete line of residential heating equipment. At the present time we are manufacturing and have available a gas fired forced air condensing furance in Canada. Plans to market this gas fired forced air condensing furnace in the United States requires testing under the provisions of 10 CFR Part 430, Subpart B, Appendix N.

Duo-Matic/Olsen Inc. requests a waiver from the existing Department of Energy test procedure requirements relating to the measurement of losses due to cycling in determining the annual fuel utilization efficiency (AFUE) improvement attributable to the condensing of flue gases. We ask that the waiver be granted to permit the optional use of tests outlined in the National Bureau of Standards document NBS1R 81-2110, April 1981, entitled, "Recommended Testing and Calculation Procedures for Estimating the Seasonal Performance of Residential Condensing Furnaces and Boilers."

Duo-Matic/Olsen Inc. also seeks to use a direct measurement method to determine the steady state efficiency improvement attributable to the condensing of flue gases needed to determine output capacity. The disclosure of the direct measurement method is published in the **Federal Register** Notice of December 3, 1982, "Energy Conservation Program for Consumer Products, Petition for Waiver of Furnace; Test Procedures From Amana Refrigeration, Inc."

If there is any other information required regarding this petition, please contact us.

Yours truly,

Duo-Matic/Olsen Inc.

Dennis Koestler,

*P. Eng., Project Engineer.*

[FR Doc. 83-10638 Filed 4-20-83; 8:45 am]

BILLING CODE 6450-01-M

## Energy Information Administration

### Agency Forms Under Review by the Office of Management and Budget

**AGENCY:** Energy Information Administration, Energy.

**ACTION:** Notice of submission of request for clearance to the Office of Management and Budget.

**SUMMARY:** Under provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35), Department of Energy (DOE) notices of proposed collections under review will be published in the **Federal Register** on the Thursday of the week following their submission to the Office of Management and Budget (OMB). Following this notice is a list of the DOE proposals sent to OMB for approval since Thursday, April 14, 1983. The listing does not contain information collection requirements contained in regulations which are to be submitted under 3504(h) of the Paperwork Reduction Act.

Each entry contains the following information and is listed by the DOE sponsoring office: (1) The form number; (2) Form title; (3) Type of request, e.g., new, revision, or extension; (4) Frequency of collection; (5) Response obligation, i.e., mandatory, voluntary, or required to obtain or retain benefit; (6) Type of respondent; (7) An estimate of the number of respondents; (8) Annual respondent burden, i.e., an estimate of the total number of hours needed to fill out the form; and (9) A brief abstract describing the proposed collection.

**DATES:** Last Notice published Thursday, April 14, 1983.

**FOR FURTHER INFORMATION CONTACT:**

John Gross, Director, Forms Clearance and Burden Control Division, Energy Information Administration, M.S. 1H-023, Forrestal Building, 1000 Independence Ave., NW., Washington, DC 20585; (202) 252-2308;

Jefferson B. Hill, Department of Energy Desk Officer, Office of Management and Budget, 726 Jackson Place, NW., Washington, DC 20503; (202) 395-7340; or

Vartkes Broussalian, Federal Energy Regulatory Commission Desk Officer, Office of Management and Budget, 726 Jackson Place, NW., Washington, DC 20503; (202) 395-3087.

**SUPPLEMENTARY INFORMATION:** Copies of proposed collections and supporting documents may be obtained from Mr. Gross. Comments and questions about the items on this list should be directed to the OMB reviewer; comments should also be provided Mr. Gross. If you anticipate commenting on a form, but find that time to prepare these comments will prevent you from submitting comments promptly, you should advise the OMB reviewer of your intent as early as possible.

Issued in Washington, D.C. April 15, 1983.

**Yvonne M. Bishop,**

*Director, Statistical Standards, Energy Information Administration.*

DOE Forms Under Review By OMB

| Form No. (1) | Form title (2) | Type of request (3) | Response frequency (4) | Response obligation (5) | Respondent description (6) | Estimated number of respondents (7) | Annual respondent burden (8) | Abstract (9) |
|---|---|---|---|---|---|---|---|---|
| FERC: FERC-16A. | Winter supply report monitoring program. | Revision | Annually; every 2 weeks during winter. | Mandatory | Natural gas pipeline companies. | 28 | 1,688 | Data are collected to ensure that the FERC has timely information available for analyzing the natural gas supply available for the winter months and to determine potential areas where shortages or surplus supplies may exist or develop. Data are published in the "Impact of Winter Gas Supplies for Twenty-Eight Pipeline Companies." |

[FR Doc. 83-10636 Filed 4-20-83; 8:45 am]

BILLING CODE 6450-01-M

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**[Form EIA-119M]**

## Monthly Report of Electric Energy, Capability and Peak Load; Cancellation

*Correction*

In FR Doc. 83-6468 beginning on page 10732 in the issue of Monday, March 14, 1983, the Draft-Form EIA-714 which began in the first column of page 10733 and ended on page 10734 should have read as follows:

BILLING CODE 1505-01-M

DRAFT-FORM EIA-714-DRAFT
ANNUAL UTILITY OPERATIONS REPORT
SCHEDULE 5

NET GENERATION, ENERGY RECEIPTS AND DELIVERIES AND SYSTEM PEAKS BY MONTHS FOR THE YEAR

General Instructions

1. In column 2, show the total net generation of system plants by months for the year.

2. In columns 3, 4, 5, and 6 give a monthly accounting of all energy transfers to and from the facilities of other systems during the year, including gross sales for resale, purchases, interchanges and transfers for resale, whether on a firm interchange or any other basis, and all energy received from small power producers, cogenerators, other industrial power, or off-system share of jointly owned units.

Energy Transfer Instructions Part A & B

Part A is for the recording of "run-load", other systems's In-Load, and borderline energy transfers; and Part B is for the recording of all other energy transfers.

Part A

A1. Show in column 3 the amounts of energy received as firm purchases and reported as firm sales for resale by the other system. Firm sales for resale are full or partial requirement power intended to meet the full customer load requirement of another system or the partial customer load of another system taking into account the other system's generation resources. If customers of respondent received energy directly from another system for the account of the respondent, (border-line receipts), such transfers should be included in column 3. If part of the energy deliveries to system were delivered as firm sales and reported in column 4 are received back into the reporting system through another interconnection, such receipts should also be entered in column 3. All other receipts should be entered in column 5.

A2. Show in column 4 the amounts of energy delivered as firm sales for resale. If the respondent's system delivered energy to customers of another system ("border-line customers"), such deliveries should be included in column 4.

Part B

B1. Report in column 5 all energy (except that reported in column 3) received from each utility system, small power producer, cogenerator, or off-system generating plant or unit as the case may be.

B2. Report in column 6 the amounts of energy delivered for resale except those amounts reported in column 4. Do not report sales to industrial customers.

3. In column 10, enter the total maximum load which a generating unit, generating station, or other apparatus can carry under specific conditions without exceeding approved limits of temperature and stress at the time of the monthly peak load which were owned or operated by the respondent regardlessof whether they were available or unavailable for load at the time of the peak load. This should be the respondent's best estimate of the net generating capability of the system at the time of the monthly peak load.

4 In column 11, enter the capability of respondent-owned or -operated generating units that were unavailable at the time of the peak load due to scheduled maintenances, full forced outages, and other outages. These other outages may be partial outages, legal restriction on generating unit or plant output, or derating not considered in the determination of generating unit capability according to the system's rating criteria.

5. In column 12, show the maximum megawatt load on the system for each month of the year. Load data in this column should be the maximum integrated demand based on net energy for load as computed in column 7 for 60-minute clock-hour intervals. Enter the numerical day of the reporting month and hour of the day in columns 13 and 14, respectively. Where integrated demands for 60-minute clock-hour intervals are not available, it is desired that available data be adjusted to approximate such intervals. Adjustments made should be explained in notes. Where such adjustments cannot be made, load data should be furnished in the form available.

6. In column 15, the minimum hourly loads experienced during each month should be based on net energy for load as computed in column 7.

DRAFT-FORM EIA-714-DRAFT
ANNUAL UTILITY OPERATIONS REPORT

SCHEDULE 5

NET GENERATION, ENERGY RECEIPTS AND DELIVERIES AND SYSTEM PEAKS BY MONTHS FOR THE YEAR

| | | Energy Transfers - MWh | | | | Net Energy | Net Energy |
|---|---|---|---|---|---|---|---|
| | | Part A | | Part B | | for Load-MW | for System-MW |
| Mon. | System Net Generation | Receipts | Deliveries | Receipts | Deliveries | col 2+5-6 MWh | col 7+3-4 MWh |
| | (2) | (3) | (4) | (5) | (6) | (7) | (8) |
| Jan | | | | | | | |
| Feb | | | | | | | |
| Mar | | | | | | | |
| Apr | | | | | | | |
| May | | | | | | | |
| Jun | | | | | | | |
| Jul | | | | | | | |
| Aug | | | | | | | |
| Sep | | | | | | | |
| Oct | | | | | | | |
| Nov | | | | | | | |
| Dec | | | | | | | |
| Year | | | | | | | |

| | Total Capability at Time of Pk Ld | Unavailable Capability at Time of Peak | Load Data | | | Minimum |
|---|---|---|---|---|---|---|
| | | | | Demand Interval | | |
| Mon. | MW | MW | Peak Load MW | Date | Clock-hour End | Hourly Load |
| (9) | (10) | (11) | (12) | (13) | (14) | (15) |
| Jan | | | | | | |
| Feb | | | | | | |
| Mar | | | | | | |
| Apr | | | | | | |
| May | | | | | | |
| Jun | | | | | | |
| Jul | | | | | | |
| Aug | | | | | | |
| Sep | | | | | | |
| Oct | | | | | | |
| Nov | | | | | | |
| Dec | | | | | | |
| Year | | | | | | |

NOTES:

BILLING CODE 1505-01-C

## Federal Energy Regulatory Commission

[Docket No. ER83-451-000]

### Carolina Power & Light Co.; Filing

April 15, 1983.

The filing Company submits the following:

Take notice that Carolina Power & Light Company (Carolina) on April 8, 1983, tendered for filing changes outlined below in its agreement with Lumbee River EMC and Randolph EMC.

1. *Lumbee River EMC.*

*Laurinburg 23 KV*—The termination and removal of special metering facilities that had been required to provide metering pulse information. The metering pulse information was provided under the Company's additional facilities plan. The name of the point of delivery also was changed to reflect the delivery voltage.

*Red Springs 23 KV*—The termination and removal of special metering facilities that had been required to provide metering pulse information. The metering pulse information was provided under the company's additional facilities plan. The name of the point of delivery also was changed to reflect the delivery voltage.

*Rockfish 115 KV*—Customer has allowed Company to purchase energy generated from a hydroelectric facility located on customer's distribution facilities served from the Rockfish 115 KV POD. The name of the point of delivery also was changed to reflect the delivery voltage.

2. *Randolph EMC.*

*Gray's Chapel 115 KV*—A change in delivery voltage from 69 KV to 115 KV.

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, N.E., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). All such motions or protests should be filed on or before May 3, 1983. 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.

**Kenneth F. Plumb,**

*Secretary.*

[FR Doc. 83-10606 Filed 4-20-83; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. ER83-455-000]

### Centel Corp; Filing

April 15, 1983.

The filing Company submits the following:

Take notice that on April 8, 1983, Centel Corporation-Western Power tendered for filing an addendum to its Rate Schedule FPC No. 75, with CMS Electric Cooperative, Inc., providing for the addition of one point of delivery.

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, N.E., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). All such motions or protests should be filed on or before May 3, 1983. 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.

**Kenneth F. Plumb,**

*Secretary.*

[FR Doc. 83-10607 Filed 4-20-83; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. ER83-454-000]

### Centel Corp.; Filing

April 15, 1983.

The filing Company submits the following:

Take notice that on April 8, 1983, Centel Corporation-Western Power tendered for filing an addendum to its Rate Schedule FPC No. 81, with Smoky Hill Electric Cooperative Association, Inc., providing for the addition of one point of delivery and increased capacities at two existing points of delivery.

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, N.E., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). All such motions or protests should be filed on or before May 3, 1983. 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.

**Kenneth F. Plumb,**

*Secretary.*

[FR Doc. 83-10608 Filed 4-20-83; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. ER83-453-000]

### Centel Corp.,

April 15, 1983.

The filing Company submits the following:

Take notice that Centel Corporation-Western Power on April 8, 1983, tendered for filing an addendum to its Rate Schedule FPC No. 79, with Ninnescah Rural Electric Cooperative Association, providing for an increase in capacity at one existing point of delivery.

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, N.E., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). All such motions or protests should be filed on or before May 3, 1983. 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.

**Kenneth F. Plumb,**

*Secretary.*

[FR Doc. 83-10609 Filed 4-20-83; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. ER83-452-000]

### Central Illinois Public Service Co.; Filing

April 15, 1983.

The filing Company submits the following:

Take notice that on April 8, 1983, Central Illinois Public Service Company (CIPS) tendered for filing Appendix A—CIPS–IP Connection 2—North Pana,

dated February 28, 1983, to the Interconnection Agreement between CIPS, Illinois Power Company and Union Electric Company dated February 18, 1972. Also included in the filing is Appendix "T" dated February 28, 1983, to the Facility Use Agreement between CIPS and Illinois Power Company dated February 14, 1972.

Copies of this filing were sent to the Public Service Commission of Missouri, Union Electric Company, Illinois Power Company and the Illinois Commerce Commission.

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, N.E., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). All such motions or protests should be filed on or before May 3, 1983. 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.

**Kenneth F. Plumb,**

*Secretary.*

[FR Doc. 83-10610 Filed 4-20-83; 8:45 am]

BILLING CODE 6717-01-M

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**[Docket No. ER83-449-000]**

## Duke Power Co.; Filing

April 15, 1983.

The filing Company submits the following:

Take notice that on April 6, 1983, Duke Power Company (Duke) tendered for filing an interconnection agreement between Duke and the South Carolina Public Service Authority (Santee Cooper) dated March 7, 1983. This agreement provides for an interconnection between Duke and Santee Cooper at the Southeastern Power Administration's Clarks Hill Project and for the delivery of capacity and energy pursuant to service schedules included as part of such agreement.

Duke states that the rates filed are the same as the rates previously filed for similar contracts and accepted for filing by the Commission.

Duke has requested that the contract become effective on the date of tender for filing or May 1, 1983, or as soon as the Commission deems appropriate. If waiver is not granted, however, Duke requests an effective date no later than sixty days after the date of tender for filing or June 6, 1983.

Copies of the filing were served on the South Carolina Public Service Authority, The North Carolina Utilities Commission, and the South Carolina Public Service Commission.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protests with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). All such motions or protests should be filed on or before April 28, 1983. 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.

**Kenneth F. Plumb,**

*Secretary.*

[FR Doc. 83-10611 Filed 4-20-83; 8:45 am]

BILLING CODE 6717-01-M

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**[Docket No. ER83-450-000]**

## Pennsylvania Power & Light Co.; Filing

April 15, 1983.

The filing Company submits the following:

Take notice that Pennsylvania Power & Light Company (PP&L) tendered for filing on April 6, 1983, as a rate schedule an executed agreement dated as of March 1, 1983 between PP&L and Niagara Mohawk Power Corporation (Niagara Mohawk). The proposed rate schedule provides for the sale of interruptible energy by PP&L to Naiagra Muhawk.

PP&L states that the rate schedule provides for a maximum energy reservation charge rate of $24.70 per megawatt hour and an energy charge rate based upon the incremental cost of providing the energy.

PP&L requests an effective date of April 6, 1983, and therefore requests waiver of the Commission's notice requirements.

Copies of the filing have been served upon Niagara Mohawk and the Pennsylvania Public Utility Commission.

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, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). All such motions or protests should be filed on or before April 28, 1983. 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.

**Kenneth F. Plumb,**

*Secretary.*

[FR Doc. 83-10612 Filed 4-20-83; 8:45 am]

BILLING CODE 6717-01-M

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## Office of the Secretary

## International Atomic Energy Agreement; Proposed Subsequent Arrangement; European Atomic Energy Community and Sweden

Pursuant to section 131 of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2160) notice is hereby given of a proposed "subsequent arrangement" under the Additional Agreement for Cooperation Between the Government of the United States of America and the European Atomic Energy Community (EURATOM) Concerning Peaceful Uses of Atomic Energy, as amended, and the Agreement for Cooperation Between the Government of the United States of America and the Government of Sweden Concerning Civil Uses of Atomic Energy, as amended.

The subsequent arrangement to be carried out under the above mentioned agreements involves approval for the following retransfer: RTDF/SW(EU)-125, from the Federal Republic of Germany to Sweden, 8000 kilograms of uranium, enriched to 3.5% in U-235. This material is being returned to Sweden after purification of unirradiated scrap, for use as power reactor fuel.

In accordance with section 131 of the Atomic Energy Act of 1954, as amended, it has been determined that this subsequent arrangement will not be inimical to the common defense and security.

This subsequent arrangement will take effect no sooner than fifteen days after the date of publication of this notice.

Dated: April 18, 1983.

For the Department of Energy.

**George Bradley,**

*Principal Deputy Assistant Secretary for International Affairs.*

[FR Doc. 83-10639 Filed 4-20-83; 8:45 am]

BILLING CODE 6450-01-M

### International Atomic Energy Agreements; Proposed Subsequent Arrangement; Japan

Pursuant to section 131 of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2160) notice is hereby given of a proposed "subsequent arrangement" under the Agreement for Cooperation Between the Government of the United States of America and the Government of Japan Concerning Civil Uses of Atomic Energy, as amended.

The subsequent arrangement to be carried out under the above mentioned agreement involves approval of the following sale:

Contract Number S–JA–330, to the Japan Atomic Energy Research Institute, 20 grams of uranium-235, 20 grams of uranium-238, and 14.8 grams of plutonium-239, to be used as standards for small sample perturbation measurements at the fast critical assembly.

In accordance with section 131 of the Atomic Energy Act of 1954, as amended, it has been determined that the furnishing of the nuclear material will not be inimical to the common defense and security.

This subsequent arrangement will take effect no sooner than fifteen days after the date of publication of this notice.

Dated: April 18, 1983.

For the Department of Energy.

**George Bradley,**

*Principal Deputy Assistant Secretary for International Affairs.*

[FR Doc. 83-10640 Filed 4-20-83; 8:45 am]

BILLING CODE 6450-01-M

### Oak Ridge Operations Office; Trespassing on DOE Property

**AGENCY:** Department of Energy.

**ACTION:** Designation of cylinder storage yard K–1066–K as off-limits area.

**SUMMARY:** The Department of Energy hereby designates the Cylinder Storage Yard K–1066–K an Off-Limits Area in accordance with 10 CFR Part 860, making it a federal crime under 42 U.S.C. 2278a for unauthorized persons to enter into or upon the Cylinder Storage Yard K–1066–K. If unauthorized entry into or upon the site is into an area enclosed by a fence, wall, roof, or other standard barrier, conviction for such unauthorized entry may result in a fine of not more than $5,000 or imprisonment for not more than one year or both. If unauthorized entry into or upon the site is into an area not enclosed by a fence, wall, roof, or other standard barrier, conviction for such unauthorized entry may result in a fine of not more than $1,000.

**FOR FURTHER INFORMATION CONTACT:**

William Luck, Office of General Counsel, U.S. Department of Energy, 1000 Independence Ave. SW., Washington, D.C. 20585, (202) 252–6975; or

James Leonard, Supply Division, U.S. Department of Energy, Oak Ridge Operations Office, P.O. Box E, Oak Ridge, Tennessee 37830; (615) 576–0999.

Notice: Pursuant to section 229 of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2278a), Section 104 of the Energy Reorganization Act of 1974 (42 U.S.C. 5814), as implemented by 10 CFR Part 860 published in the **Federal Register** on July 9, 1975 (40 FR 28789), and Section 301 of the Department of Energy Organization Act (42 U.S.C. 7151), the Department of Energy hereby gives notice that the Cylinder Storage Yard K–1066–K is designated an Off-Limits Area and prohibits the unauthorized entry and the unauthorized introduction of weapons or dangerous materials, as provided in 10 CFR 860.3 and 860.4 into or upon the Cylinder Storage Yard K–1066–K of the Oak Ridge Operations Office of the Department of Energy.

The Cylinder Storage Yard K–1066–K is located in the Third Civil District, Roane County, Tennessee, within the corporate limits of the City of Oak Ridge, on Perimeter Road, approximately 1.3 miles in a northerly direction from the point of intersection between State Route 58 and Perimeter Road. This facility covers approximately 11.9 acres of land, bounded on the east by Perimeter Road which circumscribes the Oak Ridge Gaseous Diffusion Plant, bounded on the north, west, and south by open Federal Government land, and is enclosed by a chain link fence seven feet in height, topped by three strands of barbed wire.

Notices stating the pertinent prohibitions of 10 CFR 860.3 and 860.4 and penalties of 10 CFR 860.5 will be posted at all entrances of said areas and at intervals along its perimeter as provided in 10 CFR 860.6.

Dated at Washington, D.C. this 31 day of March 1983.

**Troy E. Wade, II,**

*Acting Assistant Secretary for Defense Programs.*

[FR Doc. 83-10637 Filed 4-20-83; 8:45 am]

BILLING CODE 6450-01-M

## ENVIRONMENTAL PROTECTION AGENCY

**[OPTS-53048; TSH-FRL 2350-6]**

### Premanufacture Notices; Monthly Status Report for March 1983

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** Section 5(d)(3) of the Toxic Substances Control Act (TSCA) requires EPA to issue a list in the **Federal Register** at the beginning of each month reporting the premanufacture notices (PMNs) pending before the Agency and the PMNs for which the review period has expired since publication of the last monthly summary. This is the report for March 1983.

**DATE:** Written comments are due no later than 30 days before the applicable notice review period ends on the specific chemical substance. Nonconfidential portions of the PMNs may be seen in Rm. E–106 at the address below between 8:00 a.m. and 4:00 p.m., Monday through Friday, excluding legal holidays.

**ADDRESS:** Written comments are to be identified with the document control number "[OPTS–53048]" and the specific PMN number should be sent to: Document Control Officer (TS–793), Management Support Division, Office of Pesticides and Toxic Substances, Environmental Protection Agency, Rm. E–409, 401 M Street, SW., Washington, D.C. 20460, (202–382–3532).

**FOR FURTHER INFORMATION CONTACT:** Kirk Maconaughey, Chemical Control Division (TS–794), Office of Toxic Substances, Environmental Protection Agency, Rm. E–208, 401 M Street, SW., Washington, D.C. 20460, (202–382–3746).

**SUPPLEMENTARY INFORMATION:** The monthly status report published in the **Federal Register** as required under section 5(d)(3) of TSCA (90 stat. 2012 (15 U.S.C. 2504)), will identify: (a) PMNs received during March; (b) PMNs received previously and still under review at the end of March; (c) PMNs for which the notice review period has ended during March; (d) chemical substances for which EPA has received a notice of commencement to manufacture during March; and (e) PMNs for which the review period has been suspended. Therefore, the March 1983 PMN Status Report is being published.

Dated: April 12, 1983.

**Linda A. Travers,**

*Acting Director Management Support Division.*

# Premanufacture Notices Monthly Status Report, March 1983

## I. 87 Premanufacture Notices Received During the Month

| PMN No. | Identity and generic name | FR citation | Expiration date |
|---|---|---|---|
| 83-520 | Generic name: Polyester polycarboxylate salt | 48 FR 10470 (3/11/83) | May 29, 1983. |
| 83-521 | Generic name: Carbomonocyclic ester | 48 FR 10470 (3/11/83) | Do. |
| 83-522 | Reaction product of succinic anhydride and 1,2-ethanediamine, N-[3-(trimethoxysilyl)propyl] | 48 FR 10470 (3/11/83) | Do. |
| 83-523 | 1,1'(isopropylidenebis(6-hydroxy-m-phenylene))bis(tetrahydrothiophenium hydroxide) mixed salts | 48 FR 10470 (3/11/83) | Do. |
| 83-524 | Generic name: Polymer of trisubstituted methane, alkyl phenol and substituted bis benzene derivative | 48 FR 10470 (3/11/83) | Do. |
| 83-525 | Generic name: Substituted benzindolium, salt | 48 FR 10470 (3/11/83) | Do. |
| 83-526 | Generic name: Isocyanate-derived polyamide | 48 FR 10470 (3/11/83) | Do. |
| 83-527 | Generic name: Sulfonaphtholazonaphthol, chromium complex | 48 FR 10470 (3/11/83) | May 30, 1983. |
| 83-528 | Generic name: Dimer-trimer triglycidyl ester | 48 FR 10470 (3/11/83) | Do. |
| 83-529 | Generic name: Dicarboxylic acid, polyamine polymer | 48 FR 10470 (3/11/83) | Do. |
| 83-530 | Generic name: Disubstituted carbomonocyclic ester | 48 FR 10470 (3/11/83) | Do. |
| 83-531 | Generic name: Polyoxo arylene triazino epoxy derivative | 48 FR 10470 (3/11/83) | Do. |
| 83-532 | Generic name: Glyceryl propoxy diacrylate | 48 FR 10470 (3/11/83) | Do. |
| 83-533 | Generic name: Alkaneamine, alkane acid epoxy propyl ester, alkane aldehyde polymer | 48 FR 11500 (3/18/83) | June 1, 1983. |
| 83-534 | Generic name: Etheric aromatic ester | 48 FR 11500 (3/18/83) | Do. |
| 83-535 | N,N'-bis(2,2,6,6-tetramethyl-4-piperidyl) hexamethylenediamine polymer with ethane-1,2-dibromo | 48 FR 11500 (3/18/83) | June 4, 1983. |
| 83-536 | Polymer of poly(oxytetramethylene)diol, toluene diisocyanate polymer, isocyanate terminated and benzenamine, 4,4'-methylenebis and 2-butanone oxime. | 48 FR 11500 (3/18/83) | Do. |
| 83-537 | Generic name: Waterborne urethane-acrylic polymer | 48 FR 11500 (3/18/83) | Do. |
| 83-538 | Generic name: Polymer of diethylenetriamine and higher polyamine with dibasic ester | 48 FR 11500 (3/18/83) | June 5, 1983. |
| 83-539 | Generic name: Substituted aralkylsilanes | 48 FR 11500 (3/18/83) | Do. |
| 83-540 | Generic name: Polyamidoamine | 48 FR 11500 (3/18/83) | Do. |
| 83-541 | Generic name: Polymer of carbonic acid and mixed aromatic diols containing sulfone diol | 48 FR 11500 (3/18/83) | Do. |
| 83-542 | Generic name: Alkyl, alkylene maleate | 48 FR 11500 (3/18/83) | Do. |
| 83-543 | Generic name: Polymer of diethylenetriamine and higher polyamines with dibasic esters, reacted with epichlorohydrin | 48 FR 11500 (3/18/83) | June 6, 1983. |
| 83-544 | Generic name: Unsaturated polyester | 48 FR 11501 (3/18/83) | June 7, 1983. |
| 83-545 | Benzene, 1-3-bis(isocyanatomethyl) | 48 FR 11501 (3/18/83) | Do. |
| 83-546 | Generic name: Substituted phenolazo, substituted pyrazolone | 48 FR 11501 (3/18/83) | Do. |
| 83-548 | Carboxylic acids, $C_6$-$C_{24}$ mono-and $C_6$-$C_{24}$ di-, $C_6$-$C_{11}$ di-, polymers with phthalic anhydride and propylene glycol | 48 FR 11501 (3/18/83) | Do. |
| 83-549 | Generic name: Substituted acetamide | 48 FR 11501 (3/18/83) | Do. |
| 83-550 | Generic name: Polymer of formaldehyde and substituted phenols | 48 FR 12590 (3/25/83) | June 8, 1983. |
| 83-551 | Generic name: Modified polymer of formaldehyde and substituted phenols | 48 FR 12590 (3/25/83) | Do. |
| 83-552 | Generic name: Phenol formaldehyde butanol resin | 48 FR 12591 (3/25/83) | Do. |
| 83-553 | Ethanesulfonic acid, 2-[bis (2-cyanoethyl)phosphinol]-potassium salt | 48 FR 12591 (3/25/83) | June 11, 1983. |
| 83-554 | Generic name: 1,3-benzenedicarboxylic acid, 5-substituted polymer with 1,2-ethanediol and oxo-heteropolycycle | 48 FR 12591 (3/25/83) | Do. |
| 83-555 | Generic name: 1,3-benzenedicarboxylic acid, 5-substituted polymer with 1,2-ethanediol and oxo-heteropolycycle | 48 FR 12591 (3/25/83) | Do. |
| 83-556 | Generic name: Polyester polyurethane | 48 FR 12591 (3/25/83) | June 12, 1983. |
| 83-557 | Generic name: Disubstituted heteromonocycle | 48 FR 12591 (3/25/83) | Do. |
| 83-558 | Generic name: Modified epoxy resin | 48 FR 12591 (3/25/83) | Do. |
| 83-559 | Generic name: Organo phosphate | 48 FR 12591 (3/25/83) | Do. |
| 83-560 | Generic name: Organo phosphate polymer | 48 FR 12591 (3/25/83) | Do. |
| 83-561 | Generic name: Acrylic alkyd polymer | 48 FR 12591 (3/25/83) | Do. |
| 83-562 | Generic name: Acrylic alkyd polymer | 48 FR 12591 (3/25/83) | Do. |
| 83-563 | Generic name: Substituted indolium, salt | 48 FR 12591 (3/25/83) | Do. |
| 83-564 | Generic name: Dialkyl cycloaliphatic diester | 48 FR 12591 (3/25/83) | Do. |
| 83-565 | Generic name: Sodium salt of a polymer of acrylic acid, acrylamide, and substituted acrylamide | 48 FR 12592 (3/25/83) | June 13, 1983. |
| 83-566 | Generic name: Substituted chlorobenzene | 48 FR 12592 (3/25/83) | June 14, 1983. |
| 83-567 | Generic name: Modified acrylic copolymer | 48 FR 12592 (3/25/83) | Do. |
| 83-568 | Generic name: Substituted styrene | 48 FR 12592 (3/25/83) | Do. |
| 83-569 | Generic name: Phenyl substituted butane | 48 FR 12592 (3/25/83) | Do. |
| 83-570 | Generic name: Substituted alkane diols | 48 FR 14035 (4/1/83) | June 15, 1983. |
| 83-571 | Generic name: Fatty acids, carbomonocyclic ester | 48 FR 14035 (4/1/83) | Do. |
| 83-572 | Generic name: Polyester polycarboxylate salt | 48 FR 14035 (4/1/83) | Do. |
| 83-573 | Generic name: Unsaturated polyester | 48 FR 14035 (4/1/83) | Do. |
| 83-574 | Polymer of malonic acid, diethyl ester, trimethylolpropane, 1,6-hexanediol, neopentylglycol | 48 FR 14035 (4/1/83) | Do. |
| 83-575 | Polymer of bisphenol A-oxirane polymer neodecanoic acid, 2,3-epoxypropyl ester, diethylaminopropylamine, diethanolamine | 48 FR 14035 (4/1/83) | Do. |
| 83-576 | Generic name: Polymer of diphenylmethane diisocyanate, alkyl epoxides, alkane triol, and trisubstituted alkanol | 48 FR 14035 (4/1/83) | Do. |
| 83-577 | Generic name: 2-(2-haloaryl)amino-6-(N,N-dialkylamino)fluoran | 48 FR 14035 (4/1/83) | Do. |
| 83-578 | Generic name: Alkoxymethylpolysilazanes | 48 FR 14036 (4/1/83) | June 18, 1983. |
| 83-579 | Invalid | 48 FR 14036 (4/1/83) | Do. |
| 83-580 | Generic name: Thio-substituted aromatic amine | 48 FR 14036 (4/1/83) | Do. |
| 83-581 | Generic name: (Substituted-acetacetanilidylazophenyl)-(substituted) benzothiazole alkanolamine salt | 48 FR 14036 (4/1/83) | June 19, 1983. |
| 83-582 | Dimethylsila-14-crown-5 | 48 FR 14036 (4/1/83) | Do. |
| 83-583 | Generic name: Organotrimethoxysilane | 48 FR 14036 (4/1/83) | Do. |
| 83-584 | Generic name: Blocked isocyanate | 48 FR 14036 (4/1/83) | Do. |
| 83-585 | Generic name: Polymer of styrene, mixed acrylates and acrylic amide | 48 FR 14036 (4/1/83) | June 20, 1983. |
| 83-586 | Generic name: Mixed acrylic copolymer | 48 FR 14036 (4/1/83) | Do. |
| 83-587 | Generic name: Mixed metal oxide | 48 FR 14036 (4/1/83) | June 21, 1983. |
| 83-588 | 2,6-bis(picrylamino)pyridine | 48 FR 15180 (4/7/83) | June 22, 1983. |
| 83-589 | 2,6-bis(picrylamino)-3,5-dinitropyridine | 48 FR 15180 (4/7/83) | Do. |
| 83-590 | Generic name: Arylsulfonic acid, [[(arylamino) phenyl]azol] compound with alkanolamine | 48 FR 15180 (4/7/83) | Do. |
| 83-591 | Generic name: Styrene-acrylic terpolymer | 48 FR 15181 (4/7/83) | Do. |
| 83-592 | Generic name: Acrylic acid polymer | 48 FR 15181 (4/7/83) | Do. |
| 83-593 | Generic name: Dialkylamino xylenol | 48 FR 15181 (4/7/83) | Do. |
| 83-594 | Generic name: Alkyl amino propyl carbamide | 48 FR 15181 (4/7/83) | Do. |
| 83-595 | Generic name: Alkyl amino propyl amine | 48 FR 15181 (4/7/83) | Do. |
| 83-596 | Generic name: Modified acrylic polymer | 48 FR 15181 (4/7/83) | Do. |
| 83-597 | Generic name: Cycloaliphatic isocyanate-amine based polyol prepolymer | 48 FR 15181 (4/7/83) | June 26, 1983. |
| 83-598 | Generic name: Polyester resin of aliphatic polyols, mixed aromatic diacids and aliphatic diacid | 48 FR 15181 (4/7/83) | Do. |
| 83-599 | Generic name: Polyester resin of aliphatic polyol, mixed aromatic diacids, aliphatic diacid, and aromatic diisocyanate | 48 FR 15181 (4/7/83) | Do. |
| 83-600 | Generic name: Modified rosin ester | 48 FR 15181 (4/7/83) | Do. |

## I. 87 Premanufacture Notices Received During the Month—Continued

| PMN No. | Identity and generic name | FR citation | Expiration date |
|---|---|---|---|
| 83-601 | Generic name: Halogenated alkene acid ester | 48 FR 15181 (4/7/83) | Do. |
| 83-602 | Generic name: Brominated polyol diester | 48 FR 15181 (4/7/83) | June 27, 1983. |
| 83-603 | Generic name: Substituted nitrile | 48 FR 15181 (4/7/83) | Do. |
| 83-604 | Generic name: Reaction product of a mixture of mono and disubstituted dioxocarbopolycyclic compounds and 1,4-disubstituted benzene with sulfur. | 48 FR 15182 (4/7/83) | June 28, 1983. |
| 83-605 | Anthraquinone, 2,2'-benzo[1,2-d:4,5-d']bisthiazole-2,6-diylbis[1-amino- | 48 FR 15182 (4/7/83) | Do. |
| 83-606 | 9,10-Anthracenedione, 2-methyl-l-nitro | 48 FR 15182 (4/7/83) | Do. |
| 83-607 | Generic name: Di (mixed alkyl) magnesium | 48 FR 15182 (4/7/83) | Do. |

## II. 74 Premanufacture Notices Received Previously and Still Under Review at the End of the Month:

| PMN No. | Identity and generic name | FR citation | Expiration date |
|---|---|---|---|
| 83-446 | Iso hexadecyl isostearate | 48 FR 6588 (2/14/83) | May 1, 1983. |
| 83-447 | Generic name: Polyvinyl alcohol derivative | 48 FR 6589 (2/14/83) | Do. |
| 83-448 | 2,6-bis(picrylamino)-3,5-dinitropyridine | 48 FR 6589 (2/14/83) | Do. |
| 83-449 | 2-ethyl-2-methyl butanoic acid | 48 FR 6589 (2/14/83) | Do. |
| 83-450 | 2,2-dimethyl pentanoic acid | 48 FR 6589 (2/14/83) | Do. |
| 83-451 | Generic name: Disubstituted bis(phenylazo) 4-amino-5-hydroxy-2,7-naphthalenedisulfonic acid, alkali metal salt | 48 FR 6589 (2/14/83) | May 2, 1983. |
| 83-452 | Generic name: Substituted 2-phenylazo-1-hydroxy-3-naphthalenesulfonic acid, metal complex, alkali metal salt | 48 FR 6589 (2/14/83) | Do. |
| 83-453 | Generic name: Polymer of mixed alkane diols, alkane triol, propylene oxide, alkanoic acid, aliphatic isocyanate, and isophorone diisocyanate. | 48 FR 6589 (2/14/83) | Do. |
| 83-454 | Generic name: Acrylamide copolymer | 48 FR 6589 (2/14/83) | May 3, 1983. |
| 83-455 | Generic name: Alkenoyl disubstituted cycloalkane | 48 FR 6589 (2/14/83) | Do. |
| 83-456 | Generic name: Substituted anthraquinone | 48 FR 6589 (2/14/83) | Do. |
| 83-457 | N,N'-hexanedioyl-bis[3,4,5,6-tetrahydro-2(1H) pyrimidinone] | 48 FR 7299 (2/18/83) | May 4, 1983 |
| 83-458 | Generic name: Substituted polyhydric alcohol | 48 FR 7300 (2/18/83) | Do. |
| 83-459 | Generic name: Dialkyl dithiophosphate | 48 FR 7300 (2/18/83) | Do. |
| 83-460 | Generic name: Dialkyl dithiophosphate | 48 FR 7300 (2/18/83) | Do. |
| 83-461 | Generic name: Substituted alkoxy silane | 48 FR 7300 (2/18/83) | Do. |
| 83-462 | Generic name: Succinate ester amide | 48 FR 7300 (2/18/83) | May 7, 1983. |
| 83-463 | Generic name: Amino aliphatic propoxylate | 48 FR 7300 (2/18/83) | Do. |
| 83-464 | Generic name: Sodium sulfosuccinate of ethoxylated substituted phenol | 48 FR 7300 (2/18/83) | Do. |
| 83-465 | Generic name: Metal polyisobutenylsuccinate | 48 FR 7300 (2/18/83) | Do. |
| 83-466 | Generic name: Ether-olefin-sulfone terpolymer | 48 FR 7300 (2/18/83) | Do. |
| 83-467 | Generic name: Alkyl cyclohexane carboxaldehyde | 48 FR 7300 (2/18/83) | Do. |
| 83-468 | Complex sodium polyethylene glycolate salt | 48 FR 7300 (2/18/83) | Do. |
| 83-469 | Generic name: Aromatic polyamide solution | 48 FR 7300 (2/18/83) | May 8, 1983. |
| 83-470 | Generic name: Polymer of substituted acrylic ester and substituted acrylamide | 48 FR 7300 (2/18/83) | Do. |
| 83-471 | Generic name: Metal salt of saccharin | 48 FR 7301 (2/18/83) | Do. |
| 83-472 | 2-propenoic acid, (2,4,6-trioxo-1,3,5-triazine-1,3,5 (2H, 4H, 6H)-triyl) di-2,1-ethanediyl ester | 48 FR 7301 (2/18/83) | Do. |
| 83-473 | 2-propenoic acid, (2,4,6-trioxo-1,3,5-triazine-1,3,5 (2H, 4H, 6H)-triyl) di-2,1-ethanediyl ester | 48 FR 7301 (2/18/83) | Do. |
| 83-474 | 2-propenoic acid, (2,4,6-trioxo-1,3,5-triazine-1,3,5 (2H, 4H, 6H)-triyl) di-2,1-ethanediyl ester | 48 FR 7301 (2/18/83) | Do. |
| 83-475 | Generic name: Chlorendic anhydride based alkyd polymer | 48 FR 7301 (2/18/83) | Do. |
| 83-476 | Generic name: Polyether modified alkyd | 48 FR 7301 (2/18/83) | Do. |
| 83-477 | Generic name: Aliphatic phosphite ester | 48 FR 7301 (2/18/83) | May 9, 1983. |
| 83-478 | Generic name: Carboxylic acid derivatives of alkoxylated phenol derivatives and alkoxylated polyamines | 48 FR 7301 (2/18/83) | Do. |
| 83-479 | Generic name: Monoazo substituted aromatic | 48 FR 7301 (2/18/83) | Do. |
| 83-480 | Aminopropyl aminoethyl piperazine | 48 FR 7301 (2/18/83) | May 10, 1983. |
| 83-481 | $C_{11}$-$C_{15}$ alkoxy propylamino propylamine | 48 FR 7301 (2/18/83) | Do. |
| 83-482 | Generic name: Modified polyester of a carbomoncyclic anhydride and a substituted alkanediol | 48 FR 7301 (2/18/83) | Do. |
| 83-483 | Generic name: Mixed fatty acids; alkanopolyol; benzenecarboxylic acids polymer | 48 FR 7302 (2/18/83) | Do. |
| 83-484 | Generic name: Copolymer of unsaturated organic compounds with polyols and isocyanates | 48 FR 8343 (2/28/83) | May 14, 1983. |
| 83-485 | Generic name: Alkyl branched alkanoate | 48 FR 8343 (2/28/83) | Do. |
| 83-486 | Generic name: Zirconium propanoate, substituted | 48 FR 8343 (2/28/83) | May 15, 1983. |
| 83-487 | Generic name: Alkyl sulfide | 48 FR 8343 (2/28/83) | Do. |
| 83-488 | Generic name: Polymer of acrylic ester and substituted acrylamide | 48 FR 8344 (2/28/83) | Do. |
| 83-489 | Generic name: Styrene, acrylate methacrylate copolymer | 48 FR 8344 (2/28/83) | Do. |
| 83-490 | Generic name: Modified coconut-phthalic-mixed polyol alkyd polymer | 48 FR 8344 (2/28/83) | May 16, 1983. |
| 83-491 | Generic name: Sodium carboxyalkyl thiosulfate | 48 FR 8344 (2/28/83) | May 17, 1983. |
| 83-492 | 4-(4-methyl-1-piperidinyl) pyridine | 48 FR 8344 (2/28/83) | Do. |
| 83-493 | Generic name: Alkoxylated alcohol compounds | 48 FR 8344 (2/28/83) | Do. |
| 83-494 | Generic name: Propylene glycol compounds | 48 FR 8344 (2/28/83) | Do. |
| 83-495 | Generic name: Metal complexed substituted aromatic salt | 48 FR 9366 (3/4/83) | May 18, 1983. |
| 83-496 | Generic name: Polyester from a carbomonocyclic anhydride and alkanediol | 48 FR 9366 (3/4/83) | May 22, 1983. |
| 83-497 | Generic name: Reaction product of 1,3-benzenediamine, hydroxybenzene, and oxo alkane with sodium sulfide | 48 FR 9366 (3/4/83) | Do. |
| 83-498 | Generic name: Polymer of alkyl diamine and substituted oxiranes | 48 FR 9366 (3/4/83) | Do. |
| 83-499 | Generic name: Reaction product of polyalkylene polyamines, phenols and polymeric epoxide derivatives | 48 FR 9366 (3/4/83) | Do. |
| 83-500 | Generic name: Reaction product of polyalkylene polyamines, phenols and polymeric epoxide derivatives | 48 FR 9366 (3/4/83) | Do. |
| 83-501 | Generic name: Modified rosin condensation | 48 FR 9366 (3/4/83) | Do. |
| 83-502 | Generic name: Aminoheterocyclyl branched alkane | 48 FR 9366 (3/4/83) | Do. |
| 83-503 | Generic name: Substituted alkoxy silane | 48 FR 9366 (3/4/83) | Do. |
| 83-504 | Generic name: α-cyano carbocycliccarboxylate | 48 FR 9366 (3/4/83) | Do. |
| 83-505 | Generic name: Polyester resin-saturated | 48 FR 9367 (3/4/83) | Do. |
| 83-506 | Generic name: Modified acrylic polymer | 48 FR 9367 (3/4/83) | May 23, 1983. |
| 83-507 | Generic name: Monocyclic sulfur derivative | 48 FR 9367 (3/4/83) | Do. |
| 83-508 | Generic name: Substituted benzenesulfonic acid salt | 48 FR 10468 (3/11/83) | May 25, 1983. |
| 83-509 | Generic name: Disubstituted benzotriazole | 48 FR 10469 (3/11/83) | Do. |
| 83-510 | Generic name: Reaction product of an aromatic dianhydride with a substituted $C_{8-14}$ alcohol and epichlorohydrin | 48 FR 10469 (3/11/83) | Do. |
| 83-511 | Generic name: Polyester | 48 FR 10469 (3/11/83) | Do. |
| 83-512 | Generic name: Polymer of amino-alkyl-carbomono-cycle, hexamethylene diisocyanate, propylene oxide, alkane triol, alkan-one, and disubstituted alkane diol. | 48 FR 10469 (3/11/83) | Do. |
| 83-513 | Generic name: Polymer of isophorone diisocyanate, alkanoic acid, mixed alkane diols, alkane triol, oxo-heteropolycycle, and neopentyl glycol. | 48 FR 10469 (3/11/83) | Do. |
| 83-514 | Generic name: Substituted indolium, salt | 48 FR 10469 (3/11/83) | Do. |
| 83-515 | Generic name: Styrene co-polymer | 48 FR 10469 (3/11/83) | Do. |
| 83-516 | Generic name: Aromatic polyester with substituted alkanes | 48 FR 10469 (3/11/83) | Do. |
| 83-517 | Generic name: Polyurethane polymer, with an aromatic polyester | 48 FR 10469 (3/11/83) | Do. |

## II. 74 Premanufacture Notices Received Previously and Still Under Review at the End of the Month:—Continued

| PMN No. | Identity and generic name | FR citation | Expiration date |
|---|---|---|---|
| 83-518 | 1, 1' [isopropylidenebis (6-hydroxy-m-phenylene)]bis[tetrahydiathiophenium hydroxide) bis (inner salt) tetrahydrate | 48 FR 10469 (3/11/83) | Do. |
| 83-519 | Generic name: Functionalized acrylic polymer | 48 FR 10469 (3/11/83) | Do. |

## III. 191 Premanufacture Notices for Which the Notice Review Period has Ended During the Month. (Expiration of the Notice Review Period Does Not Signify That the Chemical Had Been Added to the Inventory)

| PMN No. | Identity and generic name | FR citation | Expiration date |
|---|---|---|---|
| 83-23 | Generic name: Substituted phenol | 47 FR 46373 (10/18/82) | Mar. 22, 1983. |
| 83-24 | Generic name: Substitute pyridine | 47 FR 46373 (10/18/82) | Mar. 19, 1983. |
| 83-35 | Generic name: Sulfophenylazonaphthyl dye | 47 FR 47067 (10/22/82) | Mar. 27, 1983. |
| 83-38 | Generic name: Sulfophenylazonaphthyl dye | 47 FR 47068 (10/22/82) | Do. |
| 83-49 | Generic name: Substituted pyridine | 47 FR 49073 (10/29/82) | Mar. 30, 1983. |
| 83-75 | Generic name: Sodium 2-substituted propanoate | 47 FR 50339 (11/5/82) | Mar. 9, 1983. |
| 83-111 | Generic name: Aromatic acid diester | 47 FR 52223 (11/19/82) | Mar. 4, 1983. |
| 83-129 | Syncrude (full range, dewaxed dearsenited shale oil) | 47 FR 54357 (12/2/82) | Mar. 31, 1983. |
| 83-130 | Light straight run naphtha (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-131 | Heavy straight run naphtha (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-132 | Straight run middle distillate (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-133 | Straight run gas oil (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-134 | Atmosphere tower residuum (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-135 | Vacuum tower condensate (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-136 | Light vacuum gas oil (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-137 | Heavy vacuum gas oil (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-138 | Vacuum residuum (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-139 | Full range catalytic cracked naphtha (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-140 | Light catalytic cracked distillate (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-141 | Catalytic cracked clarified oil (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-142 | Catalytic cracked light olefins (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-143 | Full range catalytic reformed naphtha (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-144 | Full range alkylate naphtha (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-145 | Light hydrocracked naphtha (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-146 | Heavy hydrocracked naphtha (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-147 | Light hydrocracked distillate (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-148 | Light thermal cracked naphtha (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-149 | Heavy thermal cracked naphtha (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-150 | Light thermal cracked distillate (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-151 | Heavy thermal cracked distillate (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-152 | Coke (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-153 | Sweetened naphtha (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-154 | Hydrodesulfurized heavy naphtha (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-155 | Hydrodesulfurized middle distillate (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-156 | Full range straight run naphtha (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-157 | Straight run kerosive (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-158 | Light paraffinic distillate (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-159 | Heavy paraffinic distillate (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-160 | Light catalytic cracked naphtha (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-161 | Heavy catalytic cracked naphtha (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-162 | Intermediate catalytic cracked distillate (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-163 | Heavy catalytic cracked distillate (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-165 | Light catalytic reformed naphtha (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-166 | Heavy catalytic reformed naphtha (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-167 | Catalytic reformer fractionator residue (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-168 | Light alkylate naphtha (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-169 | Heavy alkylate naphtha (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-170 | Alkylate distillate (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-171 | Polymerization naphtha (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-172 | Viscous polymer (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-173 | Isomerization naphtha (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-174 | Heavy hydrocracked distillate (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-175 | Hydrocracked residuum (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-176 | Sweetened middle distillate (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-177 | Normal paraffins (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-178 | Sorption process raffinate (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-179 | Solvent refined light naphtha (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-180 | Solvent refined heavy naphtha (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-181 | Solvent refined middle distillate (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-182 | Solvent refined gas oil (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-183 | Solvent refined light paraffinic distillate (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-184 | Solvent refined heavy paraffinic distillate (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-185 | Solvent deasphalted residual oil (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-186 | Solvent decarbonized heavy paraffinic distillate (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-187 | Solvent refined residual oil (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-188 | Solvent refined spent lube oil (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-189 | Light naphtha solvent extract (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-190 | Heavy naphtha solvent extract (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-191 | Middle distillate solvent extract (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-192 | Gas oil solvent extract (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-193 | Light paraffinic distillate solvent extract (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-194 | Heavy paraffinic distillate solvent extract (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-195 | Residual oil solvent extract (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-196 | Heavy paraffinic distillate decarbonization raffinate (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-197 | Clay treated light paraffinic distillate (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-198 | Clay treated heavy paraffinic distillate (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-199 | Clay treated paraffin wax (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-200 | Chemically neutralized spent lube oil (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-201 | Hydrotreated light naphtha (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-202 | Hydrotreated heavy naphtha (shale oil) | 47 FR 54357 (12/2/82) | Do. |

III. 191 PREMANUFACTURE NOTICES FOR WHICH THE NOTICE REVIEW PERIOD HAS ENDED DURING THE MONTH. (EXPIRATION OF THE NOTICE REVIEW PERIOD DOES NOT SIGNIFY THAT THE CHEMICAL HAD BEEN ADDED TO THE INVENTORY)—Continued

| PMN No. | Identity and generic name | FR citation | Expiration date |
|---|---|---|---|
| 83-203 | Hydrotreated light distillate (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-204 | Hydrotreated middle distillate (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-205 | Hydrotreated light paraffinic distillate (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-206 | Hydrotreated heavy paraffinic distillate (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-207 | Hydrotreated paraffin wax (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-208 | Hydrotreated microcrystalline wax (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-209 | Hydrotreated vacuum gas oil (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-210 | Hydrotreated residual oil (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-211 | Solvent dewaxed light paraffinic distillate (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-212 | Solvent dewaxed heavy paraffinic distillate (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-213 | Solvent dewaxed residual oil (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-214 | Slack wax (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-215 | Petrolatum (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-216 | Foots oil (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-217 | Paraffin wax (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-218 | Microcrystalline wax (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-219 | Catalytic dewaxed naphtha (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-220 | Catalytic dewaxed middle distillate (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-221 | Catalytic dewaxed light paraffinic oil (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-222 | Catalytic dewaxed heavy paraffinic oil (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-223 | Hydrodesulfurized light naphtha (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-224 | Hydrosulfurized kerosine (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-225 | Hydrosulfurized gas oil (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-226 | Hydrodesulfurized atmospheric tower residuum (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-227 | Hydrodesulfurized heavy vacuum gas oil (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-228 | Hydrodesulfurized heavy vacuum gas oil (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-229 | Steam cracked residuum (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-230 | Light aliphatic solvent naphtha (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-231 | Medium aliphatic solvent naphtha (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-232 | Heavy aliphatic solvent naphtha (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-233 | Light aromatic solvent naphtha (shale oil) | 47 FR 54358 (12/2/82) | Do. |
| 83-234 | Heavy aromatic solvent naphtha (shale oil) | 47 FR 54358 (12/2/82) | Do. |
| 83-235 | Calcined coke (shale oil) | 47 FR 54358 (12/2/82) | Do. |
| 83-264 | Condensation polymer of ethyl acrylate and ethanol amine | 47 FR 55423 (12/9/82) | Mar. 1, 1983. |
| 83-265 | Generic name: Substituted alkyl polyalkylene oxy quarternary ammonium chloride compound | 47 FR 55423 (12/9/82) | Do. |
| 83-266 | Generic name: Poly(oxyalkyl disubstituted silane) alkyl, alkoxy-terminated, polymer with titanium alkoxide | 47 FR 57333 (12/23/82) | Mar. 2, 1983. |
| 83-267 | Generic name: Polyester from carbomonocyclic anhydrides and substituted alkanediols | 47 FR 57333 (12/23/82) | Do. |
| 83-268 | Generic name: Azobis-(nitrosulfophenyl-alkylsulfobenzene) compound with oxyalkylamine | 47 FR 57333 (12/23/82) | Do. |
| 83-269 | Generic name: Substituted naphthalenylazo naphthalenedisulfonic acid salt | 47 FR 57333 (12/23/82) | Do. |
| 83-270 | Generic name: Tetra(substituted sulfonic acid) derivative of transition metal—arylcyanine complex | 47 FR 57333 (12/23/82) | Do. |
| 83-271 | Generic name: Hydrocarbon complex with platinum halide | 47 FR 57333 (12/23/82) | Do. |
| 83-272 | Generic name: Substituted pyridine | 47 FR 57333 (12/23/82) | Mar. 8, 1983. |
| 83-273 | Generic name: Blocked isocyanate | 47 FR 57333 (12/23/82) | Mar. 5, 1983. |
| 83-274 | Generic name: Polymer of alkane polyols, alkanedioic acids and aromatic polyacid | 47 FR 57333 (12/23/82) | Do. |
| 83-275 | Generic name: Modified polyisocyanate | 47 FR 57333 (12/23/82) | Do. |
| 83-276 | Generic name: Modified polyioscyanate | 47 FR 57333 (12/23/82) | Do. |
| 83-277 | 2-Oxepanone, polymer with 2,2'-[oxybismethylene)] bis[2-(hydroxymethyl)-1,3-propanediol | 47 FR 57333 (12/23/82) | Do. |
| 83-278 | 2-Oxepanone, polymer with 2,2-bis[3-(hydroxy-2,2-bis(hydroxymethyl)propoxy]methyl]-1,3-propanediol | 47 FR 57333 (12/23/82) | Do. |
| 83-279 | Generic name: Chlorinated, oleated hydrocarbon polymer | 47 FR 57334 (12/2/82) | Do. |
| 83-280 | Generic name: 2-Anthracenesulfonic acid, 1-amino-9,10-dihydro-9,10-dioxo-4-[(substituted phenyl)amino] | 47 FR 57334 (12/23/82) | Mar. 6, 1983. |
| 83-281 | Generic name: Benzenesulfonamide salt | 47 FR 57334 (12/23/82) | Do. |
| 83-282 | Generic name: Polyester based complex alkanediol | 47 FR 57334 (12/23/82) | Do. |
| 83-283 | Generic name: Substituted cyclosiloxane | 47 FR 57334 (12/23/82) | Do. |
| 83-284 | Generic name: Polyester polyol | 47 FR 57334 (12/23/82) | Do. |
| 83-285 | Generic name: Phosphate ester | 47 FR 57334 (12/23/82) | Do. |
| 83-286 | Generic name: 1,1-dimethyl ethyl peroxyester | 47 FR 57334 (12/23/82) | Do. |
| 83-287 | Generic name: 1,1-dimethylpropyl peroxyester | 47 FR 57334 (12/23/82) | Do. |
| 83-288 | Generic name: 1-methyl-1-phenyl ethyl peroxyester | 47 FR 57334 (12/23/82) | Do. |
| 83-289 | Copolymer from acrylonitrile, styrene and p-isopropenylphenol | 47 FR 57334 (12/23/82) | Do. |
| 83-290 | Generic name: Asphalt styrenated resin | 47 FR 57334 (12/23/82) | Do. |
| 83-291 | Generic name: Vinylic copolymer | 47 FR 57334 (12/23/82) | Do. |
| 83-292 | Generic name: N-substituted-N-mixed alkoxy-propylmaleaminc acid derivatives | 47 FR 57334 (12/23/82) | Do. |
| 83-293 | Hydrogenated acrylonitrile-butadiene copolymer (H-NBR) | 47 FR 57335 (12/23/82) | Mar. 7, 1983. |
| 83-294 | Generic name: Organophosphorus compound | 47 FR 57335 (12/23/82) | Do. |
| 83-295 | Generic name: Organosulfur compounds | 47 FR 57335 (12/23/82) | Do. |
| 83-296 | Generic name: Rosin metallic salt | 47 FR 57335 (12/23/82) | Mar. 8, 1983. |
| 83-297 | Generic name: (Substituted) anthracenylimino-(substituted) carbomonocylic acid alkylamine salt | 47 FR 57335 (12/23/82) | Do. |
| 83-303 | Polymer of: trimethyl pentane diol, adipic acid and phthalic anhydride | 47 FR 57336 (12/23/82) | Mar. 9, 1983. |
| 83-304 | Bis (benzyl-thioureidoethyl)-dithio carbamic acid-s-propoylester- -sulfonic acid sodium | 47 FR 57336 (12/23/82) | Do. |
| 83-305 | Generic name: Urethane polyester prepolymer acrylate capped | 47 FR 57337 (12/23/82) | Do. |
| 83-311 | 3-dimethylureidylmethyl-3,5,5-trimethylcyclo-hexyl dimethyl urea | 47 FR 57337 (12/23/82) | Mar. 12, 1983. |
| 83-312 | Generic name: Aromatic aliphatic branched polyester resin | 47 FR 57337 (12/23/82) | Mar. 13, 1983. |
| 83-313 | Generic name: Polymer of alkane polyols, alkane dioic acid and aromatic acid | 47 FR 57337 (12/23/82) | Do. |
| 83-314 | Generic name: Ester of aromatic acids and aliphatic polyols | 47 FR 57337 (12/23/82) | Do. |
| 83-315 | Generic name: 2-substituted propanoic acid | 47 FR 57337 (12/23/82) | Do. |
| 83-316 | Generic name: Modified ethylene-chlorotri-fluoroethylene polymer | 47 FR 57337 (12/23/82) | Do. |
| 83-317 | Generic name: Modified polyester polyurethane from substituted alkanediols, alkandioic acid and a diisocyanate | 47 FR 57338 (12/23/82) | Mar. 14, 1983. |

III. 191 PREMANUFACTURE NOTICES FOR WHICH THE NOTICE REVIEW PERIOD HAS ENDED DURING THE MONTH. (EXPIRATION OF THE NOTICE REVIEW PERIOD DOES NOT SIGNIFY THAT THE CHEMICAL HAD BEEN ADDED TO THE INVENTORY)—Continued

| PMN No. | Identity and generic name | FR citation | Expiration date |
|---|---|---|---|
| 83-318 | Generic name: Acrylic copolymer of styrene and methacrylate monomers | 47 FR 57338 (12/23/82) | Mar. 15, 1983. |
| 83-319 | Generic name: Modified alkyd polymer from mixed fatty oils, carbomonocyclic anhydride, carbomonocyclic acid and a substituted alkane diol. | 47 FR 57338 (12/23/82) | Do. |
| 83-320 | Generic name: Polymeric acrylate | 47 FR 57338 (12/23/82) | Do. |
| 83-321 | Generic name: Mixed glycol oligoesters of mixed dicarboxylic acids | 48 FR 72 (1/3/83) | Mar. 16, 1983 |
| 83-322 | Generic name: Polyester of aliphatic polyol, mono basic acids and aromatic diacids | 48 FR 72 (1/3/83) | Do. |
| 83-323 | Generic name: Polyester of aliphatic polyols, vegetable oil, and aromatic dibasic acid | 48 FR 72 (1/3/83) | Do. |
| 83-324 | Generic name: Modified bisphenol A, epichlorohydrin polymer | 48 FR 72 (1/3/83) | Do. |
| 83-325 | Generic name: Polyester polyurethane from carbomonocyclic anhydride, alkanediols and diisocyanates | 48 FR 72 (1/3/83) | Do. |
| 83-326 | Generic name: Functionalized acrylic polymer | 48 FR 72 (1/3/83) | Do. |
| 83-327 | Generic name: Blocked isocyanate | 48 FR 72 (1/3/83) | Do. |
| 83-328 | Generic name: Modified copolymer of alkenoic esters and substituted alkenoic esters with styrene | 48 FR 72 (1/3/83) | Do. |
| 83-329 | Generic name: Substituted phenyl, azo substituted naphthalenedisulfonic acid, sodium salt | 48 FR 72 (1/3/83) | Do. |
| 83-330 | Generic name: Substituted phenate | 48 FR 73 (1/3/83) | Do. |
| 83-331 | Generic name: Bis-alkylated phenol | 48 FR 73 (1/3/83) | Do. |
| 83-332 | Generic name: Aromatic alkyd—silicone modified | 48 FR 73 (1/3/83) | Do. |
| 83-334 | Generic name: Polymer of alkane polyols, alkanedioic acid, and aromatic diacid | 48 FR 73 (1/3/83) | Do. |
| 83-336 | Methanesulfonic acid, tin (2+) salt | 48 FR 73 (1/3/83) | Do. |
| 83-337 | Methanesulfonic acid, lead (2+) salt | 48 FR 73 (1/3/83) | Do. |
| 83-338 | Generic name: Substituted-1,8-triphenodioxazine-disulfonic acid, sodium salt | 48 FR 862 (1/7/83) | Mar. 26, 1983 |
| 83-339 | Generic name: 5-[4-chloro-6-[3-[2-(hydroxy-sulfonyloxy)ethylsulfonyl]anilino]-1,3,5-triazin-2-ylamino]-3-[1,5-disulfo-2-naphthyl-azo)-4-hydroxy-2, 7-naphthalenedisulfonic acid, pentasodium salt. | 48 FR 862 (1/7/83) | Do. |
| 83-340 | Generic name: 3-[4-[4-[4-chloro-6-[3-[2-(hydroxysulfonyloxy)ethylsulfonyl]anilino]-1,3,5-triazin-2-ylamino]-5-sulfonaphthylazo]-6-sulfonaphthylazo-1,5-naphthalenedisulfonic acid, pentasodium salt. | 48 FR 862 (1/7/83) | Do. |
| 83-342 | Generic name: 3-[5-[4-chloro-6-[3-[2-(hydroxysulfonyloxy)ethylsulfonyl]anilino]-1,3,5-triazin-2-ylamino]-2-sulfophenylazo]-4-hydroxy-5-propionylamino-2,7-naphthalenedisulfonic acid tetrasodium salt. | 48 FR 862 (1/7/83) | Do. |
| 83-343 | Generic name: 4-amino-6-[5-[4-chloro-[3-[2-(hydroxysulfonyloxy)ethylsulfonyl]anilino]-1,3,5-triazin-2-ylamino]-2-sulfophenylazo]-5-hydroxy-3-(4-sulfophenylazo]-2,7-naphthalenedisulfonic acid, pentasodium salt. | 48 FR 862 (1/7/83) | Do. |
| 83-344 | Generic name: Mercapto-substituted, heterocyclic nitrogen compound | 48 FR 862 (1/7/83) | Do. |
| 83-345 | Generic name: Alkyl thiocyanate | 48 FR 862 (1/7/83) | Do. |
| 83-346 | Polymer of 2-propenoic acid, 2-methyl-, methyl ester and 1,3-butyleneglycol diacrylate | 48 FR 862 (1/7/83) | Do. |
| 83-347 | Partially hydrogenated polybenzylated toluene | 48 FR 862 (1/7/83) | Mar. 27, 1983. |
| 83-348 | Polybenzylated toluene | 48 FR 862 (1/7/83) | Do. |
| 83-349 | Generic name: Poly polymethacrylate | 48 FR 862 (1/7/83) | Do. |
| 83-351 | Polymer of trimethylol propane, ethylene glycol, adipic acid, phthalic anhydride | 48 FR 862 (1/4/83) | Mar. 29, 1983. |
| 83-352 | Generic name: Aliphatic secondary naphthalene | 48 FR 862 (1/14/83) | Do. |
| 83-353 | Generic name: Aliphatic secondary naphthalene | 48 FR 862 (1/14/83) | Do. |
| 83-354 | Generic name: Aliphatic bis(secondary naphthalene amine) | 48 FR 862 (1/14/83) | Do. |
| 83-355 | Generic name: Substituted aromatic secondary naphthalene amine | 48 FR 862 (1/14/83) | Do. |

IV. 53 CHEMICAL SUBSTANCES FOR WHICH EPA HAS RECEIVED NOTICES OF COMMENCEMENT TO MANUFACTURE

| PMN No. | Chemical identification | FR citation | Date of commencement |
|---|---|---|---|
| 80-60 | Polymer of: methyl methacrylate; methyl acrylate; butylacrylate; 2-hydroxyethyl acrylate | 45 FR 25131 (4/14/80) | Mar. 5, 1983. |
| 80-223 | 1,6-Hexanediol, terephthalic acid, neopentyl glycol, trimelletic anhydride, adipic acid, and isophthalic acid | 45 FR 61019 (9/15/80) | Oct. 9, 1981. |
| 80-327 | Generic name: Toluene diisocyanate blocked prepolymer | 45 FR 83020 (12/17/80) | Feb. 10, 1983. |
| 81-51 | Polymer of tall oil fatty acids, neopentyl glycol, pentaerythritol, isophthalic acid, and benzoic acid | 46 FR 16319 (3/12/81) | Feb. 9, 1983. |
| 81-64 | Polymer of neopentyl glycol, adipic acid, trimellitic anhydride, and an aromatic aliphatic ester | 46 FR 16933 (3/16/81) | Apr. 15, 1982. |
| 81-226 | Polymer of acrylic acid, acrylonitrile, butylacrylate, 2-hydroxyethyl acrylate, and vinylidene chloride | 46 FR 31940 (6/18/81) | Mar. 5, 1983. |
| 81-331 | Generic name: Acrylic modified alkyd resin | 46 FR 38580 (7/28/81) | Feb. 17, 1983. |
| 81-464 | Generic name: Alkyl styrenated acrylate terpolymer | 46 FR 47855 (9/30/81) | Aug. 3, 1982. |
| 81-500 | 2-dodecyl-9-H-thioxanthen-9-one | 46 FR 50147 (10/9/81) | Feb. 15, 1983. |
| 81-621 | Generic name: Polyester of propanediol, adipic acid, phthalic anhydride, aromatic aliphatic ester | 46 FR 60982 (12/14/81) | Apr. 7, 1982. |
| 81-625 | Generic name: Blocked isocyanate | 46 FR 61505 (12/17/81) | Mar. 4, 1983. |
| 81-656 | Generic name: Halogenated nitrotoluene derivative | 47 FR 1020 (1/8/82) | Dec. 16, 1982. |
| 82-59 | Generic name: Aromatic disazo dye | 47 FR 5330 (2/4/82) | June 21, 1982. |
| 82-233 | Generic name: Organic salt of phosphorus | 47 FR 15407 (4/9/82) | Mar. 21, 1983. |
| 82-272 | Generic name: Heterocyclic-alkylphenyl azo substance | 47 FR 16405 (4/16/82) | Dec. 9, 1982. |
| 82-277 | Generic name: Polymer of aliphatic and aromatic diacids and an aliphatic diol | 47 FR 17666 (4/23/82) | Mar. 7, 1983. |
| 82-319 | Generic name: Alkyl oligoglycosides | 47 FR 19782 (5/7/82) | Feb. 21, 1983. |
| 82-327 | Generic name: Hydroxy, amine-substituted anthraquinone | 47 FR 20853 (5/14/82) | Oct. 11, 1982. |
| 82-386 | Generic name: Metal complex of disazo aromatic acids, sodium salt | 47 FR 25400 (6/11/82) | Sept. 21, 1982. |
| 82-483 | Generic name: Polymer of acrylic acid and acrylic esters | 47 FR 31063 (7/16/82) | Mar. 10, 1983. |
| 82-485 | Generic name: Chlorotriazine modified copper phthalocyanine, sodium salt | 47 FR 31063 (7/16/82) | Oct. 21, 1982. |
| 82-567 | Generic name: Alkylbenzenesulfonic acid compound with dialkyl amine | 47 FR 39242 (9/7/82) | Feb. 14, 1983. |
| 82-502 | Generic name: Mixed glycol oligoesters of mixed dicarboxylic acids | 47 FR 39243 (9/7/82) | Mar. 7, 1983. |
| 82-630 | Generic name: Unsaturated alkyl fatty amine | 47 FR 39885 (9/10/82) | Mar. 4, 1983. |
| 82-631 | Generic name: Unsaturated amine adduct | 47 FR 39685 (9/10/82) | Mar. 8, 1983. |
| 82-661 | Generic name: Modified polyurethane | 47 FR 42152 (9/24/82) | Mar. 4, 1983. |
| 82-662 | Generic name: Modified polyurethane | 47 FR 42152 (9/24/82) | Do. |
| 82-663 | Generic name: Modified diol | 47 FR 42152 (9/24/82) | Do. |
| 82-671 | Generic name: Vinyl chloride-ethylene copolymer | 47 FR 42153 (7/16/82) | May 2, 1983 |
| 82-683 | Generic name: Halogenated ketone | 47 FR 43161 (9/30/82) | Mar. 15, 1983. |
| 82-701 | Generic name: Aromatic disazo dye | 47 FR 44609 (10/8/82) | Feb. 25, 1983. |
| 82-702 | Generic name: Metal complexed, substituted aromatic azo compound | 47 FR 44609 (10/8/82) | Feb. 14, 1983. |
| 83-24 | Generic name: Substituted pyridine | 47 FR 46373 (10/18/82) | Mar. 16, 1983. |
| 83-32 | Generic name: Modified polyester polyurethane from substituted alkanediols, alkanedioic acid and a diisocyanate | 47 FR 47067 (10/22/82) | Feb. 17, 1983. |
| 83-51 | Generic name: Alkoxylated alkyl amine | 47 FR 49072 (10/29/82) | Mar. 17, 1983. |
| 83-91 | Polymer of tall oil rosin, gum rosin, paraformaldehyde, calcium hydroxide, phenol | 47 FR 52222 (11/19/82) | Feb. 8, 1983. |
| 83-105 | 1,2-benzenediamine, 4-ethoxy, sulfate (1:1) | 47 FR 52223 (11/19/82) | Feb. 28, 1983. |
| 83-119 | Generic name: Polyester from a carbomonocyclic anhydride and substituted alkanediols | 47 FR 52224 (11/19/82) | Feb. 15, 1983. |
| 83-127 | Polymer of acrylic acid, butyl acrylate, 2-hydroxy ethyl acrylate, methyl acrylate, and 2-ethylhexyl acrylate | 47 FR 53782 (11/29/82) | Mar. 5, 1983. |
| 83-242 | Generic name: Polymer of aliphatic polyols, aliphatic and aromatic dicarboxylic acids | 47 FR 53783 (11/29/82) | After Mar. 1, 1983. |
| 83-258 | Generic name: Polymer of styrene, methacrylate ester, acrylic ester, and acrylic acid | 47 FR 55422 (12/9/82) | Do. |
| 83-261 | 2,2-bis[4-(4-amino phenoxy)phenyl] hexafluoro-propane | 47 FR 55422 (12/9/82) | Mar. 7, 1983. |

## IV. 53 Chemical Substances for Which EPA Has Received Notices of Commencement To Manufacture—Continued

| PMN No. | Chemical identification | FR citation | Date of commencement |
|---|---|---|---|
| 83-269 | Generic name: Substituted naphthalenylazo naphthalenedisulfonic acid salt | 47 FR 57333 (12/23/82) | Mar. 3, 1983. |
| 83-270 | Generic name: Tetra(substituted sulfonic acid) derivative of transition metal-acrylcyanine complex | 47 FR 57333 (12/23/82) | Do. |
| 83-271 | Generic name: Hydrocarbon complex with platinum halide | 47 FR 57333 (12/23/82) | Do. |
| 83-290 | Generic name: Asphalt styrenated resin | 47 FR 57334 (12/23/82) | Mar. 11, 1983. |
| 83-291 | Generic name: Vinylic copolymer | 47 FR 57334 (12/23/82) | Mar. 6, 1983. |
| 83-294 | Generic name: Organophosphorus compound | 47 FR 57335 (12/23/82) | Mar. 6, 1983. |
| 83-295 | Generic name: Organosulfur compound | 47 FR 57335 (12/23/82) | Do. |
| 83-382 | Generic name: N-substituted-N-mixed alkyloxy-propylmaleamic acid derivatives | 47 FR 57334 (12/23/82) | Apr. 15, 1983. |
| 83-383 | Generic name: N-substituted-N-mixed alkyloxy-propylmaleamic acid derivatives | 47 FR 57334 (12/23/82) | Do. |
| 83-384 | Generic name: N-substituted-N-mixed alkyloxy-propylmalmeamic acid derivatives | 47 FR 57334 (12/23/82) | Do. |
| 83-385 | Generic name: N-substituted-N-mixed alkyloxy-propylmalmeamic acid derivatives | 47 FR 57334 (12/23/82) | Do. |

## V. 142 Premanufacture Notices for Which the Review Period Has Been Suspended

| PMN No. | Identity and generic name | FR citation | Date suspended |
|---|---|---|---|
| 80-137 | Benzeneamine, 4,4'-methylene bis [*N*-(1-methylbutylidene)] | 45 FR 46243 (7/18/80) | Sept.22,1980. |
| 80-138 | Benzeneamine, 4,4'-methylene bis [*N*-(1-methybutylidene)] | 45 FR 46243 (7/18/80) | Do. |
| 80-146 | Phosphorodithioic acid O,O'-di(isohexyl, isoheptyl, isooctyl, isononyl, isodecyl) mixed esters, zinc salt | 45 FR 49153 (7/23/80) | Sept. 17, 1982. |
| 80-147 | Phosphorodithioic acid O,O'-di(isohexyl, isoheptyl, isooctyl, isononyl, isodecyl) mixed esters | 45 FR 49153 (7/23/80) | Do. |
| 80-264 | Generic name: benzeneamine, [*N*-(1-methylhexylidene)-*N*-(1-methyl butylidene)-4,4'-methylene bis] | 45 FR 73127 (11/4/80) | Dec. 24, 1980. |
| 81-558 | 4-hydroxy-3-(5-(2-hydroxysulfonyloxy) ethyl-sulfonyl)-2-methoxyphenylazo)-7-succinyl-amino-2-naphthalenesulfonic acid disodium salt. | 46 FR 55146 (11/6/81) | Jan. 27, 1982. |
| 81-561 | 4-[4-[2-(hydroxysulfonyoxy)ethylsulfonyl]-5-methyl-2-methoxyphenylazo]-3-methyl-1-(3-sulfophenyl)-5-pyrazolone disodium salt | 45 FR 55146 (11/6/81) | Do. |
| 81-660 | 4-hydroxy-3-(2-methoxy-5-methyl-4-(2-(hydroxy-sulfonyloxy)ethylsulfonyl)phenylozo)-1-naphthalene sulfonic acid disodium salt | 47 FR 1021 (1/8/82) | Mar. 28, 1982. |
| 81-661 | 4-hydroxy-3-(2-methoxy-5-methyl-4-(2-(hydroxy-sulfonyloxy)ethylsulfonyl)phenylazo)-6-(3-sulfophenyl)amino-2-naphthalenesulfonic acid trisodium salt. | 47 FR 1021 (1/8/82) | Do. |
| 82-60 | Generic name: Zinc, O,O-bis alkylphosphoro dithioate | 47 FR 5932 (2/9/82) | Apr. 15, 1982. |
| 82-387 | Phosphorodithioic acid, O,O', secondary butyl and isooctyl mixed esters | 47 FR 25401 (6/11/82) | July 30, 1982. |
| 82-388 | Phosphorodithioic acid, O,O', secondary butyl and isooctyl mixed esters, zinc salt | 47 FR 25401 (6/11/82) | Do. |
| 82-678 | Generic name: Chlorinated aromatic azo anthraquinone pigment | 47 FR 43161 (9/30/82) | Nov. 22, 1982. |
| 82-679 | Generic name: Chlorinated aromatic azo pigment | 47 FR 43161 (9/30/82) | Do. |
| 83-1 | Generic name: Polyhalogenated aromatic alkylated hydrocarbon | 47 FR 46371 (10/18/82) | Oct. 22, 1982. |
| 83-25 | Generic name: Substituted pyridine | 47 FR 46373 (10/18/82) | Dec. 24, 1982. |
| 83-36 | Generic name: Acrylated alkoxylated aliphatic glycol | 47 FR 47068 (10/22/82) | Dec. 27, 1982. |
| 83-37 | Generic name: Acrylated alkoxylated aliphatic glycol | 47 FR 47068 (10/22/82) | Do. |
| 83-110 | Generic name: Saturated acid diester | 47 FR 52223 (11/19/82) | Jan. 26, 1983. |
| 83-129 | Syncrude (full range, dewaxed dearsenited shale oil | 47 FR 54357 (12/2/82) | Mar. 1 through 31, 1983. |
| 83-130 | Light straight run naphtha (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-131 | Heavy straight run naphtha (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-132 | Straight run middle distillate (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-133 | Straight run gas oil (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-134 | Atmosphere tower residuum (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-135 | Vacuum tower condensate (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-136 | Light vacuum gas oil (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-137 | Heavy vacuum gas oil (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-138 | Vacuum residuum (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-139 | Full range catalytic cracked naphtha (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-140 | Light catalytic cracked distillate (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-141 | Catalytic cracked clarified oil (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-142 | Catalytic cracked light olefins (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-143 | Full range catalytic reformed naphtha (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-144 | Full range alkylate naphtha (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-145 | Light hydrocracked naphtha (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-146 | Heavy hydrocracked naphtha (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-147 | Light hydrocracked distillate (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-148 | Light thermal cracked naphtha(shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-149 | Heavy thermal cracked naphtha (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-150 | Light thermal cracked distillate (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-151 | Heavy thermal cracked distillate (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-152 | Coke (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-153 | Sweetened naphtha (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-154 | Hydrodesulfurized heavy naphtha (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-155 | Hydrodesulfurized middle distillate (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-156 | Full range straight run naphtha (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-1e57 | Straight run kerosive (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-158 | Light Paraffinic distillate (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-159 | Heavy paraffinic distillate (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-160 | Light catalytic cracked naphtha (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-161 | Heavy catalytic cracked naphtha (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-162 | Intermediate catalytic cracked distillate (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-163 | Heavy catalytic cracked distillate (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-165 | Light catalytic reformed naphtha (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-166 | Heavy catalytic reformed naphtha (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-167 | Catalytic reformer fractionator residue (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-168 | Light alkylate naphtha (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-169 | Heavy alkylate naphtha (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-170 | Alkylate distillate (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-171 | Polymerization naphtha (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-172 | Viscous polymer (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-173 | Isomerization naphtha (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-174 | Heavy hydrocracked distillate (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-175 | Hydrocracked residuum (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-176 | Sweetened middle distillate (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-177 | Normal paraffins (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-178 | Sorption process raffinate (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-179 | Solvent refined light naphtha (shale oil) | 47 FR 54357 (12/2/82) | Do. |

V. 142 PREMANUFACTURE NOTICES FOR WHICH THE REVIEW PERIOD HAS BEEN SUSPENDED—Continued

| PMN No | Identity and generic name | FR citation | Date suspended |
|---|---|---|---|
| 83-180 | Solvent refined heavy naphtha (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-181 | Solvent refined middle distillate (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-182 | Solvent refined gas oil (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-183 | Solvent refined light paraffinic distillate (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-184 | Solvent refined heavy paraffinic distillate (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-185 | Solvent deasphalted residual oil (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-186 | Solvent decarbonized heavy paraffinic distillate (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-187 | Solvent refined residual oil (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-188 | Solvent refined spent lube oil (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-189 | Light naphtha solvent extract (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-190 | Heavy naphtha solvent extract (shale oil) | 47 FR 54357 (12/2/82) | Do. |
| 83-191 | Middle distillate solvent extract (shale oil) | 47- FR 54357 (12/2/82) | Do. |
| 83-192 | Gas oil solvent extract (shale oil) | 47- FR 54357 (12/2/82) | Do. |
| 83-193 | Light paraffinic distillate solvent extract (shale oil) | 47- FR 54357 (12/2/82) | Do. |
| 83-194 | Heavy paraffinic distillate solvent extract (shale oil) | 47- FR 54357 (12/2/82) | Do. |
| 83-195 | Residual oil solvent extract (shale oil) | 47- FR 54357 (12/2/82) | Do. |
| 83-196 | Heavy paraffinic distillate decarbonization raffinate (shale oil) | 47- FR 54357 (12/2/82) | Do. |
| 83-197 | Clay treated light paraffinic distillate (shale oil) | 47- FR 54357 (12/2/82) | Do. |
| 83-198 | Clay treated heavy paraffinic distillate (shale oil) | 47- FR 54357 (12/2/82) | Do. |
| 83-199 | Clay treated paraffin wax (shale oil) | 47- FR 54357 (12/2/82) | Do. |
| 83-200 | Chemically neutralized spent lube oil (shale oil) | 47- FR 54357 (12/2/82) | Do. |
| 83-201 | Hydrotreated light naphtha (shale oil) | 47- FR 54357 (12/2/82) | Do. |
| 83-202 | Hydrotreated heavy naphtha (shale oil) | 47- FR 54357 (12/2/82) | Do. |
| 83-203 | Hydrotreated light distillate (shale oil) | 47- FR 54357 (12/2/82) | Do. |
| 83-204 | Hydrotreated middle distillate (shale oil) | 47- FR 54357 (12/2/82) | Do. |
| 83-205 | Hydrotreated light paraffinic distillate (shale oil) | 47- FR 54357 (12/2/82) | Do. |
| 83-206 | Hydrotreated heavy paraffinic distillate (shale oil) | 47- FR 54357 (12/2/82) | Do. |
| 83-207 | Hydrotreated paraffin wax (shale oil) | 47- FR 54357 (12/2/82) | Do. |
| 83-208 | Hydrotreated microcrystalline wax (shale oil) | 47- FR 54357 (12/2/82) | Do. |
| 83-209 | Hydrotreated vacuum gas oil (shale oil) | 47- FR 54357 (12/2/82) | Do. |
| 83-210 | Hydrotreated residual oil (shale oil) | 47- FR 54357 (12/2/82) | Do. |
| 83-211 | Solvent dewaxed light paraffinic distillate (shale oil) | 47- FR 54357 (12/2/82) | Do. |
| 83-212 | Solvent dewaxed heavy paraffinic distillate (shale oil) | 47- FR 54357 (12/2/82) | Do. |
| 83-213 | Solvent dewaxed residual oil (shale oil) | 47- FR 54357 (12/2/82) | Do. |
| 83-214 | Slack wax (shale oil) | 47- FR 54357 (12/2/82) | Do. |
| 83-215 | Petrolatum (shale oil) | 47- FR 54357 (12/2/82) | Do. |
| 83-216 | Foots oil (shale oil) | 47- FR 54357 (12/2/82) | Do. |
| 83-217 | Paraffin wax (shale oil) | 47- FR 54357 (12/2/82) | Do. |
| 83-218 | Microcrystalline wax (shale oil) | 47- FR 54357 (12/2/82) | Do. |
| 83-219 | Catalytic dewaxed naphtha (shale oil) | 47 FR 54358 (12/2/82) | Do. |
| 83-220 | Catalytic dewaxed middle distillate (shale oil) | 47 FR 54358 (12/2/82) | Do. |
| 83-220 | Catalytic dewaxed light paraffinic oil (shale oil) | 47 FR 54358 (12/2/82) | Do. |
| 83-222 | Catalytic dewaxed heavy paraffinic oil (shale oil) | 47 FR 54358 (12/2/82) | Do. |
| 83-223 | Hydrodesulfurized light naphtha (shale oil) | 47 FR 54358 (12/2/82) | Do. |
| 83-224 | Hydrosulfurized kerosene (shale oil) | 47 FR 54358 (12/2/82) | Do. |
| 83-225 | Hydrosulfurized gas oil (shale oil) | 47 FR 54358 (12/2/82) | Do. |
| 83-226 | Hydrodesulfurized atomospheric tower residuum (shale oil) | 47 FR 54358 (12/2/82) | Do. |
| 83-227 | Hydrodesulfurized heaby vacuum gas oil (shale oil) | 47 FR 54358 (12/2/82) | Do. |
| 83-228 | Hydrodesulfurized heavy vacuum gas oil (shale oil) | 47 FR 54358 (12/2/82) | Do. |
| 83-229 | Steam cracked residuum (shale oil) | 47 FR 54358 (12/2/82) | Do. |
| 83-230 | Light aliphatic solvent naphtha (shale oil) | 47 FR 54358 (12/2/82) | Do. |
| 83-231 | Medium aliphatic solvent naphtha (shale oil) | 47 FR 54358 (12/2/82) | Do. |
| 83-232 | Heavy aliphatic solvent naphtha (shale oil) | 47 FR 54358 (12/2/82) | Do. |
| 83-233 | Light aromatic solvent naphtha (shale oil) | 47 FR 54358 (12/2/82) | Do. |
| 83-234 | Heavy aromatic solvent naphtha (shale oil) | 47 FR 54358 (12/2/82) | Do. |
| 83-235 | Calcined coke (shale oil) | 47 FR 54358 (12/2/82) | Do. |
| 83-237 | Generic name: Substituted pyridine | 47 FR 53782 (11/29/82) | Jan. 25, 1983. |
| 83-255 | Generic name: Dicarboxylic acid monoester | 47 FR 54537 (12/3/82) | Feb. 17, 1983. |
| 83-263 | Generic name: Substituted thiocyclic compound | 47 FR 55423 (12/9/82) | Feb. 27, 1983 |
| 83-298 | Generic name: Toluene alkylate | 47 FR 57336 (12/23/82) | Mar. 4, 1983. |
| 83-299 | Generic name: Toluene alkylate | 47 FR 57336 (12/23/82) | Do. |
| 83-300 | Generic name: Dialkyl benzene | 47 FR 57336 (12/23/82) | Do. |
| 83-301 | Generic name: Dialkyl benzene | 47 FR 57336 (12/23/82) | Do. |
| 83-302 | Generic name: Alkyl benzene | 47 FR 57336 (12/23/82) | Do. |
| 83-306 | Generic name: Poly alkyl benzene sulfonate | 47 FR 57337 (12/23/82) | Do. |
| 83-307 | Generic name: Poly alkyl benzene sulfonate | 47 FR 57337 (12/23/82) | Do. |
| 83-308 | Generic name: Poly alkyl benzene sulfonate | 47 FR 57337 (12/23/82) | Do. |
| 83-309 | Generic name: Poly alkyl benzene sulfonate | 47 FR 57337 (12/23/82) | Do. |
| 83-310 | Generic name: Benzene alkyl sulfonate | 47 FR 57337 (12/23/82) | Do. |
| 83-333 | Generic name: Reaction product of polycyclesulfonic acid salt with phosphorus halide/halogen, subsequent reaction with an amine, subsequent reaction with an aldehyde/sodium busulfite alkali. | 48 FR 73 (1/3/83) | Mar. 14, 1983. |
| 83-335 | Generic name: ((Substituted phenyl)azo) naphthalenesulfonic acid, sodium salt | 48 FR 73 (1/3/83) | Mar. 17, 1983. |
| 83-341 | Generic name: 7-[4-[4-chloro-6-[3-[2-[hydroxy-sulfonyloxy)ethylsulfonyl]anilino]-1,3,5-triazin-2-ylamino]-2-ureidophenylazo]-1,3,6-naphthalenetrisulfonic acid, tetrasodium salt. | 48 FR 862 (1/7/83) | Mar. 21, 1983. |
| 83-350 | 2-propoxyethyl acetate | 48 FR 862 (1/7/83) | Do. |

[FR Doc. 83-10457 Filed 4-20-83 8:45 am]

BILLING CODE 6560-5—M

## ENVIRONMENTAL PROTECTION AGENCY

[SAB-FRL 2352-1]

### Science Advisory Board, High-Level Radioactive Waste Disposal Subcommittee; Amended Notice of Meeting

Under Pub. L. 92-463, notice is hereby given of a change in the location of the May 2-3, 1983 meeting of the High-Level Radioactive Waste Disposal Subcommittee of the Science Advisory Board, notice of which was published in the **Federal Register**, 47 FR 15950, April 13, 1983.

The Subcommittee will meet as scheduled on May 2-3, 1983, in Room 3906/3908, U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, D.C. The meeting will begin at 9:00 a.m. and last until 5:00 p.m. each day.

**Terry F. Yosie,**

*Staff Director, Science Advisory Board.*

April 14, 1983.

[FR Doc. 83-10739 Filed 4-20-83; 8:45 am]

BILLING CODE 6560-50-M

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[OPTS-51451B; TSH-FRL 2351-7]

### Naphthalenetrisulfonic Acid, Chlorotriazinylamino-Methoxymethylphenylazo; Premanufacture Notice; Extension of Review Period

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** EPA is extending the review period for an additional 90 days for premanufacture notice (PMN) PMN 83-401, under the authority of section 5(c) of the Toxic Substances Control Act (TSCA). The review period will now expire on July 16, 1983.

**FOR FURTHER INFORMATION CONTACT:** Richard Green, Chemical Control Division (TS-794), Environmental Protection Agency, Rm. E-201, 401 M St., SW., Washington, D.C. 20460; (202-382-3740).

**SUPPLEMENTARY INFORMATION:** Under section 5 TSCA, anyone who intends to manufacture or import a new chemical substance for commercial purposes in the United States must submit a PMN to EPA 90 days before manufacture or import begins. Under section 5(c) EPA may, for good cause, extend the notice period for additional periods, not to exceed a total of 180 days from the date of receipt.

On January 18, 1983, EPA received PMN 83-401 to be imported for use as an industrial dye for fibers and fabric. The submitter of the PMN claimed its identity, and the specific chemical identity to be confidential business information. Notice of receipt of the PMN was published in the **Federal Register** of February 4, 1983 (48 FR 5304). The original 90-day review period is scheduled to expire on April 17, 1983.

EPA's detailed analysis of the substance described in the PMN addressed the following: chemical analysis of the PMN substance, effects on human health, human exposure, import volume, environmental release, ecological effects, degree of risk relative to available commercial substitutes, potential marketability, and the identification of other information which may be required to resolve outstanding issues.

As a result of this analysis, EPA has reason to believe the following:

1. Human exposure to the PMN substance may result in adverse health effects, among which may be carcinogenicity.

2. During processing of the PMN substance, the potential exists for significant worker exposure.

3. Processing and use of the PMN substance may result in its release to waterways.

4. Consumers may be exposed to the PMN substance in drinking waters.

Based on this analysis, EPA finds that there is a possibility that the substance submitted for review in PMN 83-401 may be regulated under section 5(e) of TSCA. The Agency requires an extension of the review period to further investigate potential health effects and use conditions, to examine its regulatory options and to prepare the necessary documents, should regulatory action be required. An administrative order under section 5(e) must be issued no later than 45 days prior to expiration of the review period. Therefore, EPA has determined that good cause exists to extend the review period for an additional 90 days, to July 16, 1983.

PMN 83-401 is available for public inspection in Rm. E-107, at the EPA Headquarters, address given above, from 8:00 a.m. to 4:00 p.m., Monday through Friday, except legal holidays.

Dated: April 14, 1983.

**Don R. Clay,**

*Acting Assistant Administrator for Pesticides and Toxic Substances.*

[FR Doc. 83-10620 Filed 4-20-83; 8:45 am]

BILLING CODE 6560-50-M

## FEDERAL HOME LOAN BANK BOARD

### New North Mississippi Federal Savings and Loan Association; Oxford, Mississippi; Appointment of Conservator

Notice is hereby given that, pursuant to the authority contained in section 5(d)(6)(A) of the Home Owners' Loan Act of 1933, as amended ("HOLA") (12 U.S.C. 1464(d)(6)(A) (1976)), section 5(d)(6)(B) of the HOLA, as amended by the Garn-St Germain Depository Institutions Act of 1982, Pub. L. No. 97-320 ("Garn-St Germain Act"), 114, 96 Stat. 1469, 1475 (to be codified as amended at 12 U.S.C. 1464(d)(6)(B)), section 406(a) of the National Housing Act, as amended ("NHA") (12 U.S.C. 1729 (a)(1976)), and section 406 (b)(1)(A)(iv) of the NHA, as amended by the Garn-St German Act, 122(b), 96 Stat. 1469, 1481-1482 (to be codified as amended at 12 U.S.C. 1729(b)(1)(A)(iv)), the Federal Home Loan Bank Board appointed and designated H. Lawrence Stacy as Conservator of New North Mississippi Federal Savings and Loan Association, Oxford, Mississippi, effective as of April 11, 1983.

Dated: April 18, 1983.

By the Federal Home Loan Bank Board.

**J. J. Finn,**

*Secretary.*

[FR Doc. 83-10644 Filed 4-20-83; 8:45 am]

BILLING CODE 6720-01-M

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### North Mississippi Savings and Loan Association; Oxford, Mississippi; Appointment of Receiver

Notice is hereby given that pursuant to the authority contained in section 406(c)(1)(B) of the National Housing Act ("NHA") as added by the Garn-St Germain Depository Institutions Act of 1982, Pub. L. No. 97-320, 122(d), 96 Stat. 1469, 1482 (to be codified at 12 U.S.C. 1729(c)(1)(B)), the Federal Home Loan Bank Board appointed and designated the Federal Savings and Loan Insurance Corporation as sole receiver for North Mississippi Savings and Loan Association, Oxford, Mississippi, on April 11, 1983.

Dated: April 18, 1983.

**J. J. Finn,**

*Secretary.*

[FR Doc. 83-10643 Filed 4-20-83; 8:45 am]

BILLING CODE 6720-01-M

## FEDERAL RESERVE SYSTEM

### Acquisition of Bank Shares by a Bank Holding Company; First Illinois Corp.

The company listed in this notice has applied for the Board's approval under section 3(a)(3) of the Bank Holding Company Act (12 U.S.C. 1842(a)(3)) to acquire voting shares or assets of a bank. The factors that are considered in acting on the application are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

The application may be inspected at the offices of the Board of Governors, or at the Federal Reserve Bank indicated. With respect to the application, interested persons may express their views in writing to the address indicated. Any comment on the 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.

A. **Federal Reserve Bank of Chicago** (Franklin D. Dreyer, Vice President) 230 South LaSalle Street, Chicago, Illinois 60690:

1. *First Illinois Corporation*, Evanston, Illinois; to acquire 100 percent of the voting shares or assets of the Wilmette Bank, Wilmette, Illinois. Comments on this application must be received not later than May 16, 1983.

Board of Governors of the Federal Reserve System, April 15, 1983.

**James McAfee,**

*Associate Secretary of the Board.*

[FR Doc. 83-10592 Filed 4-20-83; 8:45 am]

BILLING CODE 6210-01-M

### Acquisition of Bank Shares by Bank Holding Companies; Independence Bancorp, Inc.

The companies listed in this notice have applied for the Board's approval under section 3 (a)(3) of the Bank Holding Company Act (12 U.S.C. 1842 (a)(3)) to acquire voting shares or assets of a bank. 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)).

Each application may be inspected at the offices of the Board of Governors, or at the Federal Reserve Bank indicated for that application. With respect to each application, interested persons may express their views in writing to the address indicated for that application. 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.

**Federal Reserve Bank of Philadelphia** (Thomas K. Desch, Vice President) 100 North 6th Street, Philadelphia, Pennsylvania 19105:

1. *Independence Bancorp, Inc.*, Perkasie, Pennsylvania; to acquire 100 percent of the voting shares or assets of Union Bank and Trust Company of Eastern Pennsylvania, Bethlehem, Pennsylvania. Comments on this application must be received not later than May 13, 1983.

Board of Governors of the Federal Reserve System, April 15, 1983.

**James McAfee,**

*Associate Secretary of the Board.*

[FR Doc. 83-10593 Filed 4-20-83; 8:45 am]

BILLING CODE 6210-01-M

### Formation of Bank Holding Companies; Belmont Bancorp

The companies listed in this notice have applied for the Board's approval under section 3(a)(1) of the Bank Holding Company Act (12 U.S.C. 1842(a)(1)) to become bank holding companies by acquiring voting shares or assets of a bank. 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)).

Each application may be inspected at the offices of the Board of Governors, or at the Federal Reserve Bank indicated for that application. With respect to each application, interested persons may express their views in writing to the address indicated for that application. 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.

A. **Federal Reserve Bank of Cleveland** (Lee S. Adams, Vice President) 1455 East Sixth Street, Cleveland, Ohio 44101:

1. *Belmont Bancorp*, Bridgeport, Ohio; to become a bank holding company by acquiring 100 percent of the voting shares of Belmont County National Bank, St. Clairsville, St. Clairsville, Ohio. Comments on this application must be received not later than May 16, 1983.

B. **Federal Reserve Bank of Atlanta** (Robert E. Heck, Vice President) 104 Marietta Street, N.W., Atlanta, Georgia 30303:

1. *First United Bancorp, Inc.*, Florence, Alabama; to become a bank holding company by acquiring 100 percent of the voting shares of The First National Bank of Florence, Florence, Alabama. Comments on this application must be received not later than May 16, 1983.

C. **Federal Reserve Bank of Minneapolis** (Bruce J. Hedblom, Vice President) 250 Marquette Avenue, Minneapolis, Minnesota 55480:

1. *Clearlake Bancorp, Inc.*, Clearlake, Wisconsin; to become a bank holding company by acquiring 80.6 percent of the voting shares of Bank of Clearlake, Clearlake, Wisconsin. Comments on this application must be received not later than May 16, 1983.

Board of Governors of the Federal Reserve System, April 15, 1983.

**James McAfee,**

*Associate Secretary of the Board.*

[FR Doc. 83-10591 Filed 4-20-83; 8:45 am]

BILLING CODE 6210-01-M

### Bank Holding Companies; Proposed de Novo Nonbank Activities; Barclays Bank PLC

The organizations identified in this notice have applied, pursuant to section 4(c)(8) of the Bank Holding Company Act (12 U.S.C 1843(c)(8)) and § 225.4(b)(1) of the Board's Regulation Y (12 CFR 225.4(b)(1)), for permission to engage *de novo* (or continue to engage in an activity earlier commenced *de novo*), directly or indirectly, solely in the activities indicated, which have been determined by the Board of Governors to be closely related to banking.

With respect to these applications, interested persons may express their views 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 comment that requests a hearing must include 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 aggrieved by approval of that proposal.

The applications may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank indicated. Comments and requests for a hearing should identify clearly the specific application to which they relate, and should be submitted in writing and

received by the appropriate Federal Reserve Bank not later than the date indicated.

A. **Federal Reserve Bank of New York** (A. Marshall Puckett, Vice President) 33 Liberty Street, New York, New York 10045:

1. *Barclays Bank PLC* and its subsidary, Barclays Bank International Limited, each a bank holding company whose principal office is in London, England (consumer finance and insurance activities; North Carolina): To engage through their subsidiaries, BarclaysAmerican/Financial, Inc. ("BAF"), BarclaysAmerican/Mortgage, Inc. ("BAM"), and BarclaysAmerican/Financial Services, Inc. ("BAFS"), all of which are subsidiaries of BarclaysAmerican Corporation ("BAC"), in making direct consumer loans, including loans secured by real estate, and purchasing sales finance contracts representing extensions of credit such as would be made or acquired by a consumer finance company, and wholesale financing (floor planning); and acting as agency for the sale of related credit life, credit accident and health and credit property insurance. Credit life and credit accident and health insurance sold as agent may be underwritten or reinsured by BAC's insurance underwriting subsidiaries. These activities would be conducted from an office of BAF, BAM and BAFS in Kinston, North Carolina, serving customers in Kinston and surrounding areas in North Carolina. This notification is for the relocation of an existing office located in Kinston, North Carolina. Comments on this application must be received not later than May 10, 1983.

B. **Federal Reserve Bank of Dallas** (Anthony J. Montelaro, Vice President) 400 South Akard Street, Dallas, Texas 75222:

1. *Texas Commerce Bancshares, Inc.*, Houston, Texas (insurance activities; Texas): To engage *de novo* through its subsidiary, Pyramid Agency, Inc. in acting as a managing general agency with respect to property and casualty insurance directly related to extensions of credit by its banking subsidiaries. These activities would be conducted from a branch office of Pyramid Agency, Inc. in El Paso, El Paso County, Texas, serving the State of Texas. Comments on this application must be received not later than May 13, 1983.

C. **Federal Reserve Bank of San Francisco** (Harry W. Green, Vice President) 400 Sansome Street, San Francisco, California 94120:

1. *BankAmerica Corporation*, San Francisco, California (financing, servicing, and insurance activities; Florida): To engage, through its two indirect subsidiaries, FinanceAmerica Corporation and FinanceAmerica Industrial Plan Inc., both Florida corporations, in the activities of making or acquiring for its own account loans and other extensions of credit such as would be made or acquired by a finance company; servicing loans and other extensions of credit; and offering credit-related life insurance and credit-related accident and health insurance. The aforementioned types of credit-related insurance permissible under Section 4(c)(8)(A) of the Bank Holding Company Act of 1956, as amended by the Garn-St Germain Depository Institutions Act of 1982. Credit-related property insurance will not be offered. Such activities will include, but not be limited to, making consumer installment loans, purchasing installment sales finance contracts, making loans secured by real and personal property, and offering credit-related life and credit-related accident and health insurance directly related to extensions of credit made or acquired by FinanceAmercia Corporation and FinanceAmercia Industrial Plan Inc. Credit-related life and credit-related accident and health insurance may be reinsured by BA Insurance Company, Inc., an affiliate of both FinanceAmerica Corporation and FinanceAmerica Industrial Plan Inc. these activities will be conducted from a *de novo* office located in Gainesville, Florida serving the entire State of Florida. Comments on this application must be received not later than May 13, 1983.

Board of Governors of the Federal Reserve System, April 15, 1983.

**James McAfee,**

*Associate Secretary of the Board.*

[FR Doc. 83-10594 Filed 4-20-83; 8:45 am]

BILLING CODE 6210-01-M

## Bank Holding Companies; Proposed de Novo Nonbank Activities; Manufacturers Hanover Corp.

The organizations identified in this notice have applied, pursuant to section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.4(b)(1) of the Board's Regulation Y (12 CFR 225.4(b)(1)), for permission to engage *de novo* (or continue to engage in an activity earlier commenced *de novo*), directly or indirectly, solely in the activities indicated, which have been determined by the Board of Governors to be closely related to banking.

With respect to these applications, interested persons may express their views 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 comment that requests a hearing must include 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 that proposal.

The applications may be inspected at the office of the Board of Governors or at the Federal Reserve Bank indicated. Comments and requests for hearing should identify clearly the specific application to which they relate, and should be submitted in writing and received by the appropriate Federal Reserve Bank not later than the date indicated.

A. **Federal Reserve Bank of New York** (A. Marshall Puckett, Vice President) 33 Liberty Street, New York, New York 10045:

1. *Manufacturers Hanover Corporation*, New York, New York (finance and insurance activities; Idaho, Utah): To continue to engage through its subsidiary, Finance One Mortgage of Arizona, Inc. ("Finance One"), in the activities of arranging, making, or acquiring, for its own account or the account of others, extensions of credit, such as could be made by a finance company, and of selling as agent or broker credit life and credit accident and health insurance directly related to extensions of credit by Finance One. These activities are permissible under section 601(A) of the Garn-St Germain Depository Institutions Act of 1982. These activities would continue to be conducted from Finance One's existing office in Phoenix, Arizona, after this office expands its service area to include the states of Idaho and Utah. This application does not involve the commencement of any new activities. Comments on this application must be received not later than May 17, 1983.

B. **Federal Reserve Bank of Atlanta** (Robert E. Heck, Vice President) 104 Marietta Street, N.W., Atlanta, Georgia 30303:

1. *Citizens and Southern Georgia Corporation*, Atlanta, Georgia (finance and insurance activities; Florida): To engage, through its subsidiaries, Family Credit Services, Inc., Family Credit Services, Inc. (FLA), and Family Mortgage Brokers, Inc., in consumer and commercial finance activities, including

the extension of direct loans to consumers, the discount of retail and installment notes or contracts, the purchase of real estate notes, the extension of direct loans to dealers for the financing of inventory (floor planning), and for working capital purposes and the making, acquiring, or soliciting, for its own account or for the account of others, loans and other extensions of credit; and to engage, through Family Credit Service, Inc. and Family Credit Services, Inc. (FLA), in the activity of acting as agent for the sale of credit life, accident and health, and physical damage insurance directly related to their extensions of credit. These insurance activities are permissible pursuant to Section 601 (A) and (D) of the Garn- St Germain Depository Institutions Act of 1982, since both subsidiaries engaged in these insurance activities prior to May 1, 1982. These activities would be conducted from offices located in St. Petersburg and South Daytona, Florida, serving the areas in and surrounding Tampa/St. Petersburg and South Daytona, Florida, and central Florida. Comments on this application must be received not later than May 10, 1983.

C. **Federal Reserve Bank of Chicago** (Franklin D. Dreyer, Vice President) 230 South LaSalle Street, Chicago, Illinois 60690:

1. *Franklin Capital Corporation,* Wilmette, Illinois (servicing activities; Illinois): To engage, through its subsidiary, Affiliated Secured Lending Services, Inc., in servicing asset based loans for the account of affiliated banks. The activity would be performed from an office in Wilmette, Illinois, serving the State of Illinois. Comments on this application must be received not later than May 11, 1983.

Board of Governors of the Federal Reserve System, April 15, 1983.

**James McAfee,**

*Associate Secretary of the Board.*

[FR Doc. 83-10595 Filed 4-20-83; 8:45 am]

BILLING CODE 6210-01-M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration

### Health Financing Research and Demonstration Grants; Availability of Funds for Grants

*Correction*

In FR Doc. 83-9021 appearing on page 15006 in the issue of Wednesday, April 6, 1983, make the following correction:

In the third column of page 15006, seventh line from the top, "not possible" should have read "now possible".

BILLING CODE 1505-01-M

### Office of Human Development Services

### Federal Council on the Aging; Meeting

Agency Holding the Meeting: Federal Council on the Aging.

Time and Date: Meeting begins at 8:45 a.m. on Monday, May 16, 1983 and ends at 12:30 p.m. on Tuesday, May 17, 1983.

Place: Room 800, Hubert H. Humphrey Building (HHH), 200 Independence Avenue, SW, Washington, DC 20201 on May 16, 1983 from 8:45 a.m.–2:30 p.m. Rooms 303–305A on May 16, from 3:30 p.m.–5:30 p.m. and on May 17, from 9:00 a.m.–12:30 p.m.

Status: Meeting is open to the public.

Contact Person: Rita Lowry, Room 309D, HHH Building, 245–2451.

The Federal Council on the Aging (FCA) was established by the 1973 Amendments to the Older Americans Act of 1965 (Pub. L. 93–29, 42 U.S.C. 3015) for the purpose of advising the President, the Secretary of Health and Human Services, the Commissioner on Aging and the Congress on matters relating to the special needs of older Americans.

Notice is hereby given pursuant to the Federal Advisory Committee Act (Pub. L. 92–453, 5 U.S.C. App. 1, Sec. 10, 1976) that the Council will hold a meeting May 16 and 17, 1983.

As part of the activities in celebration of Older Americans Month, the Federal Council on the Aging, in conjunction with the Administration on Aging (AoA), will participate in the AoA-sponsored symposium on Community-Based Care on May 16, from 8:45 a.m.–2:30 p.m. in Room 800, HHH Building. At 2:30 p.m., the FCA will convene in Rooms 303–305A, HHH Building, at which time committee discussions will take place. FCA Committees will reconvene on May 17, from 9:00 a.m.–12:30 p.m. in Rooms 303–305A, HHH Building.

Dated: April 18, 1983.

**Adelaide Attard,**

*Chairperson, Federal Council on the Aging.*

[FR Doc. 83-10676 Filed 4-20-83; 8:45 am]

BILLING CODE 4130-01-M

## DEPARTMENT OF THE INTERIOR

### Bureau of Indian Affairs

### Information Collection Submitted for Review

The proposal for the collection of information listed below has been submitted to the Office of Management and Budget for approval under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35). Copies of the proposed information collection requirement and related forms and explanatory material may be obtained by contacting the Bureau's clearance officer at the phone number listed below. Comments and suggestions on the requirement should be made directly to the Bureau Clearance Officer and the Office of Management and Budget Interior Desk Officer, at (202) 395–7340.

Title: Special Grants for Economic Development and Core Management Grants to Small Tribes.

Bureau Form Numbers: None.

Frequency: On occasion.

Description of Respondents: Indian Tribes.

Annual Responses: 210.

Annual Burden Hours: 25,500.

Bureau Clearance Office: Diana Loper (202) 343–3574.

**John W. Fritz,**

*Acting Assistant Secretary, Indian Affairs.*

[FR Doc. 83-10679 Filed 4-20-83; 8:45 am]

BILLING CODE 4310-02-M

### Bureau of Land Management

[M 53205-B(SD)]

### South Dakota; Order Providing for Termination of Classification and Opening of Public Lands

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Order.

**SUMMARY:** This order restores certain lands which were segregated from settlement, sale, location or entry under the public land laws including the mining laws to the operation of those laws. The segregation took effect on February 12, 1982, when the State of South Dakota filed an application to select these and other lands under the provisions of Sections 2275 and 2276 of the Revised Statutes. The application included lands in excess of the States entitlement and since the full amount of land due has been certified to the State and they have withdrawn their application for these lands, this

segregation serves no purpose. The order also revokes the classification made pursuant to the petition included in the application.

**EFFECTIVE DATE:** May 31, 1983.

**FOR FURTHER INFORMATION CONTACT:** Roland F. Lee, Montana State Office; 406–657–6090.

By virtue of the authority vested in me it is ordered as follows:

1. The segregative effect of the application filed by the South Dakota Commissioner of School and Public Lands on February 12, 1982 pursuant to Sections 2275 and 2276 of the Revised Statutes, as amended, 43 U.S.C. 851, 852 (1976) shall terminate on the effective date of this order. The lands affected by this order are described as follows:

**Black Hills Meridian**

T. 20 N., R. 10 E.,
Sec. 5, Lot 4.
T. 3 S., R. 22 E.,
Sec. 12, E½NW¼;
Sec. 17, SW¼NW¼;
Sec. 29, NW¼NW¼.
T. 2 S., R. 23 E.,
Sec. 33, S½SE¼.
T. 3 S., R. 23 E.,
Sec. 2, SE¼SW¼;
Sec. 3, SE¼SE¼.
T. 2 S., R. 24 E.,
Sec. 25, S½SE¼.

**Fifth Principal Meridian**

T. 103 N., R. 73 W.,
Sec. 5, Lot 1 and S½NE¼.
T. 104 N., R. 73 W.,
Sec. 32, SE¼SE¼.
T. 103 N., R. 75 W.,
Sec. 22, Lot 4.

Aggregating 617.12 acres.

2. The order classifying the lands described in Paragraph 1 pursuant to Section 7 of the Act of June 28, 1934, as amended, 43 U.S.C. 315(f)(1976) was published as **Federal Register** Document No. 82–19138 on pages 30877 and 30878 of the issue of July 15, 1982. That classification shall terminate on the effective date of this order.

3. At 8 a.m. on the effective date of this order the lands described in Paragraph 1 shall be open to settlement, sale, location and entry under the public land laws subject to valid existing rights, the provisions of existing withdrawals, and the requirements of applicable law. All applications received prior to that time shall be considered as simultaneously filed at that time. Those received thereafter shall be considered in the order of filing.

4. The lands described in Paragraph 1 will be open to location under the mining laws at 8 a.m. on the effective date of this order. They remain open to applications and offers under the mineral leasing laws.

Inquiries concerning these lands should be addressed to the Chief, Branch of Land Resources (934), Bureau of Land Management, P.O. Box 30157, Billings, Montana 59107.

Dated: April 14, 1983.

**Kannon Richards,**

*Acting State Director.*

[FR Doc. 83–10586 Filed 4–20–83; 8:45 am]

**BILLING CODE 4310–84–M**

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**[M 58046]**

## Montana; Invitation Coal Exploration License Application

Members of the public are hereby invited to participate with Western Energy Company in a program for the exploration of coal deposits owned by the United States of Amercia in the following described lands located in Big Horn and Treasure Counties; Montana:

T. 1 N., R. 38 E., P.M.M.,
Sec. 22, all;
Sec. 23, SW¼;
Sec. 26, all;
Sec. 28, Lots 1,2, E½;
Sec. 34, NE¼.
T. 2 N., R. 38 E., P.M.M.,
Sec. 10, W½SE¼;
Sec. 14, S½NE¼;
Sec. 22, W½;
Sec. 28, Lots 1,2, E½NE¼.

1981.45 acres, Big Horn County.
648.50 acres, Treasure County.
2609.95 Total Acres.

Any party electing to participate in this exploration program shall notify, *in writing* both the State Director, Bureau of Land Management, P.O. Box 30157, Billings, Montana 59107; and Western Energy Company, P.O. Box 1899, 115 N. Broadway, Billings, Montana 59101. Such written notice must refer to serial number M 58046 and be received no later than 30 calendar days after publication of this Notice in the **Federal Register** or 10 calendar days after the last publication of this Notice in the Hardin Herald, whichever is later. This Notice will be published for two consecutive weeks.

This proposed exploration program is fully described and will be conducted pursuant to an exploration plan to be approved by the District Mining Supervisor, Bureau of Land Management, 2525 4th Avenue North, Billings, Montana, and the Bureau of Land Management, Montana State Office, Granite Tower Building, 222 North 32nd Street, Billings, Montana. The exploration plan is available for public inspecton at either of these offices at the addresses given.

Dated: April 13, 1983.

**Judith I. Reed,**

*Acting Chief, Branch of Adjudication.*

[FR Doc. 83–10583 Filed 4–20–83; 8:45 am]

**BILLING CODE 4310–84–M**

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## Wyoming Availability of Draft Environmental Assessment and Public Comment Period

**AGENCY:** Bureau of Land Management (BLM), Interior.

**ACTION:** Notice of availability of draft environmental assessment and public comment period.

**SUMMARY:** In the matter of Wyoming: Amoco Production Company, Cave Creek Pipeline Project Draft, Environmental Assessment (DEA), Uinta County, Rock Springs District, Wyoming, Rich and Summit Counties, Salt Lake District, Utah.

Pursuant to Section 102(2)(c) of the National Environmental Policy Act of 1969, notice is hereby given that the Bureau of Land Management, U.S. Department of the Interior, has prepared a draft environmental assessment for a gas transmission and gathering system proposed from the Cave Creek and Deep Yellow Creek fields to the Whitney Canyon gas plant, Uinta County, Wyoming, and has made copies available for public review and comment.

Amoco Production Company proposes to construct and operate a 40-mile gas gathering and transmission system and related central facility. The transmission system would consist of a 12-inch sour gas pipeline, a 6-inch sour condensate liquid pipeline, and a 4.5-inch sweet fuel gas pipeline. The gathering system would include a combination of 8.6-inch, 6.6-inch, and 4.5-inch flowlines, and a 4.5-inch fuel gas line. A central facility for dehydration, gas-liquid separation, and line heating, would be constructed. An above-ground 4.16 KV powerline would be necessary to service the central facilities.

The DEA also analyzes the impacts of alternatives to the proposed location of the transmission system pipelines, central facility location, and no action.

**DATES:** Written comments on the proposal contained in the draft environmental assessment will be accepted up to and including June 13, 1983.

**ADDRESSES:** Written comments on the proposal in the document are to be addressed to: Kemmerer Resource Area Manager, Bureau of Land Management, Kemmerer Resource Area, P.O. Box 632,

Kemmerer, Wyoming 83101; (307) 877–3933.

A limited number of single copies of the DEA may be obtained from the above address. Copies are also available at the following locations:

Bureau of Land Management, Rock Springs District Office, P.O. Box 1869, Rock Springs, Wyoming 82901; (307) 382–5350; or

Bureau of Land Management, Bear River Resource Office, 2370 South 2300 West, Salt Lake City, Utah 84119; (801) 524–5348.

**Donald Sweep,**

*District Manager.*

[FR Doc. 83–10584 Filed 4–20–83; 8:45 am]

BILLING CODE 4310–84–M

## Colorado, Filing of Plats of Survey and Protraction Diagrams

April 14, 1983.

The plats of survey of the following described lands were officially filed in the Colorado State Office, Bureau of Land Management, Denver, Colorado, effective 10:00 a.m., April 14, 1983.

**Sixth Principal Meridian**

T. 17 S., R. 72 W.

The plat representing the corrective dependent resurvey of a portion of the south boundary, T. 17 S., R. 71 W., portions of the south and west boundaries and subdivisional lines, T. 17 S., R. 72 W., Sixth Principal Meridian, Colorado, Group No. 721, was accepted March 14, 1983.

T. 1 N., R. 80 W.

The plat representing the dependent resurvey of a portion of the subdivisional lines, the survey of the subdivision of section 15, and a portion of the center line of U.S. Highway No. 40, T. 1 N., R. 80 W., Sixth Principal Meridian, Colorado, Group No. 731, was accepted March 23, 1983.

These surveys were executed to meet certain administrative needs of this Bureau.

Protraction diagrams of the following described lands approved March 25, 1983, will be officially filed in the Colorado State Office, Bureau of Land Management, Denver, Colorado, effective June 3, 1983.

**Sixth Principal Meridian**

T. 1 N., R. 77 W.

Protraction Diagram No. 33, prepared to delineate the remaining unsurveyed public lands in T. 1 N., R. 71 W., Sixth Principal Meridian, Colorado, was approved March 25, 1983.

**New Mexico Principal Meridian**

T. 48 N., R. 15 W.

Protraction Diagram No. 34, prepared to delineate the remaining unsurveyed public lands in T. 48 N., R. 15 W., New Mexico Principal Meridian, Colorado, was approved March 25, 1983.

These diagrams were prepared to meet certain administrative needs of this Bureau.

All inquiries about these lands should be sent to the Colorado State Office, Bureau of Land Management, 1037 20th Street, Denver, Colorado 80202.

**Harold R. Martin,**

*Chief, Division of Operations.*

[FR Doc. 83–10585 Filed 4–20–83; 8:45 am]

BILLING CODE 4310–84–M

## Roswell District Advisory Council Meeting

**AGENCY:** Bureau of Land Management (BLM), Interior.

**ACTION:** Notice of district advisory council meeting.

**SUMMARY:** The Bureau of Land Management Roswell District Advisory Council will meet May 12, 1983. The primary objectives of the meeting will be briefings on recent and upcoming District activities. The meeting will be held May 12, 1983, in the Roswell District Office Conference Room, 1717 W. 2nd Street, Roswell, New Mexico, beginning at 1:00 p.m. The meeting will conclude by 4:00 p.m.

**SUPPLEMENTARY INFORMATION:** Agenda items scheduled for the advisory council briefing are:

1. BLM Minerals and Realty programs;
2. WIPP Site;
3. Roswell Land Use Plan;
4. Asset Management;
5. Public Land Access.

The meeting is open to the public. Interested persons may make oral statements to the council or may file written statements for the Council's consideration. Anyone wishing to make oral statements may do so at 3:00 p.m. the day of the meeting.

Summary minutes of the Council Meeting will be maintained in the District Office and will be available during regular business hours for public inspection or a copy can be obtained for the cost of duplication within 30 days following the meeting.

**Jim Gillham,**

*Acting District Manager.*

[FR Doc. 83–10588 Filed 4–20–83; 8:45 am]

BILLING CODE 4310–84–M

## Salem District Advisory Council; Meeting

Notice is hereby given in accordance with Section 309 of the Federal Land Policy and Management Act of 1976 that the first meeting of the newly appointed Salem District Advisory Council will be held on May 19, at 8:30 a.m. at the BLM Salem District Office, 1717 Fabry Road SE, Salem, Oregon.

Agenda for the meeting will include:

1. Introduction of members.
2. Discussion of the function of the council.
3. Election of officers.
4. Briefing and discussion of Salem District programs.
5. A review of the West Salem Decision Document.
6. Oral statements from public.

The meeting is open to the public. Anyone wishing to make an oral statement must notify the District Manager at the Salem District Office, 1717 Fabry Road SE, Salem, Oregon 97302 by May 12, 1983. Written comments will also be received for the council's consideration.

Summary minutes will be maintained in the District Office and will be available for public inspection and reproduction during regular business hours within 30 days following the meeting.

Dated: April 12, 1983.

**Joseph C. Dose,**

*District Manager.*

[FR Doc. 83–10582 Filed 4–20–83; 8:45 am]

BILLING CODE 4310–84–M

[M–56401]

## Realty Action—Proposed Modified Competitive Sale of Public Land in McCone County, Montana

**AGENCY:** Bureau of Land Management, Miles City District Office, Interior.

**ACTION:** Notice of realty action M–56401, proposed modified competitive sale of public land in McCone County.

**SUMMARY:** The following described lands have been examined and identified as suitable for disposal by sale pursuant to Section 203 of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1713 (1976), at no less than the fair market value:

**Principal Meridian**

T. 25 N., R. 47 E.,

Sec. 4, NE¼SW¼, NE¼SE¼.

The area described contains 80 acres.

The land will be offered for sale by sealed bid utilizing modified competitive bidding procedures at 9 a.m. on July 20, 1983, at: Montana State Office, Bureau of Land Management, 222 North 32nd Street, P.O. Box 30157, Billings, Montana 59107.

The subject lands are currently leased by Delbert Vine of Vida, Montana, for grazing purposes and are within his allotment boundary. This sale will be conducted as a modified competitive

bid, allowing Mr. Vine the right to meet any high bid.

The 40-acre tract in the NE¼SW¼ is isolated, adjoined by Montana State land on the west side and deeded land around the remainder. There is no legal access and physical access is available via 2-wheel drive vehicle across country trails. There are no improvements on this tract, and vegetation is native grasses with some brush species in a small drainage on the south end. A reservoir on adjoining deeded land backs water on about 5 acres of this tract. Oil and gas lease M–30545 is in effect on this tract.

The 40-acre tract in the NE¼SE¼ is isolated, adjoined by 40 acres of public land on the east side and deeded land around the remainder. Legal and physical acess are available via the county road which traverses the east side of this tract from north to south. There is one range improvement of record, a fence on the east side. A water well drilled by the U.S. Geological Survey (USGS) is present on this tract but will not be available for use, as it is for research purposes by that agency. Vegetation is native grasses with brush species in the small drainage on the south end. An oil and gas lease (M–30545) is in effect on this tract.

The proposed sale is consistent with the Bureau's planning system and McCone County government officials have been notified of the sale. The transfer of the tract into private ownership will benefit the public interest and provide for better land management.

**Terms and Conditions:**

The terms and conditions applicable to this sale are as follows:

1. Delbert Vine of Vida, Montana, will be the designated bidder and will have the right to meet any high bid if he so chooses.

2. Only the surface estate will be patented. All minerals and the right to construct and use ditches and canals will be reserved to the United States.

3. No bids less than the appraised fair market value of $8,000 will be accepted. Any bid must be for the entire 80 acres.

4. Rights of record which will be coveted in the patent will be—the county road right-of-way and the USGS well in the NE¼SE¼.

5. If Mr. Vine is not the successful bidder, the successful bidder must compensate Mr. Vine for the fence on public land in the NE¼SE¼, Section 4, T. 25 N., R. 47 E., as per the regulations in 43 CFR 4120.6–6(c).

**FOR FURTHER INFORMATION CONTACT:** For a period of 45 days from the date of this "Notice", interested parties may submit comments to the Miles City District Manager, P.O. Box 940, Miles City, Montana 59301. A copy of the Land Report/EAR is available at this address for review. Any comments will be evaluated by the District Manager and forwarded to the State Director for final determination.

**SUPPLEMENTARY INFORMATION:** *Bidder Qualifications:* The bidder must be a U.S. citizen or, in the case of a corporation, subject to the laws of any state or the U.S. a state, state instrumentality or political subdivision submitting a bid must be authorized to hold property. Any other entity submitting a bid must be legally capable of holding and conveying lands or interests therein under the laws of the State of Montana. Bids must be made by the principal or his agent.

*Bid Standards:* No bid will be accepted for less than the appraised value of $8,000, and bids must include all of the land identified in this notice.

*Method of Bidding:* The land will be sold by sealed bid. Each bid must be accompanied by a certified check, postal money order, bank draft or cashier's check, made payable to the Bureau of Land Management for not less than one-fifth of the amount bid.

The sealed bid envelope must be marked in the lower left hand corner as follows: Public Land Sale M–56401, July 20, 1983.

The sealed bid must be received at the following address prior to July 20, 1983: Bureau of Land Management, Montana State Office, P.O. Box 30157, Billings, Montana 59107.

*Modified Bidding:* For a period of 30 days following the date of the sale, Delbert Vine, the designated bidder, will be offered the right to meet the highest qualifying bid. The designated bidder must submit a bid of at least the fair market value prior to the sale date to be considered under the modified bidding provisions. If he meets the highest bid, the land will be sold to him and the other bid will be returned. His refusal to meet the highest bid or to submit any bid at all prior to the sale date shall consitute a waiver of such bidding provisions.

*Final Details:* Once a high bid is accepted, the successful bidder shall submit the remainder of the full bid price within the time period designated by the authorized officer. Failure to submit the required amount within the allotted time will result in cancellation of the sale and the deposit will be forfeited.

All bids will be either returned, accepted or rejected within 60 days of the sale date. If no bids are received prior to the sale date, the land will remain available for sale on a countinuing basis until a sale is completed, and any sealed bids received will be opened at 9:00 a.m. on each succeeding first and third Wednesdays.

**Alan R. Pierson,**

*District Manager, Acting for the State Director.*

[FR Doc. 83–10587 Filed 4–20–83; 8:45 am]

BILLING CODE 4310–84–M

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**[CA 8297]**

## California; Proposed Withdrawal and Reservation of Land

April 14, 1983.

The Bureau of Indian Affairs, U.S. Department of the Interior, has filed application to amend Serial No. CA 8297 to withdraw from settlement sale, location, or entry, including the mining and mineral leasing laws, the following described public land, subject to valid existing rights, in aid of legislation as an addition to the Bridgeport Indian Colony, California. The land is located in Mono County and adjoins the Bridgeport Indian Colony to the east. Acquisition of this parcel will provide homesites and economic development for the Indian people residing in the region.

**Mount Diablo Meridian**

T. 5 N., R. 25 E.,
Sec. 21, E½NE¼, NE¼SE¼, S½SE¼;
Sec. 28, N½NE¼, SW¼NE¼.

The area described aggregates 320 acres within Mono County, California.

For a period of 30 days from the date of publication of this notice, all persons who wish to submit comments, suggestions, or objections in connection with the proposed withdrawal may present their views in writing to the undersigned authorized officer of the Bureau of Land Management.

Pursuant to Section 204(h) of the Federal Land Policy and Management Act of 1976, notice is hereby given that an opportunity for a public hearing is afforded in connection with the proposed withdrawal. All interested persons who desire to be heard on the proposed withdrawal must submit a written request for a hearing to the undersigned. Notice of the public hearing will be published in the **Federal Register**, giving the time and place of such hearing. The public hearing will be scheduled and conducted in accordance with BLM Manual Section 2351.16.B.

The Department of the Interior's regulations provide that the authorized officer of the BLM will undertake such investigations as are necessary to

determine the existing and potential demands for the lands and their resources. He will also undertake negotiations with the applicant agency with the view of assuring that the area sought is the minimum essential to meet the applicant's needs, providing for the maximum concurrent utilization of the lands for purposes other than the applicant's, and reaching agreement on the concurrent management of the lands and their resources.

The authorized officer will also prepare a report for consideration by the Secretary of the Interior, who will determine whether or not the lands will be withddrawn and reserved as requested by the applicant agency. The determination of the Secretary on the application will be published in the Federal Register. The Secretary's determination shall, in a proper case, be subject to the provisions of Section 204(C) of the Federal Land Policy and Management Act of 1976, 90 Stat. 2752.

For a period of two years from the date of publication of this notice in the Federal Register, the lands will be segregated from entry as specified above, unless the application is rejected or the withdrawal is approved prior to that date. If the withdrawal is approved by the Congress, it will be segregated for a period of 20 years from date of approval, or for such period of time as designated in the Act.

All communications in connection with this proposed withdrawal should be addressed to the undersigned, Bureau of Land Management, Department of the Interior, Room E-2841, Federal Office Building, 2800 Cottage Way, Sacramento, California 95825.

**Eleano Wilkinson,**

*Chief, Lands and Locatable Minerals Section, Branch of Lands and Minerals Operations.*

[FR Doc. 83-10589 Filed 4-20-83; 8:45 am]

BILLING CODE 4310-84-M

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**[ES 32062, Survey Group 110]**

## Minnesota; Filing of Plat of Survey

1. On October 1, 1982, the plat representing the reestablishment of the record meander lines and a survey of new meander lines to include lands omitted from the original survey in Sec. 31, T. 62 N., R. 1 E., fourth Principal Meridian, Minnesota, was accepted. It will be officially filed in the Eastern States Office, Alexandria, Virginia at 7:30 a.m. on June 6, 1983.

The lots listed below describe the lands omitted from the original survey.

**Fourth Principal Meridian, Minnesota**

T. 62 N, R. 1 E.,
Sec. 31, Lots 9, 10, 11, 12, 13, 14, 15, 16, and 17.

2. The greater portion of omitted land in Sec. 31 is of a rolling nature with ridges approximately 110 feet above the mean high water line of Monker Lake; however, there are some legal subdivisions that are swamp in character. The soil content within the omitted area is mostly stoney clay loam in the upland and muskeg in the swamp land.

The omitted land is covered mostly by fir, birch, black spruce, poplar, maple, and cedar. Only the pine timber has been logged. The size of the remaining pine stumps and the character of the land attest to its existence at the time of the original survey.

3. Lots 15, 16 and 17, Sec. 31, were found to be over 50 percent swamp and overflowed in character within the purview of the Swamp Lands Act of September 28, 1850 (9 Stat. 519). Therefore, these lots will only be open to selection by the State of Minnesota, under that Act. Lots 9, 10, 11, 12, 13, and 14 sec. 31, were found to be over 50 percent upland in character within the purview of the Act mentioned above. They are therefore held to be public lands.

45. All inquiries relating to these lands should be sent to the Deputy State Director for Lands and Minerals Operations, 350 South Pickett Street, Alexandria, Virginia 22304 on or before June 6, 1983.

**Jeff O. Holdren,**

*Deputy State Director for Lands and Minerals Operations.*

[FR Doc. 83-10576 Filed 4-20-83; 8:45 am]

BILLING CODE 4310-84-M

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**[ES 32063, Survey Group 110]**

## Minnesota; Filing of Plat of Survey

1. On October 12, 1982, the plat representing an extension survey and the reestablishment of a portion of the record meander lines and the survey of a portion of the new meander lines of Pickerel Lake to include lands omitted from the original survey in Secs. 11 and 12, T. 62 N., R. 1 E., Fourth Principal Meridian, Minnesota was accepted. It will be oficially filed in the Eastern States Office, Alexandria, Virginia, at 7:30 a.m., on June 6, 1983.

The lots listed below describe the lands omitted from the original survey.

**Fourth Principal Meridian, Minnesota**

T. 62 N., R. 1 E.,
Sec. 11, Lots 9 and 10; and
Sec. 12, Lots 8, 9 and 10.

2. The greater portion of omitted land in Secs. 11 and 12 is of a rolling nature with ridges approximately 40 feet above the mean high water line of Pickerel Lake. There is no evidence that a lake has ever existed in this area at all. The soil content within the omitted area is mostly gravelly loam soils in the upland, while in the lowland, swamp areas of highly organic soils are found on a base of sand and gravel.

Both tracts are covered mostly by pine, fir, birch, black spruce, poplar, maple, and cedar. Large pine stumps show evidence that the area was once logged. The pine stumps, located south of the lake, were estimated to be over 100 years old. The east end of the lake was dotted with old cedar trees that are 12 to 16 inches in diameter. The size of the remaining pine stumps and the character of the land attest to its existence at the time of the original survey.

3. Lots 9 and 10 Sec. 11, and Lots 8, 9 and 10 Sec. 12, were found to be over 50 percent upland in character within the purview of the Swamp Lands Act of September 28, 1850 (9 Stat. 519). They are therefore held to be public lands.

4. All inquiries relating to these lands should be sent to the Deputy State Director for Lands and Minerals Operations, 350 South Pickett Street, Alexandria, Virginia 22304 on or before June 6, 1983.

**Jeff O. Holdren,**

*Deputy State Director for Lands and Minerals Operations.*

[FR Doc. 83-10577 Filed 4-20-83; 8:45 am]

BILLING CODE 4310-84-M

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**[ES 32064, Survey Group 110]**

## Minnesota; Filing of Plat of Survey

1. On October 19, 1982, the plat representing the reestablishment of the record meander lines of Binagami Lake, a partial subdivision of Sec. 12, and the survey of new meanders to include lands omitted from the original survey in Sec. 19, T. 62 N., R. 1 E., Fourth Principal Meridian, Minnesota, was accepted. It will be officially filed in the Eastern States Office, Alexandria, Virginia at 7:30 a.m., on June 6, 1983.

The lots listed below describe the lands omitted from the original survey.

**Fourth Principal Meridian, Minnesota**

T. 62 N., R. 1 E.,
Sec. 19, Lots 10, 11, 12, 13, and 14.

2. The omitted area is of a rolling nature with portions of swamp lying therein. The upland ranges up to 40 feet above the lake. Drainage of this land is to the lake and small ponds by small

streams. The soil is a heavy clay-sand, interspersed with large rocks and gravel deposits. The formation is of glacial origin. The soil in the swamps is a thin organic muck, overlying boulder beds.

Distinct vegetative types are related to topographic position. Most of the upland area is forested with birch, poplar, maple, and pine. Cedar, balsam fir, and tamarack are found in the lowland boggy sites. Large pine stumps show evidence that the area was once logged. The size of the remaining pine stumps and the character of the land attest to its existence at the time of the original survey.

3. Lot 10 Sec. 19, was found to be over 50 percent swamp and overflowed in character within the purview of the Swamp Lands Act of September 28, 1850 (9 Stat. 519). Therefore, this lot will only be open to the State of Minnesota under that Act.

Lots 11, 12, 13, and 14 were found to be over 50 percent upland in character within the purview of the Act referenced above. They are therefore held to be public lands.

4. All inquiries relating to these lands should be sent to the Deputy State Director for Lands and Minerals Operations, 350 South Picket Street, Alexandria, Virginia 22304 on or before June 6, 1983.

**Jeff O. Holdren,**

*Deputy State Director for Lands and Minerals Operations.*

[FR Doc. 83-10578 Filed 4-20-83; 8:45 am]

BILLING CODE 4310-84-M

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**[ES 32065, Survey Group 110]**

### Minnesota; Filing of Plat of Survey

1. On October 12, 1982, the plat representing an extension survey and the reestablishment of record meander lines in T. 62 N., R. 1 E., Fourth Principal Meridian, Minnesota, was accepted. It will be officially filed in the Eastern States Office, Alexandria, Virginia, at 7:30 a.m., on June 6, 1983.

The lots listed below describe the lands omitted from the original survey.

**Fourth Principal Meridian, Minnesota**

T. 62 N., R. 1 E.,
Sec. 25, Lot 2;
Sec. 26, Lot 2;
Sec. 35, Lot 4, 5 and 6; and
Sec. 36, Lot 3.

2. The greater portion of omitted land in Secs. 25 and 26 is swamp in nature. This area consists of dense cedar and alder swamp. The size of the cedar stumps and trees attest to its existence at the time of the original survey.

The omitted land in Sec. 35 consists of rolling hills ranging up to 40 feet above the portions of swamp and marsh. Little Lake is located almost entirely within the omitted area in Sec. 35. There is no evidence that Little Lake was ever any larger than it is now and it appears to have been a non-navigable body of water at the time of statehood.

The omitted land in Sec. 36 is mostly upland in nature with ridges approximately 80 feet above the mean high water line of Little Lake. The omitted areas found in Secs. 35 and 36 are covered mainly by poplar, fir, birch, maple, and cedar trees. Large pine stumps are found throughout this area. This along with the character of the land attest to its existence at the time of the original survey.

The soil content in the omitted areas consists primarily of gravelly loam in the upland with muskeg in the swamp areas. Large boulders were found on the uplands.

3. Lot 2 Sec. 25, Lot 2 Sec. 26, and Lot 4 Sec. 35 were found to be over 50 percent swamp and overflowed in character within the purview of the Swamp Lands Act of September 28, 1850 (9 Stat. 519). Therefore, these lots will only be open to the State of Minnesota under that Act.

Lots 5 and 6 Sec. 35, and Lot 3 Sec. 36, were found to be over 50 percent upland in character within the purview of the Act referenced above. They are therefore held to be public lands.

4. All inquiries relating to these lands should be sent to the Deputy State Director for Lands and Minerals Operations, 350 South Pickett Street, Alexandria, Virginia 22304 on or before June 6, 1983.

**Jeff O. Holdren,**

*Deputy State Director for Lands and Minerals Operations.*

[FR Doc. 83-10579 Filed 4-20-83; 8:45 am]

BILLING CODE 4310-84-M

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**[ES 32066, Survey Group 110]**

### Minnesota; Filing of Plat of Survey

1. October 12, 1982, the plat representing an extension survey, the reestablishment of a portion of the record meander lines, and the survey of a portion of the new meander lines of Elbow Lake to include lands omitted from the original survey in Secs. 10, 11, 14, 15, and a partial subdivision of Sec. 14, T. 62 N., R. 1 E., Fourth Principal Meridian, Minnesota, was accepted. It will be officially filed in the Eastern States Office, Alexandria, Virginia, at 7:30 a.m. on June 6, 1983.

The lots listed below describe the lands omitted from the original survey.

**Fourth Principal Meridian, Minnesota**

T. 62 N., R. 1 E.,
Sec. 10, Lots 6 and 7;
Sec.11, Lot 11;
Sec.14, Lots 7 and 8; and
Sec. 15, Lots 8, 9, 10, 11, and 12.

2. The omitted land area is of a rolling nature with portions of swamp lying therein. The upland ranges up to 65 feet above the lake. Drainage of this land is by Elbow Creek and other small creeks. The soil in the omitted area consists mainly of a heavy clay-sand, interspersed with large rocks and gravel deposits. The formation is of glacial origin. The soil in the swamps is a thin organic muck, overlying boulder beds.

Distinct vegetative types are related to topographic position. Most of the upland area is forested with birch, poplar, maple, and pine. Cedar, balsam fir, and tamarack are found in the lowland boggy sites. Large pine stumps show evidence that the area was once logged. The size of the remaining pine stumps and the character of the land attest to its existence at the time of the original survey.

3. Lot 7 Sec. 14, was found to be over 50 percent swamp and overflowed in character within the purview of the Swamp Lands Act of September 28, 1850 (9 Stat. 519). Therefore, this lot will only be open to the State of Minnesota under that Act.

Lots 6 and 7 Sec. 10, Lot 11 Sec. 11, Lot 8 Sec. 14, and Lots 8, 9, 10, 11 and 12 Sec. 15, were found to be over 50 percent upland within the purview of the Act mentioned above. They are therefore held to be public land. 4. All inquiries relating to these lands should be sent to the Deputy State Director for Lands and Minerals Operations, 350 South Pickett Street, Alexandria, Virginia 22304 on or before June 6, 1983.

**Jeff O. Holdren,**

*Deputy State Director for Lands and Minerals Operations.*

[FR Doc. 83-10580 Filed 4-20-83; 8:45 am]

BILLING CODE 4310-84-M

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## Minerals Management Service

### Oil and Gas and Sulphur Operations in the Outer Continental Shelf

**AGENCY:** Minerals Management Service, Interior.

**ACTION:** Notice of the receipt of a proposed development and production plan.

**SUMMARY:** Notice is hereby given that Pennzoil Exploration and Production Company has submitted a Development and Production Plan describing the activities it proposes to conduct on

Leases OCS-G 2078 and 1140, Blocks 228 and 215, Vermilion Area, offshore Louisiana.

The purpose of this Notice is to inform the public, pursuant to Section 25 of the OCS Lands Act Amendments of 1978, that the Minerals Management Service is considering approval of the Plan and that it is available for public review at the Office of the Regional Manager, Gulf of Mexico OCS Region, Minerals Management Service, 3301 North Causeway Blvd., Room 147, Metairie, Louisiana 70002.

**FOR FURTHER INFORMATION CONTACT:** Minerals Management Service, Public Records, Room 147, open weekdays 9 a.m. to 3:30 p.m., 3301 North Causeway Blvd., Metairie, Louisiana 70002, Phone (504) 837-4720, Ext. 226.

**SUPPLEMENTARY INFORMATION:** Revised rules governing practices and procedures under which the Minerals Management Service makes information contained in Development and Production Plans available to affected States, executives of affected local governments, and other interested parties became effective December 13, 1979, (44 FR 53685). Those practices and procedures are set out in a revised Section 250.34 of Title 30 of the Code of Federal Regulations.

Dated: April 13, 1983.

**John L. Rankin,**

*Acting Regional Manager, Gulf of Mexico OCS Region.*

[FR Doc. 83-10571 Filed 4-20-83; 8:45 am]

**BILLING CODE 4310-MR-M**

## Office of the Secretary

**[516 DM 6, App. 9]**

## National Environmental Policy Act; Revised Implementing Procedures

**AGENCY:** Department of the Interior.

**ACTION:** Notice of final revised instructions for the Bureau of Reclamation.

**SUMMARY:** This notice announces revisions to the actions categorically excluded from the NEPA process for the Bureau of Reclamation. The proposed revised instructions were published in the Federal Register on December 16, 1981 (46 FR 61337).

**EFFECTIVE DATE:** April 13, 1983.

**FOR FURTHER INFORMATION CONTACT:** Bruce Blanchard, Director, Office of Environmental Project Review, Office of the Secretary, Department of the Interior, Washington, DC 20240; telephone (202) 343-3891. For Bureau of Reclamation, contact Wayne Deason; telephone (202).

**SUPPLEMENTARY INFORMATION:** This is a final revision to Section 9.4 of Appendix 9 to Chapter 6, Part 516 of the Departmental Manual (516 DM 6, App. 9.4). It revises and updates categorical exclusions previously published in the Federal Register, July 17, 1980 (45 FR 47944). The Department's NEPA procedures (516 DM 1-6) were published on April 23, 1980 (45 FR 47941). This revision is based on continued experience with the NEPA process in the Bureau of Reclamation.

### Response to Comments

One letter of comment was received from the Missouri River Coordinator, Office of the Governor, Des Moines, Iowa, indicating that all water service contracts should be considered major Federal actions having significant impacts on the environment and, therefore, these minor contracts should not be categorically excluded. This comment was directed to 9.4D(4) which had been proposed to read "approval, execution, and implementation of water service contracts for minor amounts of long-term water use, or temporary or interim water use, where the action does not lead to long-term changes."

Our experience has been that contracts for small amounts of water have not historically involved or caused significant impacts, and, therefore, should be categorically excluded from the NEPA process, subject to the Departmental exceptions in 516 DM 2.3A(3). We have, however, further qualified this exclusion with the clause "and where the impacts are expected to be localized."

We do recognize that major water service contracts may cause significant impacts and have already indicated this in the list of actions that normally require an EIS in Section 9.3A(3).

Minor changes in wording have been made in other categorical exclusions and for ease in reference Section 9.4 in its entirely is published herewith.

Dated: April 13, 1983.

**Wm. D. Bettenberg,**

*Deputy Assistant Secretary, Policy, Budget and Administration.*

### 516 DM 6, Appendix 9—Bureau of Reclamation

9.4 *Categorical Exclusions.* In addition to the actions listed in the Departmental categorical exclusions outlined in Appendix 1 of 516 DM 2, many of which the Bureau also performs, the following Bureau actions are designated categorical exclusions unless the action qualifies as an exception under 516 DM 2.3A(3):

*A. General Activities*

1. Changes in regulations or policy directives and legislative proposals where the impacts are limited to economic and/or social effects.

2. Training activities of enrollees assigned to the various youth programs. Such training may include minor construction activities for other entities.

3. Research activities, such as nondestructive data collection and analysis, monitoring, modeling, laboratory testing, calibration, and testing of instruments or procedures and nonmanipulative field studies.

*B. Planning Activities*

1. Routine planning investigation activities where the impacts are expected to be localized, such as land classification surveys, topographic surveys, archeological surveys, wildlife studies, economic studies, social studies, and other study activity during any planning, preconstruction, construction, or operation and maintenance phases.

2. Special, status, concluding, or other planning reports that do not contain recommendations for action, but may or may not recommend further study.

3. Data collection studies that involve test excavations for cultural resources investigations or test pitting, drilling, or seismic investigations for geologic exploration purposes where the impacts will be localized.

*C. Project Implementation Activities*

1. Classification and certification of irrigable lands.

2. Minor acquisition of land and rights-of-way or easements.

3. Minor construction activities associated with authorized projects which correct unsatisfactory environmental conditions or which merely augment or supplement, or are enclosed within existing facilities.

4. Approval of land management plans where implementation will only result in minor construction activities and resultant increased operation and maintenance activities.

*D. Operations and Maintenance Activities*

1. Maintenance, rehabilitation, and replacement of existing facilities which may involve a minor change in size, location and/or operation.

2. Transfer of the operation and maintenance of Federal facilities to water districts, recreation agencies, fish and wildlife agencies, or other entities where the anticipated operation and maintenance activities are agreed to in a contract or a memorandum of agreement, follow approved Reclamation policy, and no major change in operation and maintenance is anticipated.

3. Administration and implementation of project repayment and water service contracts, including approval of organizational or other administrative changes in contracting entities brought about by inclusion or exclusion of lands in these contracts.

4. Approval, execution, and implementation of water service contracts for minor amounts of long-term water use or tempoarary or interim water use where the action does not lead to long-term changes and where the impacts are expected to be localized.

5. Approval of changes in pumping power and water rates charged contractors by the Bureau for project water service or power.

6. Execution and administration of recordable contracts for disposal of excess lands.

7. Withdrawal termination, modification, or revocation where the land would be opened to discretionary land laws and where such future discretionary actions would be subject to the NEPA process, and disposal or sale of acquired lands where no major change in usage is anticipated.

8. Renewal of existing grazing, recreation management, or cabin site leases which do not increase the level of use or continue unsatisfactory environmental conditions.

9. Issuance of permits for removal of gravel or sand by an established process from existing quarries.

10. Issuance of permits, licenses, easements, and crossing agreements which provide right-of-way over Bureau lands where the action does not allow for or lead to a major public or private action.

11. Implementation of improved appearance and soil and moisture conservation programs where the impacts are localized.

12. Conduct of programs of demonstration, educational, and technical assistance to water user organizations for improvement of project and on-farm irrigation water use and management.

13. Follow-on actions such as access agreements, contractual arrangements, and operational procedures for hydropower facilities which are on or appurtenant to Bureau facilities or lands which are permitted or licensed by the Federal Energy Regulatory Commission (FERC), when FERC has accomplished compliance with NEPA (including actions to be taken by the Bureau) and when the Bureau's environmental concerns have been accommodated in accordance with the Bureau/FERC Memorandum of Understanding of June 22, 1981.

14. Approval, renewal, transfer, and execution of an original, amendatory, or supplemental water service or repayment contract where the only result will be to implement an administrative or financial practice or change.

15. Approval of second party water sales agreements for small amounts of water (usually less than 10 acre-feet) where the Bureau has an existing water sales contract in effect.

16. Approval and execution of contracts requiring the repayment of funds furnished or expended on behalf of an entity pursuant to the Emergency Fund Act of June 26, 1948 (43 U.S.C. 502) where the action taken is limited to the original location of the damaged facility.

17. Minor safety of dams construction activities where the work is confined to the dam, abutment areas, or appurtenant features, and where no major change in reservoir or downstream operation is anticipated as a result of the construction activities.

*E. Grant and Loan Activities*

1. Rehabilitation and Betterment Act loans and contracts which involve repair, replacement, or modification of equipment in existing structures or minor repairs to existing dams, canals, laterals, drains, pipelines, and similar facilities.

2. Small Reclamation Projects Act grants and loans where the work to be done is confined to areas already impacted by farming or development activities, work is considered minor, and where the impacts are expected to be localized.

3. Distribution System Loans Act loans where the work to be done is confined to areas already impacted by farming or developing activities, work is considered minor, and where the impacts are expected to be localized.

[FR Doc. 83-10570 Filed 4-20-83; 8:45 am]

BILLING CODE 4310-09-M

## INTERNATIONAL TRADE COMMISSION

**[Investigation No. 337-TA-123]**

### CT Scanner and Gamma Camera Medical Diagnostic Imaging Apparatus; Cancellation of Commission Hearing on the Presiding Officer's Recommended Determination, Remedy, the Public Interest, and Bonding

**AGENCY:** U.S. International Trade Commission.

**ACTION:** Cancellation of a public hearing in investigation No. 337-TA-123, Certain CT Scanner and Gamma Camera Medical Diagnostic Imaging Apparatus, previously scheduled for Friday, April 22, 1983, in the Commission's Hearing Room, 701 E Street NW., Washington, D.C. 20436, beginning at 10:00 a.m.

**SUMMARY:** In the **Federal Register** of March 23, 1983 (48 FR 12141), the Commission announced the scheduling of a public hearing in this investigation for the purpose of hearing: (a) Oral arguments on the presiding officer's recommended determination that there is no violation of section 337 of the Tariff Act of 1930 in this case and (b) presentations concerning the appropriate remedy, the effect that such remedy would have upon the public interest, and the proper amount of the bond during the Presidential review period (in the event that the Commission determines that there is a violation and that relief should be granted). Notice is hereby given that the hearing is cancelled.

**SUPPLEMENTARY INFORMATION:** On March 4, 1983, the presiding officer issued a recommended determination that there is no violation of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) in the unauthorized importation into the United States and in the sale of the CT scanner and gamma camera imaging apparatus that are the subject of the investigation. The presiding officer's recommendation and the record upon which it is based were certified to the Commission for review and a Commission determination. All parties filed written exceptions to the recommended determination on March 23, 1983.

On April 8, 1983, the complainant, Technicare Corp., filed a motion to withdraw its complaint and terminate the investigation in its entirety (Motion No. 123-21C). The Commission investigative attorney subsequently filed a response supporting the complainant's motion. On April 15, 1983, the respondents, Elscint Ltd. and Elscint, Inc., filed an alternate motion to terminate (Motion No. 123-23C). Since the period of time for the non-moving parties to respond to each motion has not yet expired, these motions are not ripe for decision. The Commission cancels the public hearing in this investigation pending a ruling on Motions Nos. 123-23C.

Copies of the nonconfidential version of the recommended determination, the parties exceptions, the motions to terminate, and any other documents on the public record of the investigation may be obtained by contacting the Office of the Secretary, Docket Section, U.S. International Trade Commission, 701 E Street NW., Room 156, Washington, D.C. 20436, telephone 202-523-0176.

The notice instituting this investigation was published in the **Federal Register** of June 3, 1982, 47 FR 24232.

**FOR FURTHER INFORMATION CONTACT:** P. N. Smithey, Esq., Office of the General Counsel, U.S. International Trade Commission, telephone 202-523-0350.

By order of the Commission.

Issued: April 19, 1983.

**Kenneth R. Mason,**

*Secretary.*

[FR Doc. 83-10738 Filed 4-20-83; 8:45 am]

BILLING CODE 7020-02-M

## INTERSTATE COMMERCE COMMISSION

### Motor Carriers; Notice of Approved Exemptions

*Correction*

In FR Doc. 83-8113 beginning on page 13283 in the issue of Wednesday, March 30, 1983, make the following correction

On page 13284, first column, the following motor carrier was

inadvertently omitted and should be inserted above MC–F–15052:

MC–F–15046, UNITED VAN BUS DELIVERY—continuance in control exemption—SERVICE EXPRESS TRANSPORT, INC. Send pleadings to: (1) Motor Section, Room 2139, Interstate Commerce Commission, Washington, DC 20423, and (2) Petitioner's representative: Andrew R. Clark, 1600 TCF Tower, Minneapolis, MN 55402. Pleadings should refer to MC–F–15.46. Under 49 U.S.C 11343(e), the Interstate Commerce Commission exempts from the requirement of prior review and approval under 49 U.S.C. 11343(a), the continuance in control by United Van Bus Delivery Nos. MC–139066 and MC–141620), and, in turn, Arnie Hillman, who owns stock in United, of Service Express Transport LTD, upon institution of operations by Service under the authority it seeks in MC–165235.

BILLING CODE 1505-01-M

## Motor Carriers; Approved Exemptions

**AGENCY:** Interstate Commerce Commission.

**ACTION:** Notices of approved exemptions.

**SUMMARY:** The motor carriers shown below have been granted exemptions pursuant to 49 U.S.C. 11343(e), and the Commission's regulations in Ex Parte No. 400 (Sub-No. 1), *Procedures for Handling Exemptions Filed by Motor Carriers of Property Under 49 U.S.C. 1343*, 367 I.C.C. 113 (1982), 47 FR 53303 (November 24, 1982).

**DATES:** The exemptions will be effective on May 23, 1983. Petitions for reconsideration must be filed by May 11, 1983. Petitions for stay must be filed by May 2, 1983.

**FOR FURTHER INFORMATION CONTACT:** Warren C. Wood (202) 275–7977.

**SUPPLEMENTARY INFORMATION:** For further information, see the decision(s) served in the proceeding(s) listed below. To purchase a copy of the full decision contact: TS Infosystems, Inc., Room 2227, 12th and Constitution Ave., NW, Washington, DC 20423; or call (202) 289–4357 in the DC metropolitan area; or (800) 424–5403 Tool-free outside the DC area.

Agatha L. Mergenovich,
*Secretary.*

MC–F–15043, Wendy Roche, David Roche, and Lloyd B. Clark—Continuance in Control Exemption—Pawtuxet Valley Motor Express, Inc., and C–Line, Inc.

Addresses: Send pleadings to: (1) Motor Section, Room 2139, Interstate Commerce Commission, Washington, DC 20423; and (2) Petitioner's representatives: Ronald N. Cobert, Joseph Michael Roberts, 1730 M Street, N.W., Suite 501, Washington, DC 20036.

Pleadings should refer to No. MC–F–15043.

Decided: April 13, 1983.

Under 49 U.S.C. 11343(e), the Interstate Commerce Commission exempts from the requirement for prior reivew and approval under 49 U.S.C. 11343(a), the continuance in control by Wendy Roche, David Roche, and Lloyed B. Clark of Pawtuxet Valley Motor Express, Inc., (MC–39507) and C-Line, Inc. (MC–138861).

By the Commission, Division 1, Commissioners Andre, Taylor and Sterrett. Commissioner Taylor is assigned to this Division for the purpose of resolving tie votes. Since there was no tie in this matter, Commissioner Taylor did not participate.

MC–15051, Bob's Transport and Storage Company Inc.—Purchase Exemption—Haulmark Transfer, Inc.

Addresses: Send pleadings to: (1) Motor Section, Team 5, Room 2139, Interstate Commerce Commission, Washington, DC 20423; and (2) Petitioner's representative: Michael R. Werner, 241 Cedar Lane, Teaneck, NJ 07666.

Pleadings should refer to No. MC–F–15051.

Decided: April 14, 1983.

Under 49 U.S.C. 11343(e), the Interstate Commerce Commission exempts from the requirement of prior review and approval under 49 U.S.C. 11343(a), the purchase by Bob's Transport and Storage Company, Inc., (MC–148624) of a portion of Haulmark Transfer Inc., (MC–127579 (Sub-No. 40)) authorizing the transportation of general commodities (with exceptions) between points in the conterminous United States.

By the Commission, Division 1, Commissioners Andre, Taylor and Sterrett. Commissioner Taylor is assigned to this Division for the purpose of resolving tie votes. Since there was no tie in this matter, Commissioner Taylor did not participate.

MC–F–15071, Leaseway Transportation Corp.—Continuance in Control Exemption—Leaseway Deliveries, Inc., et al.

Addresses: Send pleadings to: (1) Motor Section, Room 2139, Interstate Commerce Commission, Washington, DC 20423; and (2) Petitioner's representative: J. Andrew Kundtz, Thompson, Hine and Flory, 1100 National City Bank Building, Cleveland, OH, 44114.

Pleadings should refer to No. MC–F–15071.

Decided: April 14, 1983.

Under 49 U.S.C. 11343(e), the Interstate Commerce Commission exempts from the requirement of prior review and approval under 49 U.S.C. 11343(a), the continuance in control by Leaseway Transportation Corp. of its subsidiary, Leaseway Deliveries, Inc. (MC–164713), and of the other carriers presently controlled by Leaseway Transportation: Amac Trucking, Inc. (MC–140619); Anchor Motor Freight, Inc. (MC–808); Better Home Deliveries, Inc. (MC–150511); Charlton Transport (Quebec) Limited (MC–141250); Contract Trucking Corporation (MC–156146); Cryogenic Carriers, Inc. (MC–157690); Custom Deliveries, Inc. (MC–142963); Dedicated Freight Systems, Inc. (MC–139583); Fleet Transport Company, Inc. (MC–103051 and MC–114106); General Trucking Service, Inc. (MC–143308); Gypsum Haulage, Inc. (MC–112113); LDF, Inc. (MC–147101); Leaseway Trucking, Inc. (MC–153610); Max Binswanger Trucking (MC–116314); Balser Truck Co. (MC–96630), which is controlled by Max Binswanger; Geo. McNeil Teaming Company (MC–153315); Midwestern Distribution, Inc. (MC–144901); Mitchell Transport, Inc. (MC–124212); Pep Lines Trucking Co. (MC–130184 and MC–135280); Refiners Transport & Terminal Corporation (MC–50069); A. R. Gundry, Inc. (MC–25562), which is controlled by Refiners Transport; Signal Delivery Service Inc. (MC–108393); Stam-Win, Inc. (MC–147294 and MC–150185); Sugar Transport, Inc. (MC–115924); United Home Delivery, Inc. (MC–153685); and Vernon Equipment, Inc. (MC–150412)

By the Commission, Division 1, Commissioners Andre, Taylor, and Sterrett. Commissioner Taylor is assigned to this Division for the purpose of resolving tie votes. Since there was no tie in this matter, Commissioner Taylor did not participate.

MC–F–15081, Murrell Enterprises, Inc.—Continuance in Control Exemption—Earl C. Smith, Inc. and Magra, Inc.

Address: Send pleadings to: (1) Motor Section, Room 2139, Interstate Commerce Commission, Washington, DC 20423; and (2) Petitioner's representatives: Ronald J. Mastej and Neill T. Riddell, 900 Guardian Building, Detroit, MI 48226.

Pleadings should refer to No. MC–F–15081.

Decided: April 14, 1983.

Under 49 U.S.C. 11343(e), the Interstate Commerce Commission exempts from the requirements of prior review and approval under 49 U.S.C. 11343(a), the continuance in control by Murrell Enterprises, and in turn, by Ronald C. Murrell, Lorraine M. Burman,

Robert S. Boris and James Byrne, of Earl C. Smith, Inc. (No. MC–80498) and Magra, Inc. (No. MC–164848).

By the Commission, Division 1, Commissioners Andre, Taylor, and Sterrett. Commissioner Taylor is assigned to this Division for the purpose of resolving tie votes. Since there was no tie in this matter, Commissioner Taylor did not participate.

MC–F–15076, Anderson & Webb Trucking Co. Inc.—Purchase Exemption—Cal-Tex, Inc.

Send pleadings to: (1) Motor Section, Room 2139, Interstate Commerce Commission, Washington, DC 20423; and (2) Petitioner's representative: Eric Meierhoefer, Sims Meierhoefer, Walker, & Steinfeld, 915 Pennsylvania Building, 425 13th Street, N.W., Washington, DC 20004.

Pleadings should refer to No. MC–F–15076.

Decided: April 14, 1983.

Under 49 U.S.C. 11343(e), the Interstate Commerce Commission exempts from the requirement of prior review and approval under 49 U.S.C. 11343(a), the purchase by Anderson & Webb Trucking Co., Inc., (No. MC–14415) of the operating rights of Cal-Tex, Inc. in Nos. MC–141097 and MC–146041 and subnumbers thereunder.

By the Commission, Division 2, Commissioners Gradison, Taylor, and Sterrett. Commissioner Taylor is assigned to this Division for the purpose of resolving tie votes. Since there was no tie in this matter, Commissioner Taylor did not participate.

MC–F–15085, Etranco, Inc.—Control Exemption—Ecoff Trucking, Inc., and Liquid Transport Corp.

Addresses: Send pleadings to: (1) Motor Section, Room 2139, Interstate Commerce Commission, Washington, DC 20423; and (2) Petitioner's representative: Robert W. Loser II, 512 Chamber of Commerce Bldg., Indianapolis, IN 46204.

Pleadings should refer to No. MC–F–15085.

Decided: April 14, 1983.

Under 49 U.S.C. 11343(e), the Interstate Commerce Commission exempts from the requirement of prior review and approval under 49 U.S.C. 11343(a)(4), the acquisition of control of Ecoff Trucking, Inc. (MC–119934 and MC–128161) and Liquid Transport Corp. (MC–119226) by Etranco, Inc., a noncarrier holding company controlled by Rex V. Ecoff.

By the Commission, Division 1, Commissioners Andre, Taylor, and Sterrett. Commissioner Taylor is assigned to this Division for the purpose of resolving tie votes. Since there was no tie in this matter, Commissioner Taylor did not participate.

MC–F–15087, Patrick M. Porritt—Continuance in Control Extension—Kramer Trucking Co., Inc. and Gabor Trucking, Inc.

Send pleadings to: (1) Motor Section, Room 2139, Interstate Commerce Commission, Washington, DC 20423; and (2) Petitioner's representative: Patrick M. Porritt, P.O. Box 687, Detroit Lakes, MN 56501.

Pleadings should refer to No. MC–F–15087.

Decided: April 13, 1983.

Under 49 U.S.C. 11343(e), the Interstate Commerce Commission exempts from the requirement of prior review and approval under 49 U.S.C. 11343(a), the continuance in control of the operating rights of Kramer Trucking Inc. (No. MC–116923) and Gabor Trucking, Inc. (No. MC–118838), motor common carriers.

By the Commission, Division 1, Commissioners Andre, Taylor, and Sterrett. Commissioner Taylor is assigned to this Division for the purpose of resolving tie votes. Since there was no tie in this matter, Commissioner Taylor did not participate.

MC–F–15101, Flatlands Express, Inc.—Purchase Exemption—Midwest Refrigerated Express, Inc.

Addresses: Send pleadings to: (1) Motor Section, Room 2139, Interstate Commerce Commission, Washington, DC 20423; and (2) Petitioner's representative: Arlyn L. Westergren, Westergren, Hauptman & O'Brien, P.C., Suite 201, 9202 W. Dodge Road, Omaha, NE 68114.

Pleadings should refer to No. MC–F–15101.

Decided: April 14, 1983.

Under 49 U.S.C. 11343(e), the Interstate Commerce Commission exempts from the requirement of prior review and approval under 49 U.S.C. 11344(e), the purchase by Flatlands Express, Inc. (No. MC–127602) of a portion of the operating authority of Midwest Refrigerated Express, Inc. (No. MC–124774).

By the Commission, Division 1, Commissioners Andre, Taylor, and Sterrett. Commissioner Taylor is assigned to this Division for the purpose of resolving tie votes. Since there was no tie in this matter, Commissioner Taylor did not participate.

[FR Doc. 83-10600 Filed 4-20-83; 8:45 am]
BILLING CODE 7035-01-M

## Motor Carrier; Finance Applications; Decision Notice

As indicated by the findings below, the Commission has approved the following applications filed under 49 U.S.C. 10924, 10926, 10931 and 10932.

*We find:*

Each transaction is exempt from section 11343 of the Interstate Commerce Act, and complies with the appropriate transfer rules.

This decision is neither a major Federal action significantly affecting the quality of the human environment nor a major regulatory action under the Energy Policy and Conservation Act of 1975.

Petitions seeking reconsideration must be filed within 20 days from the date of this publication. Replies must be filed within 20 days after the final date for filing petitions for reconsideration; any interested person may file and serve a reply upon the parties to the proceeding. Petitions which do not comply with the relevant transfer rules at 49 CFR 1181.4 may be rejected.

If petitions for reconsideration are not timely filed, and applicants satisfy the conditions, if any, which have been imposed, the application is granted and they will receive an effective notice. The notice will recite the compliance requirements which must be met before the transferee may commence operations.

Applicants must comply with any conditions set forth in the following decision-notices within 20 days after publication, or within any approved extension period. Otherwise, the decision-notice shall have no further effect.

*It is ordered:*

The following applications are approved, subject to the conditions stated in the publication, and further subject to the administrative requirements stated in the effective notice to be issued hereafter.

**Agatha L. Mergenovich,**

*Secretary.*

**For the following, please direct status calls to Team 3 at 202–275–5223.**

*Volume No. OP3–MCFC–167*

Decided: April 13, 1983.

By the Commission, Review Board No. 3, Members Krock, Joyce, and Dowell.

MC–FC–81240. By decision of April 13, 1983 issued under 49 U.S.C. 10926 and the transfer rules at 49 CFR Part 1181, Review Board Number 3 approved the transfer to WINONA AIR EXPEDITING, INC., Winona, MN of a portion of Certificate No. MC–153114 (Sub-No. 3) (Part 2), issued October 6, 1981, to Olympic Express, Inc., of Bloomington, MN, authorizing the transportation of *general commodities* (except classes A and B explosives), between points in LaCrosse and Douglas Counties, WI, and Goodhue, Olmsted, St. Louis, Wabash and Winona Counties, MN, on the one hand, and, on the other, points in Anoka, Carver, Dakota, Hennepin,

Ramsey, Scott and Washington Counties, MN. Representative: Stanley C. Olsen, Jr., 5200 Willson Road, Suite 307, Edina, MN 55424, (612) 927–8855.

**For the following, please direct status calls to Team 5 at 202–275–7289.**

*Volume No. OP5–FC–187*

By the Commission, Review Board No. 1, Members Parker, Chandler, and Fortier.

MC–FC 81336. By decision of April 13, 1983, issued under 49 U.S.C. 10926 and the transfer rules at 49 CFR Part 1181, Review Board Number 1, approved the transfer to H.T.L. Inc., d.b.a., HUNTER TRUCK LINE, of Council Bluffs, IA, of all of the authority in Certificate No. MC–141489 and in Permit No. MC–145064. In No. MC–141489 Sub 16X, issued July 15, 1981, and the underlying authority thereto in MC–141489 issued November 7, 1980, and in Sub 2, issued March 14, 1980, Sub 3, issued July 29, 1980, Sub 6, issued September 22, 1981, Sub 8, issued November 23, 1979, Sub 10, issued March 9, 1981, Sub 12, issued November 6, 1980, Sub 15, issued January 5, 1981, Subs 16, 17, 18, and 19, issued August 28, 1980, No. MC–140241 Sub 44 and 46 reentitled issued July 29, 1980, and that portion of No. MC–138328 issued July 26, 1974 (acquired and authorized in MC–F–13639). MC–141489 Sub 9 issued September 24, 1980, and Sub 14, issued January 5, 1981. Permit No. MC–141489 Sub 19 issued June 22, 1982. In permit No. MC–145064 Sub 13X, issued August 7, 1981 and the underlying authority thereto in Sub 3, issued October 10, 1979, Sub 4, issued July 14, 1980, Sub 6, issued April 18, 1979, Sub 9, issued July 28, 1980, Sub 10, issued April 28, 1981 and Permit No. MC–136817 issued November 22, 1972 (acquired and authorized in MC–F–13639). Permit No. MC–145064 Sub 7 issued September 7, 1979, Sub 8, issued April 18, 1979 and Sub 12, issued May 5, 1981 to Hunter Trucking, Inc., of Council Bluffs, IA. Such authority authorizes the transportation of specified commodities over regular and irregular routes, between specified points in the U.S. Representative: James F. Crosby, 7363 Pacific Street, Suite 210B, Omaha, NE.

MC–81354. By decision of April 14, 1983 issued under 49 U.S.C. 10926 and the transfer rules at 49 CFR Part 1181, Review Board Number 1, approved the transfer to K–C & CO. TRUCKING, INC., of Evanston, WY, of Certificate No. MC–155428 issued June 28, 1982, to K–C & CO. Trucking of Lima, MT, authorizing the transportation of Mercer commodities (a) between points in Idaho, Montana, Nevada, Utah, and Wyoming, and (b) between points in Idaho, Montana, Nevada, Utah, and Wyoming, on the one hand, and, on the other, points in Colorado, North Dakota, Oregon, South Dakota, Washington, and Wyoming. Representative: Wayne Koerner, P.O. Box 1196, Evanston, WY 82930.

MC–FC–81372. By decision of April 13, 1983, issued under 49 U.S.C. 10926 and the transfer rules at 49 CFR Part 1181, Review Board Number 1, approved the transfer to B. J. McCONNELL AND JACK HELMS, d/b/a ALASKA MOBILE HOME MOVERS of Anchorage, AK, of Certificate No. MC–119558 Sub 8X issued September 7, 1982 and the underlying authority thereto in Sub 7 issued July 15, 1982, to Glenn Phillips and Cecil Blanton, d/b/a. Alaska Mobile Home Movers of Anchorage, AK, authorizing the transportation of lumber or wood products, except furniture, including buildings, and mobile homes, (1) between points in AK, and (2) mobile homes, between points in AK, and points in CO, ID, IN, KS, MI, MN, MT, NE, OK, SD, WA, and WI. An application for temporary authority has been filed. Representative: Arthur R. Hauver, 750 West Second Ave., Suite 200, Anchorage, AK 99501.

MC–FC–81382. By decision of April 14, 1983, issued under 49 U.S.C. 10926 and the transfer rules of 49 CFR Part 1181, Review Board Number 1 approved the transfer to SEA RAIL CARTAGE, INC., of Portland, OR, of Certificate No. MC–149118 issued December 12, 1980, authorizing the transportation of (1) contractors equipment, materials and supplies, and (2) commodities which, because of their size or weight, require the use of special equipment (except those in (1) above), between points in Oregon, Washington, and Del Norte, Siskiyou, Modoc, Trinity and Shasta Counties, CA, restricted to the transportation of traffic originating at or destined to the facilities of Pacific Power & Light Company, MC–149118 Sub 1F issued January 5, 1981, authorizing the transportation of equipment, materials and supplies used in the transmission and switching of telephonic communications and empty telephone cable reels, between points in Oregon, Washington, and Nez Perce Counties, ID, restricted to transportation of traffic from, to, or between the facilities of Pacific Northwest Bell Telephone Company, MC–149118 Sub 2F issued January 21, 1981, authorizing the transportation of general commodities (except household goods as defined by the Commission, hazardous or secret materials, and sensitive weapons and munitions), for the United States Government, between points in United States, and MC–149118 Sub 3F issued March 20, 1981, authorizing the transportation of commodities, which because of size or weight, require the use of special equipment, beween points in Oregon and Washington, Transferee holds authority under MC–162578. Representative: Lawrence V. Smart, Jr., 419 23rd Ave., Portland, OR 97210.

[FR Doc 83–10599 Filed 4–20–83; 8:45 am]
BILLING CODE 7035–01–M

## Motor Carrier; Permanent Authority Decisions; Decision-Notice

*Motor Common and Contract Carriers of Property (fitness-only); Motor Common Carriers of Passengers (fitness-only); Motor Contract Carriers of Passengers; Property Brokers (other than household goods).*

The following applications for motor common or contract carriage of property and for a borker of property (other than household goods) are governed by Subpart A of Part 1160 of the Commission's General Rules of Practice. See 49 CFR Part 1160, Subpart A, published in the **Federal Register** on November 1, 1982, at 47 FR 49583, which redesignated the regulations at 49 CFR 1100.251, published in the **Federal Register** on December 31, 1980. For compliance procedures, see 49 CFR 1160.19. Persons wishing to oppose an application must follow the rules under 49 CFR Part 1160, Subpart B.

The following applications for motor common or contract carriage of passengers filed on or after November 19, 1982, are governed by Subpart D of the Commission's Rules of Practice. See 49 CFR Part 1160, Subpart D, published in the **Federal Register** on November 24, 1982, at 49 FR 53271. For compliance procedures, see 49 CFR 1160.86. Persons wishing to oppose an application must follow the rules under 49 CFR Part 1160, Subpart E.

These applications may be protested *only* on the grounds that applicant is not fit, willing, and able to provide the transportation service or to comply with the appropriate statutes and Commission regulations.

Applicant's representative is required to mail a copy of an application, including all supporting evidence, within three days of a request and upon payment to applicant's representative of $10.00.

Amendments to the request for authority are not allowed. Some of the applications may have been modified prior to publication to conform to the Commission's policy of simplifying grants of operating authority.

**Findings**

With the exception of those applications involving duly noted problems (e.g., unresolved common control, fitness, or jurisdictional questions) we find, preliminarily, that each applicant has demonstrated that it is fit, willing, and able to perform the service proposed, and to conform to the requirements of Title 49, Subtitle IV, United States Code, and the Commission's regulations. This presumption shall not be deemed to exist where the application is opposed. Except where noted, this decision is neither a major Federal action significantly affecting the quality of the human environment nor a major regulatory action under the Energy Policy and Conservation Act of 1975.

In the absence of legally sufficient opposition in the form of verified statements filed on or before 45 days from date of publication, (or, if the application later becomes unopposed) appropriate authorizing documents will be issued to applicants with regulated operations (except those with duly noted problems) and will remain in full effect only as long as the applicant maintains appropriate compliance. The unopposed applications involving new entrants will be subject to the issuance of an effective notice setting forth the compliance requirements which must be satisfied before the authority will be issued. Once this compliance is met, the authority will be issued.

Within 60 days after publication an applicant may file a verified statement in rebuttal to any statement in opposition.

To the extent that any of the authority granted may duplicate an applicant's other authority, the duplication shall be construed as conferring only a single operating right.

**Agatha L. Mergenovich,**

*Secretary.*

**Note.**—All applications are for authority to operate as a motor common carrier in interstate or foreign commerce, over irregular routes unless noted otherwise. Applications for motor contract carrier authority are those where service in for a named shipper "under contract."

**Please direct status inquiries to Team 1, (202) 275-7992.**

*Volume No. OP1-140*

Decided: April 15, 1983.

By the Commission, Review Board No. 2, Members Carleton, Williams, and Ewing.

MC 167230, filed April 4, 1983. Applicant: SCHUEFFNER TRUCKING, INC., Route 2, Sheboygan Falls, WI 53085. Representative: James A. Spiegel, Olde Towne Office Park, 6333 Odana Rd., Madison, WI 53719, (608)-273-1003. Transporting (1) *food and other edible products and by-products intended for human consumption* (except alcoholic beverages and drugs), *agricultural limestone and fertilizers, and other soil conditioners* by the owner of the motor vehicle in such vehicle, and (2) for or on behalf of the U.S. Government, *general commodities* (except used household goods, hazardous or secret materials, and sensitive weapons and munitions), between points in the U.S. (except AK and HI).

MC 167301, filed April 8, 1983. Applicant: JOE SCHMID, d.b.a. JS INTERNATIONAL CUSTOMHOUSE BROKER, 110 W. Ocean Blvd, Suite 361, Long Beach, CA 90802. Representative: Frank Rivera (same address as applicant), (213) 436-9927. As a *broker* of *general commodities* (except household goods), between points in the U.S.

**For the following, please direct status calls to Team 3 at 202-275-5223.**

*Volume No. OP3-158*

Decided: April 13, 1983.

By the Commission, Review Board No. 3, Members Krock, Joyce, and Dowell.

MC 76574 (Sub-6), filed March 23, 1983. Applicant: ARMSTRONG TRANSFER AND STORAGE CO., INC., 3927 Winchester Rd., Memphis, TN 38118. Representative: Carroll B. Jackson, 1810 Vincennes Rd., Richmond, VA 23229, (804) 282-3809. As a *broker* of *general commodities* (except household goods), between points in the U.S.

MC 155114 (Sub-1), filed April 6, 1983. Applicant: LONERGAN'S CHARTER SERVICE, INC., 1109 Boucher Ave., Annapolis, MD 21403. Representative: Steven L. Weiman, Suite 200, 444 N. Frederick Ave., Gaithersburg, MD 20877, (301) 840-8565. Transporting *passengers*, in special and charter operations, between points in the U.S. (except HI).

**Note.**—Applicant seeks to provide privately-funded special and charter transportation.

MC 165344, filed March 22, 1983. Applicant: WAYNE A. LOVE, d.b.a. LOVE TRANSPORTATION, 1799 Harvey Ave., Kelowna, B. C. Canada V1Y 6G4. Representative: Wayne A. Love (same address as applicant), (604) 860-2665. Transporting *passengers*, in charter and special operations, beginning and ending at ports of entry on the international boundary line between the United States and Canada, in WA, MT, ND, and MN, and extending to points in the U.S. (except HI).

**Note.**—Applicant seeks to provide privately-funded special and charter transportation.

MC 166985, filed March 23, 1983. Applicant: MICHAEL A. ZOZ, RR 1, Alvo, NE 68304. Representative: (Same as applicant), (402) 867-3482. Transporting *food and other edible products and byproducts intended for human consumption* (except alcoholic beverages and drugs), *agricultural limestone and fertilizer, and other soil conditioners* by the owner of the motor vehicle in such vehicle, between points in the U.S. (except AK and HI).

MC 167154, filed March 29, 1983. Applicant: GUST TRANSPORTATION, INC., P.O. Box 9426, Fresno, CA 93792. Representative: Arden Riess, P.O. Box 7965, Stockton, CA 95207, (209) 957-6128. As a *broker of general commodities* (except household goods), between points in the U.S. (except AK and HI).

MC 167255, filed April 4, 1983. Applicant: WASHINGTON TOURS, INC., 11212 Grandview Ave., Suite 102, Wheaton, MD 20902. Representative: Russell R. Sage, P.O. Box 11278, Alexandria, VA 22312, (703) 750-1112. Transporting *passengers*, in special and charter operations, between points in the U.S. (except HI).

**Note.**—Applicant seeks to provide privately-funded charter and special transportation.

*Volume No. OP3-164*

Decided: April 14, 1983.

By the Commission, Review Board No. 3, Members Krock, Joyce, and Dowell.

MC 113105 (Sub-4), filed April 4, 1983. Applicant: SHERIDAN-INDIANAPOLIS BUS LINE, INC., 144 S. Union St., Westfield, IN 46074. Representative: Walter F. Jones, Jr., 1111 E. 54th St., Suite 155, Indianapolis, IN 46220, (317) 257-4066. Transporting *passengers*, in charter and special operations, between points in the U.S. (except HI).

**Note.**—Applicant seeks to provide privately-funded charter and special transportation.

MC 96345 (Sub-8), filed April 4, 1983. Applicant: AMERICAN EAGLE MOTOR COACH, INC., 72 Sycamore St., Fairhaven, MA 02719. Representative: Robert J. Brooks, 1828 L St., N.W., Suite 1111, Washington, D.C. 20036, (202) 466-3892. Transporting *passengers*, in charter and special operations, between points in the U.S.

**Note.**—Applicant seeks to provide privately-funded charter and special transportation.

MC 167075, filed March 28, 1983. Applicant: JEN-BAR CONSTRUCTION, INC., 6405 Harford Road, Baltimore, Md

21214. Representative: James A. Barron (same address as applicant), (301) 426–3015. As a *broker* of *general commodites* (except household goods), between points in the U.S.

MC 167204, filed April 1, 1983. Applicant: AIRTRAN-O'HARE, INC., 26W161 Plank Rd., P.O. Box 896, Naperville, IL 60566. Representative: William D. McCreary (same address as applicant), (312) 961–5500. Transporting *passengers,* in charter and special operations, between points in the U.S. (except AK and HI).

Note.—Applicant seeks to provide privately-funded charter and special transportation.

[FR Doc. 83-10601 Filed 4-20-83; 8:45 am]

BILLING CODE 7035-01-M

## Motor Carrier; Permanent Authority Decisions; Decision-Notice

*Motor Common and Contract Carriers of Property (except fitness-only); Motor Common Carriers of Passengers (public interest); Freight Forwarders; Water Carriers; Household Goods Brokers.* The following applications for motor common or contract carriers of property, water carriage, freight forwarders, and household goods brokers are governed by Subpart A of Part 1160 of the Commission's General Rules of Practice. See 49 CFR Part 1160, Subpart A, published in the **Federal Register** on November 1, 1982, at 47 FR 49583, which redesignated the regulations at 49 CFR 1100.251, published in the **Federal Register** December 31, 1980. For compliance procedures, see 49 CFR 1160.19. Persons wishing to oppose an application must follow the rules under 49 CFR Part 1160, Subpart B.

The following applications for motor common carriage of passengers, filed on or after November 19, 1982, are governed by Subpart D of 49 CFR Part 1160, published in the **Federal Register** on November 24, 1982 at 47 FR 53271. For compliance procedures, see 49 CFR 1160.86. Carriers operating pursuant to an intrastate certificate also must comply with 49 U.S.C. 10922(c)(E). Persons wishing to oppose an application must follow the rules under 49 CFR Part 1160, Subpart E. In addition to fitness grounds, these applications may be opposed on the grounds that the transportation to be authorized is not consistent with the public interest.

Applicant's representative is required to mail a copy of an application, including all supporting evidence, within three days of a request and upon payment to applicant's representative of $10.00.

Amendments to the request for authority are not allowed. Some of the applications may have been modified prior to publication to conform to the Commission's policy of simplifying grants of operating authority.

### Findings

With the exception of those applications involving duly noted problems (e.g., unresolved common control, fitness, water carrier dual operations, or jurisdictional questions) we find preliminarily, that each applicant has demonstrated that it is fit, willing, and able to perform the service proposed, and to conform to the requirements of Title 49, Subtitle IV, U.S.C., and the Commission's regulations.

We make an additional preliminary finding with respect to each of the following types of applications as indicated: common carrier of property—that the service proposed will serve a useful public purpose, responsive to a public demand or need; water common carrier—that the transportion to be provided under the certificate is or will be required by the public convenience and necessity; water contract carrier, motor contract carrier of property, freight forwarder, and household goods broker—that the transportation will be consistent with the public interest and the transportation policy of section 10101 of chapter 101 of Title 49 of the U.S.C.

These presumptions shall not be deemed to exist where the application is opposed. Except where noted, this decision is neither a major Federal action significantly affecting the quality of the human environment nor a major regulatory action under the Energy Policy and Conservation Act of 1975.

In the absence of legally sufficient opposition in the form of verified statements filed on or before 45 days from date of publication, (or, if the application later becomes unopposed) appropriate authorizing documents will be issued to applicants with regulated operations (except those with duly noted problems) and will remain in full effect only as long as the applicant maintains appropriate compliance. The unopposed applications involving new entrants will be subject to the issuance of an effective notice setting forth the compliance requirements which must be satisfied before the authority will be issued. Once this compliance is met, the authority will be issued.

Within 60 days after publication an applicant may file a verified statement in rebuttal to any statement in opposition.

To the extent that any of the authority granted may duplicate an applicant's other authority, the duplication shall be construed as conferring only a single operating right.

**Agatha L. Mergenovich,**

*Secretary.*

Note.—All applications are for authority to operate as a motor common carrier in interstate or foreign commerce over irregular routes, unless noted otherwise. Applications for motor contract carrier authority are those where service is for a named shipper "under contract." Applications filed under 49 U.S.C. 10922(c)(2)(B) to operate in intrastate commerce over regular routes as a motor common carrier of passengers are duly noted.

**Please direct status inquiries to Team 4 at (202) 275–7669.**

*Volume No. OP4–232*

Decided: April 14, 1983.

By the Commission, Review Board No. 3, Members Krock, Joyce, and Dowell.

MC 162756, filed March 22, 1983. Applicant: CARROLS DEVELOPMENT CORPORATION, 968 James St., Syracuse, NY 13203. Representative: James Robert Evans, 145 W. Wisconsin Ave., Neenah, WI 54956, (414) 722–2848. Transporting *general commodities* (except classes A and B explosives, household goods and commodities in bulk), between points in the U.S. (except AK and HI), under continuing contract(s) with Iceland Seafood Corporation of Camp Hill, PA; Golden West Foods, Inc., a subsidiary of McCormick & Co., Inc., of Bedford, VA; Paul de Lima Coffee Company, of Syracuse, NY; and Dopaco, Inc. of Downingtown, PA.

MC 3647 (Sub-472), filed April 6, 1983. Applicant: NJ TRANSIT BUS OPERATIONS, INC., 180 Boyden Ave., Maplewood, NJ 07040. Representative: Irwin I. Kimmelman, McCarter Hwy and Market St., P.O. Box 10009, Newark, NJ 07101, (201) 648–6908. Over regular routes, transporting *passengers,* (1) Between Paterson, and East Rutherford, NJ: From Paterson at junction Main St. and Broadway, then over Broadway to junction Curtis Place, then over Curtis Place to junction Ellison St., then over Ellison St. to junction Washington St., then over Washington St. to junction Market St., then over Market St. to junction Madison Ave., then over Madison Ave. to junction Park Ave., then over Park Ave. to junction Vreeland Ave., then over Vreeland Ave., to junction East Thirty Ninth St., then over East Thirty Ninth St. to junction Market St., then over Market St. to junction Lakeview Ave., then over Lakeview Ave. and access roads to Market St., then over Market St. to

junction River Dr., then over River Dr. to U.S. Hwy 46 East, then over U.S. Hwy 46 East to junction Main St., then over Main St. to junction Liberty St., then over Liberty St. to junction Moonachie Rd., then over Moonachie Rd. to junction Washington Ave., then over Washington Ave. and NJ Hwy 20 to junction NJ Hwy 3 to East Rutherford and return over NJ Hwy 20 and Washington St. to junction Moonachie Rd., then over Moonachie Rd. to junction Liberty St., then over Liberty St. to junction Main St., then over Main St. to junction Phillips Ave., then over Phillips Ave. to junction U.S. Hwy 46 West, then over U.S. Hwy 46 to junction River Dr., then over River Dr. to junction Market St., then over Market St. to junction Vreeland Ave., then over Vreeland Ave. to junction Park Ave., then over Park Ave. to junction Market St., then over Market St. to junction Main St., then over Main St. to junction Van Houten St., then over Van Houten St. to junction Curtis Place, to Paterson, serving all intermediate points. (2) Between Teterboro and Moonachie, NJ: From junction U.S. Hwy 46 and Industrial Ave., then over Industrial Ave. to junction Railroad Ave., then over Railroad Ave. to junction Industrial Ave., then over Industrial Ave. to junction Moonachie Ave., then over Moonachie Ave. to junction Moonachie Rd., to Moonachie, serving all intermediate points. (3) Between Hasbrouck Heights and Passaic, NJ: From junction U.S. Hwy 46 and NJ Hwy 17, then over NJ Hwy 17 south to junction Williams Ave., then over Williams Ave. and Union St. to junction Memorial Dr., then over Memorial Dr. to junction Passaic Ave., then over Passaic Ave. to junction Passaic St., then over Passaic St. to junction Wall St., then over Wall St. to junction Passaic St., then over Passaic St. to junction Main St., then over Main St. to junction Lexington Ave., to Passaic, NJ, and return over Lexington Ave. to junction Monroe St., then over Monroe St. to junction Main St., then over Main St. to junction Prospect St., then over Prospect St. to junction Passaic St., then over Passaic St., to junction Wall St., then over Wall St. to junction Passaic St., then over Passaic St. to junction Passaic Ave., then over Passaic Ave. to junction Memorial Dr., then over Memorial Dr. to junction Union St., then over Union St. and Williams Ave. to junction U.S. Hwy 46 and NJ Hwy 17 to Hasbrouck Heights, serving all intermediate points. (4) Between Hackensack and Ridgefield Park, NJ: From junction Anderson St. and Main St., then over Main St. to junction Ward St., then over Ward St. to junction State St., then over State St. to junction Mercer St., then over Mercer St. to junction Moore St., then over Moore St. to junction Atlantic St., then over Atlantic St. to junction Moore St., then over Moore St. to junction Court St., then over Court St. and W. Fort Lee Rd. to junction River Rd., then over River Rd. to junction Main St., then over Main St. to junction Palisade Ave., then over Palisade Ave. to junction North Ave., then over North Ave. to junction Main St. and Queen Anne Rd., to Ridgefield Park, and return over North Ave. to junction Palisade Ave., then over Palisade Ave. to junction Main St., then over Main St. to junction River Rd., then over River Rd. to junction W. Fort Lee Rd., then over W. Fort Lee Rd. and Bridge St. to junction Moore St., then over Moore St. to junction Atlantic St., then over Atlantic St. to junction Moore St., then over Moore St. to junction Mercer St., then over Mercer St. to junction Main St., then over Main St. to junction Anderson St., to Hackensack, serving all intermediate points. (5) Between points in Little Ferry, NJ: From junction U.S. Hwy 46 and Little Ferry Traffic Circle, then over U.S. Hwy 46 to junction Liberty St., then over Liberty St. to junction Main St., serving all intermediate points. (6) Between Fairview, NJ and North Bergen, NJ: From junction Anderson Ave. and Fairview Ave., then over Fairview Ave. to junction Woodcliff Ave., then over Woodcliff Ave. to junction Boulevard East to North Bergen, serving all intermediate routes.

Note.—Applicant intends to tack the above authority to its present authorized operations and seeks to provide regular route service in interstate or foreign commerce.

MC 37127 (Sub-5), filed April 12, 1983. Applicant: MECCA & SON TRUCKING CORP., 580 Henderson St., Jersey City, NJ 07302. Representative: Thomas F.X. Foley, P.O. Box F, Colts Neck, NJ 07722, (201) 946–2020. Transporting *general commodities* (except classes A and B explosives, household goods, and commodities in bulk), between points in CT, NJ, NY, and PA, on the one hand, and, on the other, points in CT, DE, IL, IN, MD, MA, NJ, NY, OH, PA, RI, VA, and DC.

MC 42487 (Sub-1073), filed April 11, 1983. Applicant: CONSOLIDATED FREIGHTWAYS, CORPORATION OF DELAWARE, 175 Linfield Dr., Menlo Park, CA 94025. Representative: V. R. Oldenburg, P.O. Box 3062, Portland, OR 97208, (503) 226–4692. Transporting *general commodities* (except classes A and B explosives, household goods, and commodities in bulk), between points in the U.S. (except AK and HI), under continuing contract(s) with Kendavis Industries International, Inc., of Fort Worth, TX, and its wholly owned subsidiaries.

MC 142126 (Sub-17), filed April 11, 1983. Applicant: FOAM TRANSPORT, INC., 201 Ballardvale St., Wilmington, MA 01887. Representative: Frank J. Weiner, 15 Court Square, Boston, MA 02108, (617) 742–3530. Transporting *rubber and plastic products,* and *pulp, paper and related products,* between points in the U.S. (except AK and HI), under continuing contract(s) with Ampco Packaging, Inc., of Jersey City, NJ, Cushion Pak, Inc., of Marlboro, NJ, and Astro Packaging, Inc., of Hawthorne, NJ.

**For the following, please direct status calls to Team 1 at 202–275–7992.**

*Volume No. OP1–141*

Decided: April 15, 1983.

By the Commission, Review Board No. 2, Members Carleton, Williams, and Ewing.

MC 36531 (Sub-7), filed April 5, 1983. Applicant: MAIN TRUCKING COMPANY, 52 Rainbow Ave., Sunbury, OH 43074. Representative: James R. Stiverson, 1396 W. Fifth Ave., P.O. Box 12241, Columbus, OH 43212, (614) 481–8821. Transporting *lime, limestone and limestone products, and commodities in bulk,* between points in IN, KY, MI, OH, PA and WV.

MC 75840 (Sub-173), filed April 8, 1983. Applicant: MALONE FREIGHT LINES, INC., P.O. Box 11103, Birmingham, AL 35202. Representative: William P. Jackson, Jr., 3426 N. Washington Blvd., P.O. Box 1240, Arlington, VA 22210, (703) 525–4050. Transporting *general commodities* (except classes A and B explosives and household goods), between points in the U.S. (except AK and HI), under continuing contract(s) with Diamond Shamrock Corporation, of Irving, TX, Kaiser Aluminum & Chemical Corporation, of Oakland, CA, Kimberly Clark Corporation, of Coosa Pines, AL, and Cascade West Transportation Brokers, of Lake Oswego, OR.

MC 136291 (Sub-25), filed April 7, 1983. Applicant: CUSTOMIZED PARTS DISTRIBUTION, INC., 3600 N.W. 82nd Ave., Miami, FL 33166. Representative: Dale A. Tibbets (same address as applicant) (305) 593–3204. Transporting *such commodities* as are dealt in by tobacco, candy and food distributors, between points in the U.S. (except AK and HI), under continuing contract(s) with (1) International Tobacco Wholesalers Alliance, Ltd., of Livonia, MI, and (2) Midwest Natural Foods Distributors, Inc., of Ann Arbor, MI.

MC 141871 (Sub-29), filed April 6, 1983. Applicant: WNI, INC., 8560 S.W. Salish Lane, Wilsonville, OR 97070. Representative: John R. Patterson, P.O. Box 2298, Green Bay, WI 54306, (414) 498–7688. Transporting *general commodities* (except classes A and B explosives and household goods), between those points in the U.S. in and east of ND, SD, NE, KS, OK, AND TX.

MC 151880 (Sub-4), filed April 6, 1983. Applicant: K & K TRUCKING, INC., 806 Cullum St., Carthage, TN 37030. Representative: J. Greg Hardeman, 618 United Southern Bank Bldg., Nashville, TN 37219, (615 244–8100) Transporting *general commodities* (except classes A and B explosives, household goods and commodities in bulk), between Davidson County, TN, on the one hand, and, on the other, points in the U.S. (except AK and HI).

Note.—Applicant intends to tack this authority with its existing regular route operations.

MC 147101 (Sub-6), filed April 5, 1983. Applicant: LDF, INC. 30 Enterprise Ave., Secaucus, NJ 07094. Representaive: J. A. Kundtz, 1100 National City Bank Bldg., Cleveland, OH 44114, (216) 566–5639. Transporting *such commodities* as are dealt in or used by retail department stores, between points in the U.S., under continuing contract(s) with Macy's New York, Inc., of New York, NY.

MC 148791 (Sub-42), filed April 7, 1983. Applicant: TRANSPORT–WEST, INC., 1850 South 1100 West, Woods Cross, UT 84087. Representative: Rick J. Hall, P.O. Box 2465, Salt Lake City, UT 84110, (801) 531–1777. Transporting *disposable medical and surgical supplies*, between points in the U.S. (except AK and HI), under continuing contract(s) with Surgikos, Inc., of Arlington, TX.

MC 148791 (Sub-43), filed April 7 1983. Applicant: TRANSPORT–WEST, INC., 1850 South 1100 West, Woods Cross, UT 84087. Representative: Rick J. Hall, P.O. Box 2465, Salt Lake City, UT 84110, (801) 531–1777. Transporting *pulp, paper and related products*, between points in the U.S. (except AK and HI), under continuing contract(s) with Packaging Corporation of America, of Evanston, IL.

MC 152621 (Sub-11), filed April 5, 1983. Applicant: RUSH TRANSPORT, INC., 163 Main St., Route 131, Sturbridge, MA 01566. Representative: James Burns, 1365 Main St., Suite 403, Springfield, MA 01103, (413) 781–8205. Transporting *general commodities* (except classes A and B explosives, household goods and commodities in bulk), between points in the U.S. (except AK and HI).

MC 158651 (Sub-9), filed April 8 1983. Applicant: GRAEBEL VAN LINES, INC., 719 North Third Avenue, Wausau, WI 54401. Representative: John E. Koci (same address as applicant), (715) 675–9481. Transporting *household goods*, between points in the U.S., under continuing contract(s) with Allen Bradley Company, of Milwaukee, WI.

MC 158651 (Sub-10), filed April 8 1983. Applicant: GRAEBEL VAN LINES, INC., 719 North Third Ave., Wausau, WI 54401. Representative: John E. Koci (same address as applicant), (715) 675–9481. Transporting *household goods*, between points in the U.S., under continuing contract(s) with Deloitte Haskins & Sells, of New York, NY.

MC 158651 (Sub-11), filed April 8, 1983. Applicant: GRAEBEL VAN LINES, INC., 719 North Third Ave., Wausau, WI 54401. Representative: John E. Koci (same address as applicant), (715) 675–9481. Transporting *household goods*, between points in the U.S., under continuing contract(s) with Texas Air Corporation, of Houston, TX.

MC 161231, filed February 23, 1983, previously published in the **Federal Register** on March 21, 1983. Applicant: PLATEAU EXPRESS, INC., Rt. 11, Box 226, McMinnville, TN 37110. Representative: Roland M. Lowell, Fifth Floor, 501 Union St., Nashville, TN 37219, (615) 255–0540. Transporting (1) *metal products*, (2) *lumber and wood products*, (3) *electric motors*, (4) *clay, concrete, glass or stone products*, and (5) *waste or scrap materials not identified by industry producing*, (a) between points in IL, MS and PA, and (b) between points in IL, MS, PA and TN, on the one hand, and, on the other, points in the U.S. (except AK and HI).

Note.—This republication corrects the territorial application.

MC 164140 (Sub-1), filed April 8, 1983. Applicant: BELT'S TRANSPORTATION SERVICES, INC., 936 Fell Street, Baltimore, MD 21231. Representative: Robert K. Goren, 11300 Rockville Pike, Suite 1017, Rockville, MD 20852, (301) 984–6266. Transporting *general commodities* (except classes A and B explosives, commodities in bulk and household goods), between points in the U.S. (except AK and HI), under continuing contract(s) with Belt's Wharf Warehouses, Inc., of Baltimore, MD.

MC 165911, filed March 28, 1983. Applicant: GULF CARRIERS, INC., P.O. Box 42888, Dept. 288, Houston, TX 77042. Representative: Larry Strickland, 11410 Valley Spring, Houston, TX 77043, (713) 453–5247. Transporting *general commodities* (except classes A and B explosives, household goods and commodities in bulk), between points in TX, on the one hand, and, on the other, points in AL, AR, LA, MS and TX.

MC 165930, filed April 6, 1983. Applicant: COLORADO AIR FREIGHT EXPRESS, INC., 3955 Newport St., Suite B, Denver, CO 80207. Representative: Robert E. Butts (same address as applicant), (303) 399–6735. Transporting *truck parts and accessories*, between points in CO, WY, and NM, under continuing contract(s) with Drive Train Industries, Inc., of Denver, CO.

MC 166221, filed April 5, 1983. Applicant: CENTURY FURNITURE COMPANY, P.O. Box 608, Hickory, NC 28601. Representative: Terrell Price, 800 Briar Creek Rd., Ste. DD504, Charlotte, NC 28205, (704) 372–8212. Transporting *general commodities* (except classes A and B explosives, household goods and commodities in bulk), between points in the U.S. (except AK and HI), under continuing contract(s) with Shuford Mills, of Hickory, NC.

MC 166820, filed April 5, 1983. Applicant: GREENVILLE TRUCK LEASING CO., INC., Route 5, Box 452, Simpsonville, SC 29681. Representative: Mitchell King, Jr., P.O. Box 5711, Greenville, SC 29606, (803)–288–6000. Transporting *general commodities* (except classes A and B explosives, household goods and commodities in bulk), between points in the U.S. (except AK and HI), under continuing contract(s) with Globe Industries, Inc., of Chicago, IL.

MC 167220, filed March 30, 1983. Applicant: GENERAL FREIGHTWAYS CO., P.O. Box 103, Clearmont, WY 82835. Representative: Vernon A. Tietjen (same address as applicant), (307) 758–4473. Transporting *general commodities* (except classes A and B explosives, household goods and commodities in bulk), between points in AZ, CA, CO, ID, KS, MT, NE, NM, NV, ND, OK, OR, SD, TX, UT, WA, and WY.

MC 167221, filed April 4, 1983. Applicant: THE STRATEGISTS, INC., 9007 Tahoe Lane, Boulder, CO 80301. Representative: Thaddeus Makowski (same address as applicant), (303) 665–9007. As a *broker* of *household goods*, between points in the U.S.

MC 167231, filed April 4, 1983. Applicant: RIVERSIDE SCRAP IRON & METAL CORPORATION, 2993 6th St., P.O. Box 5288, Riverside, CA 92517. Representative: Daniel Jay Frankel (same address as applicant), (714) 686–2120. Transporting *newsprint rolls*, between points in Riverside County, CA.

MC 167250, filed April 4, 1983. Applicant: WILLIAM L. WATSON, 3069 Connell, Central Point, OR.

Representative: William L. Watson (same address as applicant), (503) 779-1156. Transporting *general commodities* (except classes A and B explosives and household goods) between points in the U.S. under continuing contract(s) with R & R Truck Brokers, Inc., of Medford, OR.

MC 167251, filed April 8, 1983. Applicant: FLEETWOOD EXPRESS, INC., 2813 18th Ave., Scottsbluff, NE 69361. Representative: Jack L. Shultz, P.O. Box 82028, Lincoln, NE 68501, (402)-475-6761. Transporting *fertilizer*, between points in Laramie County, WY, on the one hand, and, on the other, points in Scotts Bluff, Morrill, Box Butte, Banner and Cheyenne Counties, NE.

MC 167271, filed April 7, 1983. Applicant: MR. J'S, INC., 315 Second Ave., SE, Watertown, SD 57201. Representative: John C. Wiles, P.O. Box 235, 3 East Kemp, Suite 200, Watertown, SD 57201, (605) 886-6900. Transporting *flyash*, between points in IA, SD, MN, ND and NE, under continuing contract(s) with (1) Hallett Ready Mix, Inc., (2) Jimco Ready Mix Co., and (3) Concrete Dakota & Brick, each of Watertown, SD, and (4) R.E. Lien, Inc., of Milbank, SD.

MC 167300, filed April 8, 1983. Applicant: FRANCES I. HURD, d.b.a. FRITZ HURD TRUCKING, 953 Deschutes Rd., Palo Cedro, CA 96073. Representative: Roberta L. Hurd, 2355 Smith Ave., Redding, CA 96001. Transporting *lumber and wood products and building materials*, between points in CA, OR, WA, AZ, and NV.

[FR Doc 83-10602 Filed 4-20-83; 8:45 am]
BILLING CODE 7035-01-M

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[Vol. No. OP1-139]

## Motor Carriers; Proposed Exemptions

**AGENCY:** Interstate Commerce Commission.

**ACTION:** Notices of proposed exemptions.

**SUMMARY:** The motor carriers shown below seek exemptions pursuant to 49 U.S.C. 11343(e), and the Commission's regulations in Ex Parte No. 400 (Sub-No. 1), *Procedures for Handling Exemptions Filed by Motor Carriers of Property Under 49 U.S.C. 11343*, 367 I.C.C. 113 (1982), 47 FR 53303 (November 24, 1982).

**DATE:** Comments must be received within 30 days after the date of publication in the **Federal Register**.

**FOR FURTHER INFORMATION CONTACT:** Joyce D. Lannon, (202) 275-7992.

**SUPPLEMENTARY INFORMATION:** Please refer to the petition for exemption, which may be obtained free of charge by contacting petitioner's representative. In the alternative, the petition for exemption may be inspected at the offices of the Interstate Commerce Commission during usual business hours.

Decided: April 15, 1983.

By the Commission, Herber P. Hardy, Director, Office of Proceedings.

**Agatha L. Mergenovich,**

*Secretary.*

### Petitioners

MC-F-15216. Eby Bros. Inc., No. MC-114840, seeks an exemption from the requirement of prior regulatory approval for its purchase of authorities issued to Shoemaker Trucking Company in No. MC-138875, paragraphs 1, 6 and a portion of paragraph 27 of Sub-No. 312X which involve the transportation of building materials and lumber and wood products between certain points in Idaho and Arizona, New Mexico and Wyoming and waste or scrap materials between certain points in Idaho and Oregon, Utah, Wyoming, Nevada, California, Oregon and Washington. This purchase would necessarily entail the transfer of paragraphs 5 and 13 of Sub-No. 1, paragraph 1 of Sub-No. 22 and Sub-Nos. 62 and 72, which were superceded by paragraphs 1, 6 and a portion of 27 Sub-No. 312X. *Stewart Trucking Company*, MC-FC-79592 (December 1, 1982). Petitioner's Gateway application to tack these authorities with its existing authority has already been dismissed. Send comments to: (1) Motor Section, Room 2139, Interstate Commerce Commission, Washington, DC 20423, and (2) Petitioner's Representative: Timothy R. Stivers, P.O. Box 1576, Boise, ID 83701. Comments should refer to MC-F-15216.

MC-F-15226, filed: April 4, 1983. STATE TRANSPORTATION, INC. (State) (P.O. Box 1349, Portsmouth, NH 03801)—purchase exemption—ADAMS TRUCKING, INC. (Adams) (P.O. Box 890, Sanford, ME 04073). State Transportation, Inc. (No. MC-145895), and Adams Trucking, Inc. (No. MC-157101), seek an exemption from the requirement of prior regulatory approval for the purchase by State of all of Adams' operating rights. Joseph J. O'Brien, who controls State, and who also controls Rockingham Carriage Service, Inc. (No. MC-153553) and North American Driveway, Inc. (No. MC-144983), seeks authority to acquire control of the said rights through the transaction. No application for TA has been filed. Send comments to: (1) Motor Section, Room 2139, Interstate Commerce Commission, Washington, DC 20423. (2) Petitioner's representative: Robert G. Parks, Suite 101, 20 Walnut St., Wellesley Hills, MA 02181. Comments should refer to No. MC-F-15226.

MC-F-15227, ROBERT P. LAYMAN—Continuance in Control Exemption—ALEX CITY SALT TERMINAL, INC. and NORTH ALABAMA EXPRESS, INC. Robert P. Layman seeks an exemption from the requirement under section 11343 of prior regulatory approval for his continuance in control of Alex City Salt Terminal, Inc. (No. MC-158507) and North Alabama Express, Inc. (No. MC-97260), both motor common carriers. Addresses: Send Comments to: Motor Section, Room 2139, Interstate Commerce Commission, Washington, D.C. 20423, and (2) Petitioner's representative, Donald B. Sweeney, Jr., Esq., P.O. Box 2366, Birmingham, AL 35201. Comments should refer to No. MC-F-15227.

[FR Doc. 83-10598 Filed 4-20-83; 8:45 am]
BILLING CODE 7035-01-M

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[Finance Docket No. 30169]

## Indiana Hi-Rail Corporation; Temporary Exemption; Lease and Operate Between New Castle and Rushville, IN

**AGENCY:** Interstate Commerce Commission.

**ACTION:** Notice of exemption.

**SUMMARY:** The Interstate Commerce Commission temporarily exempts the Indiana Hi-Rail Corporation's (IHR) lease and operation of a 22.21-mile rail line between Rushville and New Castle, IN from prior approval under 49 U.S.C. 10901.

**DATES:** This exemption shall be effective on April 15, 1983. Petitions to reopen must be filed by May 5, 1983.

**ADDRESSES:** Send pleadings referring to Finance Docket No. 30169 to:

(1) Rail Section, Room 5349, Interstate Commerce Commission, Washington, DC 20423; or

(2) Petitioner's representative: Anthony J. Ciccone, Jr., 2033 K Street NW., Washington, DC 20006.

**FOR FURTHER INFORMATION CONTACT:** Louis E. Gitomer, (202) 275-7245.

**SUPPLEMENTARY INFORMATION:** Additional information is contained in the Commission's decision. To purchase a copy of the entire decision, write to T. S. InfoSystems, Inc., Room 2227, Interstate Commerce Commission, Washington, DC 20423 or call 289-4357 (D.C. Metropolitan Area) or toll free 800-424-5403.

Decided: April 15, 1983.

By the Commission, Chairman Taylor, Vice Chairman Sterrett, Commissioners Andre and Gradison.

Agatha L. Mergenovich,

*Secretary.*

[FR Doc. 83-10596 Filed 4-20-83; 8:45 am]

BILLING CODE 7035-01-M

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[Ex Parte No. 388; Sub-20]

## State Intrastate Rail Rate Authority, Pub. L. 96-448, New Hampshire

**AGENCY:** Interstate Commerce Commission.

**ACTION:** Extension of time for filing to notice of certification decision and filing schedule for new plans.

**SUMMARY:** In the **Federal Register** notice of January 27, 1983 (48 FR 3892), the date comments were due in this proceeding was March 14, 1983, which date was subsequently extended to April 13, 1983, by order not published. At the request of the New Hampshire Public Utilities Commission, the date has been postponed another 30 days to May 13, 1983.

**DATES:** Revised standards and procedures are due May 13, 1983. Comments of interested parties on the submission are due June 13, 1983.

**ADDRESS:** Send an original and, if possible, 15 copies of all comments to: Rail Section, Room 5344, Interstate Commerce Commission, Washington, D.C. 20423.

**FOR FURTHER INFORMATION CONTACT:** Douglas Galloway, (202) 275-7278.

By the Commission, Reese H. Taylor, Jr., Chairman.

Dated: April 14, 1983.

Agatha L. Mergenovich,

*Secretary.*

[FR Doc. 10597 Filed 4-20-83; 8:45 am]

BILLING CODE 7035-01-M

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[Ex Parte No. 387]

## Exemptions for Contract Tariffs; Burlington Northern Railroad Co. et al.

**AGENCY:** Interstate Commerce Commission.

**ACTION:** Notices of provisional exemptions.

**SUMMARY:** Provisional exemptions are granted under 49 U.S.C. 10505 from the notice requirements of 49 U.S.C. 10713(e), and the below-listed contract tariffs may become effective on one day's notice. These exemptions may be revoked if protests are filed.

**DATE:** Protests are due within 15 days of publication in the **Federal Register.**

**ADDRESS:** An original and 6 copies should be mailed to: Office of the Secretary, Interstate Commerce Commission, Washington, DC 20423.

**FOR FURTHER INFORMATION CONTACT:** Douglas Galloway, (202) 275-7278.

**SUPPLEMENTARY INFORMATION:** The 30-day notice requirement is not necessary in these instances to carry out the transportation policy of 49 U.S.C. 10101(a) or to protect shippers from abuse of market power; moreover, the transaction is of limited scope. Therefore, we find that the exemption requests meet the requirements of 49 U.S.C. 10505(a) and are granted subject to the following conditions:

These grants neither shall be construed to mean that the Commission has approved the contracts for purposes of 49 U.S.C. 10713(e) not that the Commission is deprived of jurisdiction to institute a proceeding on its own initiative or on complaint, to review these contracts and to determine their lawfulness.

| Sub-No | Name of railroad, contract No., and specifics | Review Board [1] | Decided date |
|---|---|---|---|
| 897 | Burlington Northern Railroad Co., ICC-BN-C-0289, (Grain or grain products) via ports in State of Washington | 1 | 4-14-83 |
| 898 | Southern Pacific Transportation Co., ICC-SP-C-0496, (Plate or sheet, iron or steel) | 2 | 4-14-83 |
| 899 | Southern Pacific Transportation Co., ICC-SP-C-0495, (Plate or sheet, iron or steel) | 3 | 4-14-83 |

[1] Review Board No. 1, Members Parker, Chandler, and Fortier. Review Board No. 2, Members Carleton, Williams, and Ewing. Review Board No. 3, Members Krock, Joyce, and Dowell.

This action will not significantly affect the quality of the human environment or conservation of energy resources.

**Authority:** 49 U.S.C. 10505.

Agatha L. Mergenovich,

*Secretary.*

[FR Doc. 83-10439 Filed 4-20-83; 8:45 am]

BILLING CODE 7035-01-M

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## NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

### Music Advisory Panel; Meeting

Pursuant to Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), as amended, notice is hereby given that a meeting of the Music Advisory Panel (Composers Prescreening) to the National Council on the Arts will be held on May 9-20, 1983, from 9:00 a.m.-5:30 p.m. in Room 730-731 of the Nancy Hanks Center, 1100 Pennsylvania Avenue, N.W., Washington, D.C.

This meeting is for the purpose of Panel review, discussion, evaluation, and recommendation on applications for financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including discussion of information given in confidence to the agency by grant applicants. In accordance with the determination of the Chairman published in the **Federal Register** of February 13, 1980, these sessions will be closed to the public pursuant to subsections (c)(4), (6) and 9(b) of section 552b of Title 5, United States Code.

Further information with reference to this meeting can be obtained from Mr. John H. Clark, Advisory Committee Management Officer, National Endowment for the Arts, Washington, D.C. 20506, or call (202) 634-6070.

Dated: April 13, 1983.

**John H. Clark,**

*Director, Office of Council and Panel Operations, National Endowment for the Arts.*

[FR Doc. 83-10572 Filed 4-20-83; 8:45 am]

BILLING CODE 7537-01-M

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### Visual Arts Advisory Panel Meeting

Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), as amended, notice is hereby given that a meeting of the Visual Arts Advisory Panel (Artist Nominations Section) to the National Council on the Arts will be held on May 12, 1983, from 10:00 a.m.-5:00 p.m. at Neptune & Thomas Associates, 1560 West Colorado Boulevard, Pasadena, CA.

This meeting is for the purpose of Panel review, discussion, evaluation, and recommendation regarding the selection of artists to be commissioned to create works of art for Federal buildings under construction or renovation. In accordance with the determination of the Chairman published in the **Federal Register** of February 13, 1980, these sessions will be closed to the public pursuant to subsections (c) (4), (6) and 9 (b) of section 552b of Title 5, United States Code.

Further information with reference to this meeting can be obtained from Mr. John H Clark, Advisory Committee Management Officer, National Endowment for the Arts, Washington, D.C. 20506, or call (202) 634-6070.

**John Clark,**

*Director, Office of Council and Panel Operations, National Endowment for the Arts.*

[FR Doc.83-0573 Filed-4-20-83; 8:45 am]

BILLING CODE 7537-01-M

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### Humanities Panel Meetings

**AGENCY:** National Endowment for the Humanities.

**ACTION:** Notice of meetings.

**SUMMARY:** Pursuant to the provisions of the Federal Advisory Committee Act (Pub. L. 92–463, as amended) notice is given that the following meetings of the Humanities Panel will be held at the Old Post Office, 1100 Pennsylvania Avenue, NW., Washington, D.C. 20506:

Date: May 12–13, 1983.
Time: 8:00 a.m. to 5:30 p.m.
Room: 315.
Program: This meeting will review applications submitted for General Research: Conference Panel, Division of Research Programs, for projects beginning after October 1, 1983.

Date: May 16–17, 1983.
Time: 8:30 a.m. to 5:00 p.m.
Room: 415.
Program: This meeting will review applications submitted for Humanistics Projects in Media, Division of General Programs, for projects beginning after October 1, 1983.

Date: May 19–20, 1983.
Time: 8:30 a.m. to 5:00 p.m.
Room: 415.
Program: This meeting will review applications submitted for Humanistics Projects in Media. (Special Deadline for Children's Media and Continuing Projects that have already received NEH support and need notification before April 1, 1984 that they can move to the next phase of their projects.) Division of General Programs, for Projects beginning after October 1, 1983.

The proposed meetings are for the purpose of Panel review, discussion, evaluation and recommendation on applications for financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including discussion of information given in confidence to the agency by grant applicants. Because the proposed meetings will consider information that is likely to disclose: (1) Trade secrets and commercial or financial information obtained from a person and privileged or confidential; (2) information of a personal nature the disclosure of which would constitute a clearly unwarranted invasion of personal privacy; and (3) information the disclosure of which would significantly frustrate implementation of proposed agency action; pursuant to authority granted me by the Chairman's Delegation of Authority to Close Advisory Committee Meetings, dated January 15, 1978, I have determined that these meetings will be closed to the public pursuant to subsections (c) (4), (6) and (9)(B) of section 552b of Title 5, United States Code.

Further information about these meetings can be obtained from Mr. Stephen J. McCleary, Advisory Committee Management Officer, National Endowment for the Humanities, Washington, D.C. 20506, or call (202) 786–0322.

**Stephen J. McCleary,**

*Advisory Committee Management Officer.*

[FR Doc. 83–10577 Filed 4–20–83; 8:45 am]

BILLING CODE 7536–01–M

## Music Advisory Panel (Composers Prescreening); Meeting

Pursuant to Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), as amended, notice is hereby given that a meeting of the Music Advisory Panel (Composers Prescreening) to the National Council on the Arts will be held on May 17–20, 1983, from 9:00 a.m.–5:30 p.m. in Room 730–731 of the Nancy Hanks Center, 1100 Pennsylvania Avenue, N.W., Washington, D.C.

This meeting is for the purpose of Panel review, discussion, evaluation, and recommendation on applications for financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including discussion of information given in confidence to the agency by grant applicants. In accordance with the determination of the Chairman published in the **Federal Register** of February 13, 1980, these sessions will be closed to the public pursuant to subsections (c)(4), (6) and 9(b) of section 552b of Title 5, United States Code.

Further information with reference to this meeting can be obtained from Mr. John H. Clark, Advisory Committee Management Officer, National Endowment for the Arts, Washington, D.C. 20506, or call (202) 634–6070.

**John H. Clark,**

*Director, Office of Council and Panel Operations, National Endowment for the Arts.*

[FR Doc. 83–10574 Filed 4–20–83; 8:45 am]

BILLING CODE 7537–01–M

## National Council on the Humanities Advisory Committee; Amendment to Notice of Meeting

**AGENCY:** National Endowment for the Humanities.

**ACTION:** Amendment to notice of meeting.

**SUMMARY:** On April 11, 1983 the National Endowment for the Humanities published a notice in the **Federal Register** at page 15554 (48 FR 15554) of a meeting of the National Council on the Humanities to be held May 4–6, 1983. That notice is hereby amended by the following addition to the agenda for May 4, 1983. The Council Committee on the 1984 Jefferson Award and Address will meet from 9:30 a.m. to 5:00 p.m. in the Chairman's Conference Room, Room 506, Old Post Office, 1100 Pennsylvania Avenue, N.W., Washington, D.C. This portion of the meeting will not be open to the public pursuant to subsections (c)(4), (6) and (9)(B) of section 552b of Title 5, United States Code for the reasons stated in the original notice.

**Stephen J. McCleary,**

*Advisory Committee Management Officer.*

[FR Doc. 83–10578 Filed 4–20–83; 8:45 am]

BILLING CODE 7536–01–M

## NUCLEAR REGULATORY COMMISSION

**[Docket Nos. 50–440–OL and 50–441–OL]**

## Cleveland Electric Illuminating Company, et al. (Perry Nuclear Power Plant, Units 1 and 2); Hearing

April 15, 1983.

May 23–27 and May 31–June 3, 1983, the Atomic Safety and Licensing Board (Board) will receive limited appearance statements and conduct an evidentiary hearing at the Lake County Administration Center, Public Assembly Room, 105 Main Street, Painesville, Ohio. The principal purpose of the hearing is to receive evidence on the adequacy of Cleveland Electric Illuminating Company, *et al.*'s system for assuring itself that its contractors are doing quality work, consistent with the safety of the Perry Nuclear Power Plant and the surrounding community.

Ordinary hours of hearing, on May 24 to May 27 and June 1 to June 3, will be from 9 a.m. to 5 p.m., subject to periodic recesses and to extension of hours in order to complete the hearing during the scheduled time period.

Members of the public who are not parties to the proceeding are invited to submit written limited appearance statements and to make brief oral presentations to the Board during a limited-appearance session to be held beginning at 7:30 p.m. on May 23 and 31, 1983. The principal purpose of these statements is to inform the Board about safety and environmental issues that have been place before it by the parties or about other issues of such importance that the Board may decide to consider them even though the parties have not raised them.

Although statements generally will be permitted regardless of their direct relevance, the Board's authority is limited; in particular, it is prohibited from reaching decisions contrary to the Commission's rules and regulations. Consequently, some questions may be more effectively addressed in petitions

to the Nuclear Regulatory Commission or the Congress of the United States.

Limited appearance statements will become part of the record of the case. Generally, written statements are not limited in length. However, oral presentations will be limited to 5 minutes, subject to extension at the Board's discretion. Oral presentations should summarize the key points made in written testimony and, if additional time may be needed, these statements should indicate the specific subjects to be discussed if an extension of time is granted.

People wishing to appear may notify the Board of their intention by writing to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Attention: Docketing and Service Branch, Washington, D.C. 20555. Please refer to the Docket Nos. 50–440 and 50–441. People unable to provide advance notice of their intention to participate may schedule an oral appearance by notifying the Board of their intention, in writing, no later than 10 a.m. on Friday morning, May 20, 1983.

For the Atomic Safety and Licensing Board.

**Peter B. Bloch,**

*Chairman, Administrative Judge.*

[FR Doc. 83-10662 Filed 4-20-83; 8:45 am]

BILLING CODE 7590-01-M

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[Docket No. 50-255]

## Consumers Power Co.; Order Confirming TMI Commitments; Correction

On March 23, 1983 (48 FR 12170) an Order issued by the U.S. Nuclear Regulatory Commission (NRC) was published in the **Federal Register.** This Order confirms commitments made by the Consumers Power Company for Post-TMI related issues involving the Palisades Plant, which is located in Van Buren County, Michigan.

The March 1, 1983 completion date for Item II.F.1, Accident Monitoring, appearing in Page 4 of the Order and Attachment 1 thereto, has been changed to July 1, 1983.

For additional details, see NRC's letter to the licensee dated April 14, 1983.

Dated at Bethesda, Maryland, this 14th day of April 1983.

For the Nuclear Regulatory Commission.

**Dennis M. Crutchfield,**

*Chief, Operating Reactors Branch #5, Division of Licensing.*

[FR Doc. 83-10663 Filed 4-20-83; 8:45 am]

BILLING CODE 7590-01-M

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[Docket No. 50-409]

## Dairyland Power Cooperative, La Crosse Boiling Water Reactor; Issuance of Amendment to Provisional Operating License

The U.S. Nuclear Regulatory Commission (the Commission) has issued Amendment No. 33 to Provisional Operating License No. DPR–45, issued to Dairyland Power Cooperative (the licensee), which revised the Technical Specifications for operation of the La Crosse Boiling Water Reactor (the facility) located in Vernon County, Wisconsin. This amendment is effective as of its date of issuance.

The amendment authorizes Technical Specification changes pertaining to the required frequency of certain surveillance tests to preclude requiring the plant to shut down from power operation to perform certain routine surveillance tests.

The applications for amendment comply with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR Chapter I, which are set forth in the license amendment. Prior public notice of this amendment was not required since the amendment does not involve a significant hazards consideration.

The Commission has determined that the issuance of this amendment will not result in any significant environmental impact and that pursuant to 10 CFR 51.5(d)(4) an environmental impact statement or negative declaration and environmental impact appraisal need not be prepared in connection with issuance of this amendment.

For further details with respect to this action, see: (1) The applications for amendment dated July 14, 1980, September 29, 1982, October 29, 1982, and supplement thereto dated April 6, 1983, and application dated February 3, 1983; (2) Amendment No. 33 to License No. DPR–45; and (3) the Commission's related Safety Evaluation. These items are available for public inspection at the Commission's Public Document Room, 1717 H Street, N.W., Washington, D.C. and at the La Crosse Public Library, 800 Main Street, La Crosse, Wisconsin 54601. A single copy of item (2) may be obtained by request addressed to the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Director, Division of Licensing.

Dated at Bethesda, Maryland, this 15th day of April 1983.

For the Nuclear Regulatory Commission.

**Dennis M. Crutchfield,**

*Chief, Operating Reactors Branch #5, Division of Licensing.*

[FR Doc. 83-10664 Filed 4-20-83; 8:45 am]

BILLING CODE 7590-01-M

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[Docket Nos. 50-369 and 50-370]

## Duke Power Co.; Issuance of Amendments Facility Operating License Nos. NPF–9 and NPF–17

The U.S. Nuclear Regulatory Commission (the Commission) has issued Amendment No. 20 to Facility Operating License No. NPF–9 and Amendment No. 1 to Facility Operating License No. NPF–17, issued to Duke Power Company (licensee) for the McGuire Nuclear Station, Units 1 and 2 (the facilities) located in Mecklenburg County, North Carolina. These amendments are effective as of their dates of issuance.

These amendments increase the maximum flow rate for the centrifugal charging pump and correct several typographical errors in the initial issuance of the Technical Sspecifications.

Issuance of these amendments 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 amendments. Prior public notice of these amendments was not required since the amendments do not involve a significant hazards consideration.

The Commission has determined that the issuance of these amendments will not result in any significant environmental impact and that pursuant to 10 CFR 51.5(d)(4) an environmental impact statement, or negative declaration and environmental impact appraisal need not be prepared in connection with issuance of these amendments.

For further details with respect to this action, see: (1) Duke Power Company letter dated March 24, 1983. (2) Amendment No. 20 to Facility Operating License No. NPF–9, (3) Amendment No. 1 to Facility Operating License No. NPF–17, and (4) the Commission's related Safety Evaluation.

These items are available for public inspection at the Commission's Public Document Room, 1717 H Street, NW., Washington, D.C., and the Atkins Library, University of North Carolina, Charlotte (UNCC Station), North

Carolina 28223. A copy of these items may be obtained upon request addressed to the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Director, Division of Licensing.

Dated at Bethesda, Maryland, this 13th day of April 1983.

For the Nuclear Regulatory Commission.

**Elinor G. Adensam,**

*Chief, Licensing Branch No. 4, Division of Licensing, NRR.*

[FR Doc. 83-10065 Filed 4-20-83; 8:45 am]

BILLING CODE 7590-01-M

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**[Docket Nos. 50-315 and 50-316]**

## Indiana and Michigan Electric Co.; Issuance of Amendment To Facility Operating Licenses

The U.S. Nuclear Regulatory Commission (the Commission) has issued Amendment No. 71 to Facility Operating License No. DPR-58, and Amendment No. 53 to Facility Operating License No. DPR-74 issued to Indiana and Michigan Electric Company (the licensee), which revised Technical Specifications for operation of Donald C. Cook Nuclear Plant, Unit Nos. 1 and 2 (the facilities) located in Berrien County, Michigan. The amendments are effective as of the date of issuance.

The amendment revise the Technical Specifications to reflect revised surveillance requirements for safety-related snubbers. These amendments also add a section 4.0.5 to the Unit 1 Technical Specifications on surveillance requirements for inservice inspection and testing of components and deletes a portion of section 4.0.4 in Unit 1 and 4.0.5.a.1 in Unit 2, which are no longer applicable. These latter changes are made to clarify the Technical Specifications and make them consistent with Standard Technical Specification requirements.

The application for the amendments complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR Chapter I, which are set forth in the license amendments. Prior public notice of these amendments was not required since the amendments do not involve a significant hazards consideration.

The Commission has determined that the issuance of these amendments will not result in any significant environmental impact and that pursuant to 10 CFR 51.5(d)(4) an environmental impact statement or negative declaration and environmental impact appraisal need not be prepared in connection with issuance of these amendments.

For further details with respect to this action, see: (1) The application for amendments dated November 11, 1981, as supplemented February 25, 1983, (2) Amendment Nos. 71 and 53 to License Nos. DPR-58 and DPR-74, and (3) the Commission's related Safety Evaluation. All of these items are available for public inspection at the Commission's Public Document Room, 1717 H Street, N.W., Washington, D.C. and at the Maude Reston Palenske Memorial Library, 500 Market Street, St. Joseph, Michigan 49085. A copy of items (2) and (3) may be obtained upon request addressed to the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Director, Division of Licensing.

Dated at Bethesda, Maryland, this 13th day of April 1983.

For the Nuclear Regulatory Commission.

**Steven A. Varga,**

*Chief, Operating Reactors Branch No. 1, Division of Licensing.*

[FR Doc. 83-10066 Filed 4-20-83; 8:45 am]

BILLING CODE 7590-01-M

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**[Docket No. 50-387]**

## Pennsylvania Power & Light Co., and Allegheny Electric Cooperative, Inc.; Issuance of Amendment to Facility Operating License and Exemption From Regulations

The U.S. Nuclear Regulatory Commission (the Commission) has issued Amendment No. 13 to Facility Operating License No. NPF-14, issued to Pennsylvania Power & Light Company and Allegheny Electric Cooperative, Inc., for Susquehanna Steam Electric Station, Unit 1 (the facility) located in Luzerne County, Pennsylvania. The amendment incorporates, as an administrative change, Change M of the Susquehanna Steam Electric Station Physical Security Plan into the license condition regarding the physical security plan. This amendment also provides an exemption from the requirements of Appendix J to 10 CFR Part 50 for the first fuel cycle when performing local leak rate testing of Residual Heat Removal (RHR) relief valves in accordance with Technical Specification 4.6.1.2. The amendment and exemption are effective as of the date of issuance.

The application for the amendment and for the exemption 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. Prior public notice of the amendment was not required since the amendment does not involve a significant hazards consideration.

The Commission has determined that the issuance of this amendment and exemption will not result in any significant environmental impact and that pursuant to 10 CFR 51.5(d)(4) an environmental impact statement or negative declaration and environmental impact appraisal need not be prepared in connection with issuance of this amendment and exemption.

For further details with respect to this action, see: (1) The application for amendment dated March 14, 1983, (2) Amendment No. 13 to License; NPF-14, dated April 14, 1983; and (3) the Commission's evaluation dated April 14, 1983. All of these items are available for public inspection at the Commission's Public Document Room, 1717 H Street, N.W., Washington, D.C. 20555, and at the Osterhout Free Library, Reference Department, 71 South Franklin Street, Wilkes-Barre, Pennsylvania 18701. A copy of items (1), (2) and (3) may be obtained upon request addressed to the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Director, Division of Licensing.

Dated at Bethesda, Maryland, this 14th day of April 1983.

For the Nuclear Regulatory Commission.

**Robert A. Purple,**

*Deputy Director, Division of Licensing, Office of Nuclear Reactor Regulation.*

[FR Doc. 83-10067 Filed 4-20-83; 8:45 am]

BILLING CODE 7590-01-M

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**[Docket No. 50-259]**

## Tennessee Valley Authority; Issuance of Amendment to Facility Operating License

The U.S. Nuclear Regulatory Commission (the Commission) has issued Amendment No. 89 to Facility Operating License No. DPR-33 issued to Tennessee Valley Authority (the licensee), which revised the Technical Specifications for operation of the Browns Ferry Nuclear Plant, Unit No. 1 (the facility) located in Limestone County, Alabama. The amendment was effective January 25, 1983.

This amendment changed the Technical Specifications to permit operation of 50% power between January 25, 1983 and January 31, 1983

with one recirculation loop out of service.

The application for this amendment complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR Chapter I, which are set forth in the license amendment. Prior public notice of this amendment was not required since the amendment does not involve a significant hazards consideration.

The Commission has determined that the issuance of this amendment will not result in any significant environmental impact and that pursuant to 10 CFR 51.5(d)(4) an environmental impact statement, or negative declaration and environmental impact appraisal need not be prepared in connection with issuance of this amendment.

For further details with respect to this action, see: (1) The application for amendment dated January 25, 1983 (2) Amendment No. 89 to License No. DPR-33, and (3) the Commission's related Safety Evaluation. All of these items are available for public inspection at the Commission's Public Document Room, 1717 H Street, NW., Washington, D.C. and at the Athens Public Library, South and Forrest, Athens, Alabama 35611. A copy of items (2) and (3) may be obtained upon request addressed to the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Director, Division of Licensing.

Dated at Bethesda, Maryland, this 14th day of April 1983.

For the Nuclear Regulatory Commission.

**Domenic B. Vassallo,**

*Chief, Operating Reactors Branch #2, Division of Licensing.*

[FR Doc. 83-10668 Filed 4-20-83; 8:45 am]

BILLING CODE 7590-01-M

## RAILROAD RETIREMENT BOARD

### Agency Forms Submitted for OMB Review

**AGENCY:** Railroad Retirement Board.

**ACTION:** In accordance with the Paperwork Reduction Act of 1980 (44 U.S.C. Chapter 35), the Board has submitted the following proposal(s) for the collection of information to the Office of Management and Budget for review and approval.

Summary of Proposal(s):

(1) Collection title: Statement of death by funeral director.

(2) Form(s) submitted: G-273.

(3) Type of request: Revision.

(4) Frequency of use: On occasion.

(5) Respondents: Funeral home directors.

(6) Annual responses: 12,000.

(7) Annual reporting hours: 600.

(8) Collection description: The railraod retirement Act provides for payment of benefits to qualified individuals due to death of a railroad worker. The statement will obtain information needed to support a claim for death benefits.

Additional Information or Comments: Copies of the proposed forms and supporting documents may be obtained from Pauline Lohens, the agency clearance officer (312-751-4692). Comments regarding the information collection should be adressed to Pauline Lohens, Railroad Retirement Board, 844 Rush Street, Chicago, Illinois 60611 and the OMB reviewer, Milo Sunderhauf (202-395-6880), Office of Management and Budget Room 3201, New Executive Office Building, Washington, D.C. 20503.

**William A. Oczkowski,**

*Director of Planning and Information Management.*

[FR Doc. 83-10680 Filed 4-20-83; 8:45 am]

BILLING CODE 7905-01-M

## SECURITIES AND EXCHANGE COMMISSION

### Cincinnati Stock Exchange; Application for Unlisted Trading Privileges and of Opportunity for Hearing

April 15, 1983.

The above named national securities exchange has filed an application with the Securities and Exchange Commission pursuant to Section 12(f)(1)(B) of the Securities Exchange Act of 1934 and Rule 12f-1 thereunder, for unlisted trading privileges in the common stock of:

BSN Corp.

Common Stock, $.01 Per Value (File No. 7-6572)

This security is listed and registered on one or more other national securities exchange and is reported on the consolidated transaction reporting system.

Interested persons are invited to submit on or before May 6, 1983 written data, views and arguments concerning the above-referenced application. Persons desiring to make written comments should file three copies thereof with the Secretary of the Securities and Exchange Commission, Washington, D.C. 20549. Following this opportunity for hearing, the Commission will approve the application if it finds, based upon all the information available to it, that the extension of unlisted trading privileges pursuant to such application is consistent with the maintenance of fair and orderly markets and the protection of investors.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

**George A. Fitzsimmons,**

*Secretary.*

[FR Doc. 83-10671 Filed 4-20-83; 8:45 am]

BILLING CODE 8010-01-M

**[Release No. 19682; File No. SR-Amex-83-7]**

### Filing and Immediate Effectiveness Of Proposed Rule Change by the American Stock Exchange, Inc.

April 15, 1983.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act"), 15 U.S.C. 78s(b)(1), notice is hereby given that on April 7, 1983, the American Stock Exchange, Inc. ("Amex") filed with the Securities and Exchange Commission the proposed rule change as described herein. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

The Amex's proposed rule change provides that "all-or-none" option orders entrusted to a specialist be disclosed to the trading crowd if they match or better the bid or offer for the series. The orders would be announced to the trading crowd as part of the quoted market, but not as part of the bid or offer.

The foregoing change has become effective, pursuant to Section 19(b)(3)(A) of the Act and subparagraph (e) of rule 19b-4 under the Act. At any time within 60 days of the filing of such proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

Interested persons are invited to submit written data, views and arguments concerning the submission within 21 days after the date of publication in the **Federal Register.** Persons desiring to make written comments should file six copies thereof with the Secretary of the Commission, Securities and Exchange Commission, 450 Fifth Street, N.W., Washington, DC 20549. Reference should be made to File No. SR-Amex-83-7.

Copies of the submission, all subsequent amendments, all written statements with respect to the proposed

rule change which are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those which 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 Room. Copies of the filing and of any subsequent amendments also will be available for inspection and copying at the principal office of the above-mentioned self-regulatory organization.

For the Commission, by the Division of Market Regulation pursuant to delegated authority.

**George A. Fitzsimmons,**

*Secretary.*

[FR Doc 83-10073 Filed 4-20-83; 8:45 am]

BILLING CODE 8010-01-M

## Midwest Stock Exchange, Inc.; Applications for Unlisted Trading Privileges and of Opportunity for Hearing

April 15, 1983.

The above named national securities exchange has filed applications with the Securities and Exchange Commission pursuant to Section 12(f)(1)(B) of the Securities Exchange Act of 1934 and Rule 12f-1 thereunder, for unlisted trading privileges in the following stocks:

Acco World Corporation
Common Stock, $.05 Par Value (File No. 7-6573)
Grubb & Ellis Co.
Common Stock, $1 Par Value (File No. 7-6574)
Perry Drug Stores, Inc.
Common Stock, $.05 Par Value (File No. 7-6575)
Prairie Producing Co.
Common Stock, $.01 Par Value (File No. 7-6576)

These securities are listed and registered on one or more other national securities exchange and are reported in the consolidated transaction reporting system.

Interested persons are invited to submit on or before May 6, 1983 written data, views and arguments concerning the above-referenced applications. Persons desiring to make written comments should file three copies thereof with the Secretary of the Securities and Exchange Commission, Washington, D.C. 20549. Following this opportunity for hearing, the Commission will approve the applications if it finds, based upon all the information available to it, that the extensions of unlisted trading privileges pursuant to such applications are consistent with the maintenance of fair and orderly markets and the protection of investors.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

**George A. Fitzsimmons,**

*Secretary.*

[FR Doc. 83-10075 Filed 4-20-83; 8:45 am]

BILLING CODE 8010-01-M

**[Release No. 34-19675; File No. SR-NASD 83-1]**

## Self-Regulatory Organizations; Proposed Rule Change By National Association of Securities Dealers, Inc.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934, 15 U.S.C. 78s(b)(1), notice is hereby given that on January 20, 1983, the National Association of Securities Dealers, Inc. ("Association") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing the 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 proposed rule change adds a new section to Schedule D to Article XVI of the Association's By-Laws for the purpose of implementing a system for the exchange of information on direct participation program (primarily limited partnership) securities ("System"). The provisions of the proposed rule change describe qualifications for subscribers to the System and the securities on which information may be entered into the System.

### II. Self-Regulatory Organization's Statement Regarding 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 comments may be examined at the places specified in Item IV 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.* This proposed rule change is the result of many months study by the Association's Real Estate Committee of possible means for developing a system for the exchange of information on direct participation program securities, during which a survey of members was conducted in early 1980 to determine interest in such a System. Almost 20 percent of the membership responded, with 68 percent favoring establishment of a System.

In order to implement such an information system, the Association is proposing to amend Schedule D to Article XVI of the Association's By-Laws to incorporate certain technical rules as new Part XV. This proposed rule change is consistent with Sections 15A(b)(6) and 15A(b)(11) of the Securities Exchange Act of 1934, as amended ("Exchange Act").

*Description of System*

The proposed rule change would enable the Association to establish an "electronic bulletin board" that will provide a means of communications for an exchange of information but no execution capability. Broker/dealers participating in the System will not be required to maintain firm, continuous or two-sided quotations and will not necessarily function as market-makers in the normal sense. The System will be accessed through NASDAQ terminals and will provide subscribing members with on-line ability to enter and update indications of interest in any security approved for the System and to query a data base to review information on individual securities or groups.

*Analysis of Proposed Amendment To Schedule D to By-Laws*

Following is a discussion of the provisions of proposed part XV to Schedule D.

*Section A: General.* Section A contains a general prohibition on the entry of information into the System except in accordance with the proposed rule.

*Section B: Definitions.* Section B incorporates definitions of "direct participation program system," "eligible broker/dealer," "authorized security," and "trading unit" into the proposed rule. The terms defined in Section B are, for the most part, self-explanatory. The term "trading unit" is defined to be the minimum number of direct participation program securities which can be transferred as a unit pursuant to the terms contained in the partnership agreement of the program.

*Section C: Eligible Broker/Dealers.* Paragraph 1 of Section C sets forth the qualifying criteria which a broker/

dealer must meet in order to be considered eligible to enter information into the System. The first two criteria, Subparagraphs 1.a. and b., are the familiar requirements that a broker/dealer must be registed with the Securities and Exchange Commission and a member in good standing of the Association, as well as qualified with the Association to conduct a general securities business or a business in direct participation programs.

Subparagraph 1.c. of Section C requires that a broker/dealer must maintain net capital of at least $25,000 to be eligible to enter information into the System. The Association's interpretation of the $25,000 net capital requirement relates only to actual capital held and not to the firm's ability to hold customer funds or securities. Under this interpretation, a firm can elect to participate in the System by obtaining the requisite additional capital, although the firm is not qualified to handle customer funds and securities.

In addition, the Association has determined that broker/dealers unable to meet the $25,000 net capital standard may be able to arrange to have access to the System through other broker/dealers. Under this interpretation, a firm without sufficient net capital may be able to enter into a relationship with a firm with the requisite $25,000 net capital to clear the transaction in the System.

Paragraph 2 of Section C establishes the general requirement that a broker/dealer entering information into the System must have reasonable grounds to believe that the information represents a bona fide indication of interest in the purchase or sale of a trading unit of securities. In addition, where the indication of interest is for the sale of a trading unit, the broker/dealer must have reasonable grounds to believe that the unit will be transferred to a purchaser.

*Section D: Authorized Securities.* Paragraph 1 of Section D requires that the security be issued by a direct participation program and be currently registered under Section 12(g) of the 1934 Act; that the issuer be current in its reporting requirements under the 1934 Act; that the partnership have issued and outstanding at least 10,000 trading units owned by not less than 300 persons; and that at least one broker/dealer stands ready to enter information into the System on the security.

Paragraph 2 of Section D describes the circumstances under which an otherwise eligible security shall not be authorized for entry into the System and an authorized security will be subject to suspension or cancellation of its authorization. Such circumstances include the suspension of the security from being traded over-the-counter, failure by the issuer to promptly disclose to the public any material information which may affect the value of its securities or influence investors' decisions, and the fact that the security is no longer registered under Section 12(g) of the 1934 Act. Paragraph 2 of Section D also includes the restriction that an eligible security is not authorized where the security is the subject of a public offering which has not yet been terminated.

(B) *Self-Regulatory Organization's Statement on Burden on Competition.* The proposed rule change will promote competition to the extent that the System will provide a more efficient means to publicize offers to buy or sell partnership securities, resulting in a more efficient pricing mechanism for such securities. At the same time, the proposed rule change will have an impact on competition to the extent that only members of the Association qualified to deal in direct participation program securities that maintain net capital of at least $25,000 will be eligible to enter information into the System, while other members of the Association and non-members will not be similarly eligible. However, the Association believes that the burden imposed is not unduly burdensome or inappropriate in light of the regulatory objectives sought to be achieved in furtherance of the Association's obligations under the Exchange Act.

(C) *Self-Regulatory Organization's Statement of Comments on the Proposed Rule Change Received from Members, Participants, or Others.* The proposed rule change was published for member comment in Notice to Members 82-13 (March 9, 1982). The Association received a total of 18 comments on the rule proposal. After due consideration of the comments received, the Board of Governors approved an amended version of the rule.

### III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the publication of this Notice in the **Federal Register** or within such longer period: (i) As the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

A. By order approve such proposed rule change, or

B. Institute proceedings to determine whether the proposed rule change should be disapproved.

### IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, D.C. 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Section, 450 Fifth Street, NW., Washington, D.C. Copies of such filings will also be available for inspection and copying at the principal office of the above-mentioned self-regulatory organization. All submissions should refer to the file number in the caption above and should be submitted within 21 days after the date of this publication.

For the Commission by the Division of Market Regulation pursuant to delegated authority.

April 14, 1983.

**George A. Fitzsimmons,**

*Secretary.*

[FR Doc. 83-10672 Filed 4-20-83; 8:45 am]

BILLING CODE 8010-01-M

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**[Release No. 13164; (812-5493)]**

## Sun Life Assurance Company of Canada (U.S.), et al.; Application

April 15, 1983.

Notice is hereby given that Sun Life Assurance Company of Canada (U.S.) ("Company"), Sun Life of Canada (U.S.) Variable Account A and Sun Life of Canada (U.S.) Variable Account B ("Accounts A and B"), and Sun Life of Canada (U.S.) Variable Account C ("Account C"), separate accounts of the Company registered under the Investment Company Act of 1940 ("Act") as unit investment trusts, Money Market Variable Account, Capital Appreciation Variable Account, and High Yield Variable Account ("3 Accounts"), separate accounts registered under the Act as management investment companies, Suncan Equity Services Company, 1 Sun Life Executive Park, Wellesley Hills, MA 02181, and

Clarendon Insurance Agency, Inc., 200 Berkeley Street, Boston, MA 02116, (collectively, "Applicants"), filed an application on March 11, 1983 and an amendment thereto on April 14, 1983 for an order pursuant to Section 11 of the Act approving the terms of certain offers of exchange. All interested persons are referred to the application and amendment on file with the Commission for a statement of the representations contained therein, which are summarized below, and are referred to the Act for a statement of the relevant statutory provision.

The Company established Accounts A and B, Account C, and the 3 Accounts to fund variable annuity contracts. Suncan Equity Services Company is the distributor of the Account A and B contracts. Clarendon Insurance Agency, Inc. is the distributor of the Account C and 3 Account contracts.

Applicants propose to permit Account A contractowners to exchange their contracts for tax qualified Account C or 3 Account contracts. Applicants also propose to permit Account B contractowners to exchange their contracts for 3 Account contracts. Applicants represent that exchanges of the contracts will be made on the basis of the relative net asset values of the contracts to be exchanged without the deduction of any fees or charges. Additionally, the contingent deferred sales charge imposed on the Account C or 3 Account contract received in exchange will not be imposed on purchase payments made for the exchanged Account A or B contract or on any appreciation attributable thereto transferred pursuant to the exchange. Finally, Applicants state that the company will pay its agents a fixed amount per contract regardless of whether such contract is exchanged as reimbursement for such agents' expenses associated with this exchange offer.

Applicants request an order pursuant to Section 11 of the Act to the extent necessary approving the terms of the proposed offer of exchange described in the application.

Notice is further given that any interested person wishing to request a hearing on the application may, not later than May 10, 1983, at 5:30 p.m., do so by submitting a written request setting forth the natue of his interest, the reasons for his request, and the specific issues, if any, of fact or law that are disputed, to the Secretary, Securities and Exchange Commission, Washington, D.C. 20549. A copy of the request should be served personally or by mail upon applicants at the addresses stated above. Proof of service (by affidavit or, in the case of an attorney-at-law, by certificate) shall be filed with the request. Persons who request a hearing will receive any notices and orders issued in this matter. After said date an order disposing of the application will be issued unless the Commission orders a hearing upon request or upon its own motion.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

**George A. Fitzsimmons,**

*Secretary.*

[FR Doc. 10674 Filed 4-20-83; 8:45 am]

BILLING CODE 8010-01-M

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## Forms Under Review By Office of Management and Budget

Agency Clearance Officer: Kenneth A. Fogash (202) 272-2142.

Upon written request copy available from: Securities and Exchange Commission, Office of Consumer Affairs and Information Services, 450 Fifth Street, NW., Washington, D.C. 20549.

Proposed Revisions Regarding Accounting for Internal Costs of Developing Computer Software for Sale or Lease to Others
No. 270-3 (Regulation S-X)
No. 270-119 (Form S-18)

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.), the Securities and Exchange Commission has submitted for clearance proposed amendments to Regulation S-X and Form S-18 relating to the accounting for internal costs of developing computer software for sale or lease to others. A copy of this submission is available for public inspection and copying at the Commission's Public Reference Room, 450 Fifth Street, NW., Washington, D.C. 20549. Inquiring parties should refer to File No. 270-3.

Comments should be submitted to Mr. Robert Veeder, OMB Desk Officer, Office of Information and Regulatory Affairs, Room 3235 NEOB, Washington, D.C. 20503.

Dated: April 15, 1982.

**George A. Fitzsimmons,**

*Secretary.*

[FR Doc. 83-10669 Filed 4-20-83; 8:45 am]

BILLING CODE 8010-01-M

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## Forms Under Review By Office of Management and Budget

Agency Clearance Officer: Kenneth Fogash 202-272-2142.

Upon written request copy available from: Securities and Exchange Commission, Office of Consumer Affairs and Information Services, Washington, D.C. 20549.

**Amendment**

*Rule 15c2-11*

*No. 270-196.* Notice is hereby given that pursuant to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission has submitted for clearance a proposed amendment to Rule 15c2-11 under the Securities Exchange Act of 1934 (the "Act") which concerns initiation and resumption of quotations of securities by brokers and dealers. The potential respondents are broker-dealers that publish quotations for over-the-counter securities in certain quotation media. The proposed amendments would: (a) Extend the Rule's information-maintenance and other substantive requirements to brokers and dealers who submit unpriced entries to inter-dealer quotation media, (b) require brokers and dealers that publish quotations for American Depository Receipts or securities of a foreign private issuer that furnishes information to the Commission pursuant to Rule 12g3-2(b) of the Act to maintain in their records certain information furnished to the Commission, and (c) prohibit the initiation of quotations for the securities of reporting companies that are delinquent in meeting their filing obligations under the Act.

Submit comments to OMB Desk Officer: Robert Veeder 202-395-4814.

**George A. Fitzsimmons,**

*Secretary.*

April 14, 1983.

[FR Doc. 83-10670 Filed 4-20-83; 8:45 am]

BILLING CODE 8010-01-M

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## SMALL BUSINESS ADMINISTRATION

**[License No. 09/09-5272]**

### Los Angeles Capital Corp.; Application for a License To Operate as a Small Business Investment Company

An application for a license to operate as a small business investment company under the provisions of Section 301(d) of the Small Business Investment Act of 1958, as amended (15 U.S.C. 661 *et seq.*), has been filed by Los Angeles Capital Corporation with the Small business Administration (SBA), pursuant to 13 CFR 107.102 (1983).

The officers, directors, and stockholders of the Applicant are as follows:

Kuytae Hwang, 2280 Hobart Boulevard, Los Angeles, California 90027, President, CEO, Director (50 Percent Stockholder);

Whami Hwang, 2280 N. Hobart Boulevard, Los Angeles, California 90027, Secretary, Treasurer, Director (50 Percent Stockholder);
Richard Young Lim, 5232 Los Grandes Way, Los Angeles, California 90027, Vice President.

The Applicant, a California Corporation, with its principal place of business at 1177 Myra Avenue, Suite A, Los Angeles, California 90029, will begin operations with $506,500 of paid-in capital and paid-in surplus.

The Applicant will conduct its activities principally in the State of California.

As a small business investment company under Section 301(d) of the Act, the Applicant has been organized and chartered solely for the purpose of performing the functions and conducting the activities contemplated under the Small Business Investment Act of 1958, as amended, from time to time, and will provide assistance solely to small business concerns which will contribute to a well-balanced national economy by facilitating ownership in such concerns by persons whose participation in the free enterprise system is hampered because of social or economic disadvantages.

Matters involved in SBA's consideration of the application include the general business reputation and character of shareholders and management, and the probability of successful operations of the new compnay in accordance with the Act and Regulations.

Notice is hereby given that any person may not later than 15 days from the date of publication of this Notice, submit written comments to the Associate Administrator for Finance and Investment, Small Business Administration, 1441 "L" Street, NW., Washington, D.C. 20416.

A copy of this notice will be published in a newspaper of general circulation in Los Angeles, California.

(Catalog of Federal Domestic Assistance Program No. 59.011, Small Business Investment Companies)

Dated: April 15, 1983.

**Edwin T. Holloway,**

*Associate Administrator for Finance and Investment.*

[FR Doc. 83-10658 Filed 4-20-83; 8:45 am]

BILLING CODE 8025-01-M

## Region IV—Advisory Council; Public Meeting

The Small Business Administration Region IV Advisory Council, located in the geographical area of Birmingham, Alabama, public meeting has been cancelled for Friday, April 29, 1983, and rescheduled for Wednesday, May 11, 1983, 10:00 a.m.—12:00 noon, in the Senate Chambers, Alabama State Capitol, Montgomery, Alabama 36130, 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 James C. Barksdale, District Director, U.S. Small Business Administration, 908 South 20th Street, Room 202, Birmingham, Alabama (205) 254–13451.

**Jean M. Nowak,**

*Acting Director, Office of Advisory Councils.*

April 15, 1983.

[FR Doc. 83-10657 Filed 4-20-83; 8:45 am]

BILLING CODE 8025-01-M

# DEPARTMENT OF TRANSPORTATION

## Federal Aviation Administration

## Radio Technical Commission for Aeronautics (RTCA) Executive Committee; Meeting

Pursuant to section 10(a) (2) of the Federal Advisory Committee Act (Pub. L. 92–463; 5 U.S.C. App. I) notice is hereby given of a meeting of the RTCA Executive Committee to be held on May 13, 1983, in RTCA conference Room, 1425 K Street, N.W., Suite 500, Washington, D.C. commencing at 9:30 a.m.

The Agenda for this meeting is as follows: (1) Approval of Minutes of Meeting Held on March 25, 1983; (2) Chairman's Report on RTCA Administration and Activities; (3) Special Committee Activities Report for March and April, 1983; (4) Approval of RTCA fiscal year 1984 Budget; (5) Approval of Procedures and Guidelines for RTCA Special Committee Activities; (6) Consideration of Establishing New Special Committees; (7) Approval of Special Committee 136 Report on Minimum Operational Performance Standards For Emergency Locator Transmitters (ELT) Operating on 121.5 and 243 Megahertz; (8) Approval of Special Committee 147 Report on Functional Guidelines for Traffic Alert and Collision Avoidance System Type 1 (TCAS–1); (9) Approval of Special Committee 147 Report on Minimum Operational Performance Standards for Traffic Alert and Collision Avoidance System Airborne Equipment; and (10) Other Business.

Attendance is open to the interested public but limited to space available. With the approval of the Chairman, members of the public may present oral statements at the meeting. Persons wishing to present statements or obtain information should contact the RTCA Secretariat, 1425 K Street, N.W., Suite 500, Washington, D.C. 20005, (202) 682–0266. Any member of the public may present a written statement to the committee at any time.

Issued in Washington, D.C. on April 13, 1983.

**Karl F. Bierach,**

*Designated Officer.*

[FR Doc. 83-10467 Filed 4-20-83; 8:45 am]

BILLING CODE 4910-13-M

## Central Region Field Element Change

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

**ACTION:** Notice of Field Element Change.

**SUMMARY:** Notice is hereby given that on May 1, 1983, the General Aviation District Offices at Des Moines, Iowa, Lincoln, Nebraska, and Wichita, Kansas will be redesignated as Flight Standards District Offices (FSDOs). Each FSDO will assume responsibility for all Flight Standards functions within its present geographic area of jurisdiction, including those subject to Federal Aviation Regulations Part 121. This information will be reflected in the FAA Organization Statement the next time it is reissued.

**EFFECTIVE DATE:** May 1, 1983.

**FOR FURTHER INFORMATION CONTACT:** James O. Robinson, Manager, Flight Standards Division (ACE–200), Central Region, Federal Aviation Administration 601 East 12th Street, Kansas City, Missouri 64106; Telephone (816) 374–5003.

(Sec. 313(a) of the Federal Aviation Act of 1958, as amended (49 U.S.C. 1354(a))

Issued in Kansas City, Missouri, on April 1, 1983.

**Murray E. Smit,**

*Director, Central Region.*

[FR Doc. 83-10328 Filed 4-20-83; 8:45 am]

BILLING CODE 4910-13-M

## National Airspace Review; Meeting

**AGENCY:** Federal Aviation Administration, Department of Transportation.

**ACTION:** Notice of meeting.

**SUMMARY:** Pursuant to Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463; 5 U.S.C. App. 1) notice is hereby given of a meeting of Task Group 2–1 of the Federal Aviation Administration (FAA) National Airspace Review Advisory Committee. The agenda for this meeting is as

follows: An evaluation of the Severe Weather Avoidance Plan.

**DATE:** Beginning May 9, 1983, at 11 a.m., continuing daily, except Saturdays, Sundays, and holidays, not to exceed two weeks.

**ADDRESS:** The meeting will be held at the Federal Aviation Administration, conference room 9 A/B, 800 Independence Avenue, SW., Washington, D.C.

**FOR FURTHER INFORMATION CONTACT:** National Airspace Review Program Management Staff, Room 1005, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, D.C. 20591, (202) 426-3560. Attendance is open to the interested public, but limited to the space available. To insure consideration, persons desiring to make statements at the meeting should submit them in writing to the Executive Director, National Airspace Review Advisory Committee, Air Traffic Service, AAT-1, 800 Independence Avenue, SW., Washington, D.C. 20591, by May 4, 1983. Time permitting and subject to the approval of the chairman, these individuals may make oral presentations of their previously submitted statements.

Issued in Washington, D.C., on April 8, 1983.

**Anthony Borden,**

*Acting Manager, Special Projects Staff, Air Traffic Service.*

[FR Doc. 83-10465 Filed 4-20-83; 8:45 am]

BILLING CODE 4910-13-M

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## Federal Highway Administration

### Environmental Assessment: New Castle County, Delaware

**AGENCY:** Federal Highway Administration (FHWA) DOT.

**ACTION:** Notice of intent.

**SUMMARY:** The FHWA is issuing this notice to advise the public that an environmental assessment will be prepared for a proposed highway project in New Castle County, Delaware.

**FOR FURTHER INFORMATION CONTACT:**

George Ostensen, Field Operations Engineer, Federal Highway Administration, Delaware Division, P.O. Box 517, Dover, Delaware, 19901, Telephone: (302) 734-5323;

Nicholas S. Blendy, Environmental Planner, Environmental Studies Office, Delaware Department of Transportation, P.O. Box 778, Dover, Delaware, 19903, Telephone (302) 736-4642.

**SUPPLEMENTARY INFORMATION:** The FHWA, in cooperation with the Delaware Department of Transportation, has prepared an environmental assessment (EA) for a proposal to improve Delaware Route 7 in northern New Castle County, Delaware. The intent to process an EA differs from the original intent to prepare an Environmental Impact Statement (EIS) as announced in the July 31, 1980, **Federal Register** (Vol. 45, No. 149). This reduction in scope of the environmental document is a result of scoping and an ongoing location planning study that has enabled FHWA to conclude that the proposed action will lack any significant social, economic or environmental impacts. The location planning study is being undertaken for the portion of Delaware Route 7 from the existing Interstate I-95 Interchange near the town of Christiana south to U.S. Route 13, a distance of approximately six miles. The purpose is to establish an alignment for a relocated Delaware Route 7 within the corridor area. Improvements to the corridor are considered necessary to provide for the existing and projected traffic demand. Also included in this proposal will be a crossing of the Christina River and interchange connections with U.S. Route 13, U.S. Route 40 and the proposed Christiana Bypass (route 273).

Alternatives considered to date have included: (1) Taking no action; (2) widening the existing two-lane highway to four lanes; and (3) constructing a four-lane facility on new location. Alignment and preliminary design variations have been incorporated into and studied with the various build alternatives. A series of public information meetings and formal scoping meetings were held.

Comment or questions concerning this proposed action and the EA should be directed to the FHWA address provided above.

Issued on April 8, 1983.

**George Ostensen,**

*Acting Division Administrator, Dover, Delaware.*

[FR Doc. 83-10420 Filed 4-20-83; 8:45 am]

BILLING CODE 4910-22-M

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**[FHWA Docket No. 83-10]**

### Construction and Maintenance: Use of Innovative Technologies

**AGENCY:** Federal Highway Administration (FHWA), DOT.

**ACTION:** Notice and request for comments.

**SUMMARY:** The purpose of this document is to set forth the text of an FHWA Notice which contains procedures to increase the Federal-aid matching share for highway construction projects using innovative technologies. Section 142 of the Surface Transportation Assistance Act of 1982 (Pub. L. 97-424, 96 Stat. 2097) authorized the Secretary of Transportation to increase the Federal-aid matching share by 5 percent for certain highway projects, submitted by State highway departments, which would employ materials produced from recycled materials or contain asphalt additives to strengthen such materials. To be eligible, significant amounts of asphalt additives or recycled materials must be used in the project. Approvals for increased Federal-aid shares under this program are authorized only through September 30, 1985. Section 142 further required that a procedure be established within ninety days to implement this program. Such procedures are established by the FHWA Notice, which was issued on April 6, 1983. While the program will have effect only for a limited period, comments from the public are invited and will be fully considered should any later amendment or further guidance be deemed appropriate.

**DATE:** Comments must be received on or before June 20, 1983.

**ADDRESS:** Submit written comments, preferably in triplicate to the Federal Highway Administration, FHWA Docket No. 83-10, Room 4205, HCC-10, 400 Seventh Street, SW., Washington, D.C. 20590. All comments received will be available for examination at the above address between 7:45 a.m. and 4:30 p.m. ET, Monday through Friday. Those persons desiring notification of receipt of comments must include a self-addressed, stamped postcard.

**FOR FURTHER INFORMATION CONTACT:** Mr. Gary L. Kleindinst, Chief, Geotechnical and Materials Branch, Construction and Maintenance Division, (202) 426-0355, or Mr. James R. Dann, Office of the Chief Counsel, (202) 426-0786, Federal Highway Administration, 400 Seventh Street, SW., Washington, D.C. 20590. Office hours are from 7:45 a.m. to 4:15 p.m. ET, Monday through Friday.

Issued on: April 15, 1983.

**R. A. Barnhart,**

*Federal Highway Administrator, Federal Highway Administration.*

**Use of Innovative Technologies**

1. *Purpose.* To describe the procedures to increase the Federal-aid matching share for projects as prescribed by Section 142, Innovative Technologies, of

the Surface Transportation Assistance Act (STAA) of 1982.

2. *Definitions.* a. *Asphalt Additive*—a substance added to an asphalt paving mixture. Additives include rubber, chemical and/or natural products. Such materials as mineral fillers, chemical anti-strip agents, and defoaming agents or any other additive product routinely used should not be considered under this program. Asphalt additives could include any product not routinely used which has been proven to improve the asphalt mixture, achieve longer pavement life cycles, and lower maintenance costs.

b. *Binding Agents*—cement, asphalts, and other agents that impart increased stability to the recycled materials.

c. *Bituminous Paving Materials*—those paving materials consisting of a mixture of mineral aggregates and asphalt binder.

d. *Paving Materials*—those materials used for highway and bridge surfacing and resurfacing.

e. *Pavement*—composite of all the paving materials placed above the subgrade.

f. *Recycled Paving Materials*—a paving material containing a significant amount of salvaged materials, such as ground rubber tires, and also contains the addition of a binding agent. Salvaged materials include suitable industry by-products.

3. *Discussions.* The need to conserve energy and optimize expenditures in highway construction requires that special effort be made to identify and make maximum use of procedures that will result in reduced energy usage and minimum cost. Congress has found it to be in the national interest to encourage and promote utilization of highway materials which are produced from recycled material or which contain asphalt additives to strengthen the materials, prolong the life of the pavement, and lower maintenance costs. In an effort to support these technologies, the Congress authorized a Federal-aid share increase of 5 per centum for projects utilizing significant amounts of these materials.

a. The only additive specifically mentioned in Senate Report 97–676 was recycled rubber tires; however, reference was also made to "United States patented asphalt strengthening additives." It is also clear that the project share increase was being proposed for only those products where were "proven" to prolong pavement life and lower maintenance costs. Criteria set forth in paragraph 4a(1)(a) were developed as an aid in determining whether an asphalt additive is "proven."

b. The provisions in paragraph 4a are intended to enable the 5 per centum increase in Federal share to apply to an entire highway and bridge 3R or paving project which incorporates the qualifying paving materials as described in 4a(1)(a) and 4a(1)(b).

4. *Procedures.* When preparing plans and specifications the State may select cost-effective innovative technologies which will meet its needs for a particular project and incorporate them into its proposed plans and specifications. States that utilize a "permissive specification" which allows the contractor, at his/her option, to incorporate recycled materials qualifying for this program should have the contractor declare at bid opening the intended use of such qualifying recycled material. This is necessary to determine if the 5 per centum increase in the Federal-aid share will be applicable.

a. *Approval.* (1) On or before September 30, 1985, the Division Administrator may approve an increase in the Federal-aid share by 5 per centum for the entire project cost on highway and bridge surfacing, resurfacing, or restoration type projects, if the project:

(a) incorporates bituminous paving matrials which contain an asphalt additive in amounts consistent with standard practice and which has been proven to increase the strength of the materials and prolong the life of the pavement through a systematic evaluation program. This program shall include appropriate laboratory testing and successful in-service performance on at least three projects containing similar traffic, environmental factors, and pavement structure as the proposed project, and/or

(b) incorporates a significant amount of recycled paving materials.

(2) For the purpose of projects approved under Section 142 of STAA, proprietary products or materials meeting the above description have been determined to meet the public interest requirement as set forth in Federal-Aid Highway Program Manual (FHPM) 6–4–1–16, General Materials Requirements, paragraph 7c.

(3) Items of work or projects considered maintenance are not applicable for Federal-aid participation. The FHWA Notice N 5040.19, Resurfacing, Restoring, and Rehabilitation (R-R-R) Work, dated June 28, 1976, sets forth guidance on items of work considered maintenance.

(4) The total Federal-aid share may not exceed 100 per centum for any Federal-aid highway project.

b. *Fiscal Procedures.* (1) The amount of additional Federal funds approved by FHWA will be entered on the form FHWA-37, Project Status Record, and reported as a separate line (number 89). No special appropriation codes will be used for the increased Federal share.

(2) Normal reporting procedures will be followed as prescribed in FHWA Order H 4500.2, Fiscal Management Information System Handbook, except for the following:

(a) line number 89 will be reserved only for reporting the additional Federal funds authorized by section 142 of the STAA of 1982,

(b) line number 89 will be coded the same as the line containing the predominant cost of paving materials, except data entered in the "miles" column will not be repeated on this line, and

(c) an amount equal to the additional Federal funds reported on line number 89 will be deducted from the total cost of the predominant line and entered as the total cost column for line number 89. (The amount in the total cost field cannot be less than the amount in the Federal funds field.)

(3) The Form FHWA PR–2, Project Agreement, will contain the following statement:

> Additional Federal funds of $——— have been approved in accordance with Pub. L. 97–424, Section 142. The Federal-aid participation is——— percent.

5. *Reporting.* All projects covered by this Notice should be reported on Form FHWA 1517, Innovative Technology Report (RCS No. HHO–30–27). This form should be submitted to the Office of Highway Operations, construction and Maintenance Division (HHO–30).

[FR Doc. 83–10555 Filed 4–20–83; 8:45 am]
BILLING CODE 4910–22–M

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## Federal Highway Administration (FHWA)

## Environmental Impact Statement; Cuyahoga County, Ohio

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

**ACTION:** Notice of intent.

**SUMMARY:** The FHWA is issuing this notice to advise the public that an environmental impact statement (EIS) is being prepared for a proposed highway project in Cuyahoga County, Ohio.

**FOR FURTHER INFORMATION CONTACT:** Mr. John W. McBee, Division Administrator, or Mr. David M. Hall, District Engineer, Federal Highway Administration, 200 North High Street, Columbus, Ohio 43215. Telephone: (614) 469–5148.

**SUPPLEMENTARY INFORMATION:** The Federal Highway Administration (FHWA), in cooperation with the Ohio Department of Transportation (ODOT) and the City of Cleveland, has been preparing a draft environmental impact statement (EIS) since 1975 on the proposed construction of approximately 1.5 miles of limited access divided highway in the City of Cleveland, Ohio. The proposed facility designated Interstate Route 490, would connect Interstate Routes 90 and 71 on the west with Interstate Route 77 on the east. It would terminate at East 55th Street, a short distance east of Interstate Route 77.

The project represents a connecting link and the interchanges with the Interstates have been constructed. The required right-of-way has been largely acquired and cleared. Residential relocation has been completed.

Because of the long history of planning for this project, the fixing of the termini by construction of the interchanges with the existing Interstate Routes, the near completion of right-of-way acquisition, and the constraints of existing urban development, only one build alternative and the no-build alternative are now under consideration.

The proposed project would provide Cleveland with another route crossing the Cuyahoga River and bypassing the central business district. The proposed facility would link two major north-south freeways and increase the efficiency of Cleveland's free network. Congestion on a number of local streets would be alleviated.

To date, there has been extensive federal, state, local and public involvement with the proposed project. It is envisioned that such involvement will continue throughout further development of the project and, therefore, a formal scoping meeting has not been scheduled.

To insure that the full range of issues related to this proposed action are addressed and that all significant issues are identified, comments or questions concerning this action and the EIS should be addressed to the FHWA at the address provided above.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Research, Planning and Construction. The provisions of OMB Circular No. A-95 regarding state and local clearinghouse review of Federal and federally assisted programs and projects apply to this progam)

Issued on: April 14, 1983.

**James J. Steele,**

*Acting Division Administrator, Columbus, Ohio*

[FR Doc. 83-10569 Filed 4-20-83; 8:45 am]

**BILLING CODE 4910-22-M**

## Research and Special Programs Administration

## Grants and Denials of Applications for Exemptions

**AGENCY:** Materials Transportation Bureau, DOT.

**ACTION:** Notice of Grants and Denials of Applications for Exemptions.

**SUMMARY:** In accordance with the procedures governing the application for, and the processing of, exemptions from the Department of Transportation's Hazardous Materials Regulations (49 CFR Part 107, Subpart B), notice is hereby given of the exemptions granted in March 1983. The modes of transportation involved are identified by a number in the "Nature of Exemption Thereof" portion of the table below as follows: 1—Motor vehicle, 2—Rail freight, 3—Cargo vessel, 4—Cargo-only aircraft, 5—Passenger-carrying aircraft. Application numbers prefixed by the letters EE represent applications for Emergency Exemptions.

RENEWAL AND PARTY TO EXEMPTIONS

| Application No. | Exemption No. | Applicant | Regulation(s) affected | Nature of exemption thereof |
|---|---|---|---|---|
| 1862-X | DOT-E 1862 | Green Hydraulics, Inc., Los Angeles, CA | 49 CFR 173.302(a)(1), 175.3 | To authorize the shipment of nitrogen in hydraulic accumulators. (Modes 1, 2, 3, 4.) |
| 2587-P | DOT-E 2587 | Welding & Therapy Service, Incorporated, Louisville, KY. | 49 CFR 173.315(a)(1) | To become a party to Exemption 2587. (Mode 1.) |
| 2708-X | DOT-E 2708 | Union Carbide Corporation, Danbury, CT | 49 CFR 173.315(a), 173.316 | To authorize shipment of a flammable liquefied compressed gas in non-DOT specification cargo tanks. (Mode 1.) |
| 2709-P | DOT-E 2709 | United Technologies, Sunnyvale, CA | 49 CFR 173.52, 173.93, 177.821, 177.834(L)(1), 177.835(k). | To become a party to Exemption 2709. (Mode 1.) |
| 2805-X | DOT-E 2805 | SunOlin Chemical Company, Claymont, DE | 49 CFR 172.101, 173.315(a)(1) | To authorize shipment of liquefied ethylene in non-DOT specification insulated cargo tanks. (Mode 1.) |
| 3109-X | DOT-E 3109 | Raytheon Company, Lowell, MA | 49 CFR 173.301(e), 173.302(a)(1), 175.3 | To authorize use of non-DOT pressure vessels for shipment of a nonflammable, nonliquefied compressed gas. (Modes 1, 2, 3, 4, 5.) |
| 3109-X | DOT-E 3109 | U.S. Department of Defense, Washington, DC | 49 CFR 173.301(e), 173.302(a)(1), 175.3 | To authorize use of non-DOT pressure vessels for shipment of a nonflammable, nonliquefied compressed gas. (Modes 1, 2, 3, 4, 5.) |
| 3216-X | DOT-E 3216 | Pennwalt Corporation, Philadelphia, PA | 49 CFR 173.314(c) | To authorize use of a proposed DOT Specification 110A3000W tank car tank, for transportation of certain flammable compressed gases. (Modes 1, 3.) |
| 3353-X | DOT-E 3353 | Kerr-Mcgee Chemical Corporation, Oklahoma City, OK. | 49 CFR 173.163(a)(7), 173.239a(a)(2) | To authorize shipment of certain oxidizing material, in a non-DOT specification steel or aluminum portable tank. (Modes 1, 2.) |
| 4242-X | DOT-E 4242 | U.S. Department of Defense, Washington, DC | 49 CFR 173.134, 173.87 | To authorize use of a non-DOT specification pressure vessel, for transportation of certain pyroforic mixture. (Mode 1.) |
| 4453-P | DOT-E 4453 | Pacific Powder Company, Tenino, WA | 49 CFR 173.114a(h)(3) | To become a party to Exemption 4453. (Mode 1.) |
| 4453-X | DOT-E 4453 | Wampum Hardware Company, New Galilee, PA | 49 CFR 173.114a(h)(3) | To authorize use of a non-DOT specification bulk, hopper-type tank for transportation of blasting agent, n.o.s., or ammonium nitrate-fuel oil mixture. (Mode 1.) |
| 4453-P | DOT-E 4453 | Pacific Motor Transport, Inc., Tenino, WA | 49 CFR 173.114a(h)(3) | To become a party to Exemption 4453. (Mode 1.) |

RENEWAL AND PARTY TO EXEMPTIONS—Continued

| Application No. | Exemption No. | Applicant | Regulation(s) affected | Nature of exemption thereof |
|---|---|---|---|---|
| 4726-X | DOT-E 4726 | U.S. Department of Energy, Washington, DC | 49 CFR 173.245 | To authorize transport of certain liquid metal fluourides, in non-DOT specification seamless monel cylinders, overpacked in a strong wooden box with cushioning material. (Mode 1.) |
| 4884-X | DOT-E 4884 | Union Carbide Corporation, Danbury, CT | 49 CFR 173.302(a)(1), 175.3, 178.61 | To authorize shipment of gas-calibration mixtures of compressed gases, in non-DOT specification steel cylinders complying with DOT Specification 4BW, with certain exceptions. (Modes 1, 2, 3, 4, 5.) |
| 5206-X | DOT-E 5206 | Atlas Powder Company, Dallas, TX | 49 CFR 173.114a | To authorize privately operated bulk hopper-type units, for transportation of an oxidizing material. (Mode 1.) |
| 5248-X | DOT-E 5248 | 3M Company, St. Paul, MN | 49 CFR 173.389(g), 175.3 | To authorize shipment of a certain quantity of polonium-210 in any DOT Specification approved outer Type A packaging. (Modes 1, 2, 4, 5.) |
| 5643-X | DOT-E 5643 | Union Carbide Corporation, Danbury, CT | 49 CFR 172.101, 173.315(a)(1) | To authorize shipment of a nonflammable gas in vacuum insulated non-DOT specification portable tanks. (Modes 1, 3.) |
| 6113-P | DOT-E 6113 | Commonwealth Gas Company, Southborough, MA | 49 CFR 172.101, 173.315(a) | To become a party to Exemption 6113. (Mode 1.) |
| 6126-X | DOT-E 6126 | Dow Chemical Company, Midland, MI | 49 CFR 173.253(a) | To authorize shipment of chloracetyl chloride in DOT Specification 6D/2S or 2SL composite packaging. (Modes 1, 3.) |
| 6218-X | DOT-E 6218 | Messer Griesheim Industries, Inc., Valley Forge, PA. | 49 CFR 173.315(a) | To authorize shipment of argon or nitrogen pressurized liquid, in insulated non-DOT specification cargo tanks. (Mode 1.) |
| 6218-X | DOT-E 6218 | Welding & Therapy Service, Inc., Louisville, KY | 49 CFR 173.315(a) | To authorize shipment of argon or nitrogen pressurized liquid, in insulated non-DOT specification cargo tanks. (Mode 1.) |
| 6267-X | DOT-E 6267 | Bio-Lab, Incorporated, Conyers, GA | 49 CFR 173.217(a) | To authorize transport of certain oxidizers in non-DOT specification double-faced fiberboard boxes. (Modes 1, 2, 3.) |
| 6296-X | DOT-E 6296 | Platte Chemical Company, Fremont, NE | 49 CFR 173.377(g) | To authorize additional bag packagings, for transportation of certain Class B poisons in DOT Specification 44D multi-wall paper bags. (Modes 1, 2.) |
| 6296X | DOT-E 6296 | American Cyanamid Company, Wayne, NJ | 49 CFR 173.377(g) | To authorize additional bag packagings, for transportation of certain Class B poisons in DOT Specification 44D multi-wall paper bags. (Modes 1, 2.) |
| 6432-X | DOT-E 6432 | Messer Griesheim Industries, Inc., Valley Forge, PA. | 49 CFR 173.315(a) | To authorize shipment of liquefied argon, nitrogen and oxygen, in non-DOT Specification vacuum insulated cargo tanks. (Mode 1.) |
| 6464-P | DOT-E 6464 | Commonwealth Gas Company, Southborough, MA | 49 CFR 172.101, 173.315(a) | To become a party to Exemption 6464. (Mode 1.) |
| 6686-X | DOT-E 6686 | Chilton Metal Products Division, Chilton, WI | 49 CFR 173.304, 178.65 | To authorize use of a modified DOT Specification 39 steel cylinder, for transportation of a certain flammable gas. (Modes 1, 2.) |
| 6762-P | DOT-E 6762 | The Keeler Company, Inc., Shillington, PA | 49 CFR 173.286(b)(2), 175.3 | To become a party to Exemption 6762. (Modes 1, 2, 3, 4.) |
| 6762-P | DOT-E 6762 | Suhm Laboratories, Inc., Greendale, WI | 49 CFR 173.286(b)(2), 175.3 | To become a party to Exemption 6762. (Modes 1, 2, 3, 4.) |
| 6762-X | DOT-E 6762 | Green Chemical Company, Inc., Winchester, VA | 49 CFR 173.286(b)(2), 175.3 | To authorize transport of chemical kits in plastic inside bottles, packed in plastic boxes overpacked in fiberboard boxes. (Modes 1, 2, 3, 4.) |
| 6762-P | DOT-E 6762 | United Laboratories, Inc., Addison, IL | 49 CFR 173.286(b)(2), 175.3 | To become a party to Exemption 6762. (Modes 1, 2, 3, 4.) |
| 6762-P | DOT-E 6762 | Oxford Chemicals, Inc., Atlanta, GA | 49 CFR 173.286(b)(2), 175.3 | To become a party to Exemption 6762. (Modes 1, 2, 3, 4.) |
| 6762-X | DOT-E 6762 | Aquaphase Laboratories, Inc., Adrian, MI | 49 CFR 173.286(b)(2), 175.3 | To authorize transport of chemical kits in plastic inside bottles, packed in plastic boxes overpacked in fiberboard boxes. (Modes 1, 2, 3, 4.) |
| 6773-X | DOT-E 6773 | E. I. du Pont de Nemours & Company, Inc., Wilmington, DE. | 49 CFR 173.314(c) | To authorize shipment of a flammable compressed gas, in a DOT Specification 105A600W tank can. (Mode 2.) |
| 6774-X | DOT-E 6774 | HR Textron Inc., Pacoima, CA | 49 CFR 173.302.(a)(2), 175.3 | To authorize use of non-DOT specification cylinders complying with DOT Specification 3HT, with certain exceptions, for shipment of a nonflammable gas. (Modes 1, 4.) |
| 6874-P | DOT-E 6874 | Mitsui & Company (USA), Inc., New York, NY | 49 CFR 172.101, 173.370(a)(13) | To become a party to Exemption 6874. (Modes 1, 2, 3.) |
| 7052-P | DOT-E 7052 | Leigh Instruments Limited, Corleton Place, Ontario | 49 CFR 172.101, 175.3 | To become a party to Exemption 7052. (Modes 1, 2, 3, 4.) |
| 7052-P | DOT-E 7052 | AMS Hellesens, Soborg, Denmark | 49 CFR 172.101, 175.3 | To become a party to Exemption 7052. (Modes 1, 2, 3, 4.) |
| 7249-X | DOT-E 7249 | E. I. du Pont de Nemours & Company, Inc., Wilmington, DE. | 49 CFR 173.126(a) | To authorize use of containers not otherwise permitted by the Hazardous Materials Regulations, for transportation of certain flammable liquids. (Mode 1.) |
| 7413-X | DOT-E 7413 | Chilton Metal Products Division, Chilton, WI | 49 CFR 173.302(a), 173.304(a)(1), 175.3, 178.42 | To authorize transport of carbon dioxide or nitrogen, in a non-DOT specification brazed steel cylinder. (Modes 1, 2, 4.) |

RENEWAL AND PARTY TO EXEMPTIONS—Continued

| Application No. | Exemption No. | Applicant | Regulation(s) affected | Nature of exemption thereof |
|---|---|---|---|---|
| 7455-X | DOT-E 7455 | E. I. du Pont de Nemours & Company, Inc., Wilmington, DE. | 49 CFR 176.177(g), 176.177(h), 176.177(n), 176.177(q), 176.177(r), 176.410(e). | To authorize handling and stowage of explosive material in an anchored and unmanned barge. (Mode 3.) |
| 7495-X | DOT-E 7495 | General American Transportation Corporation, Chicago, IL. | 49 CFR 173.315(a)(1) | To authorize manufacture, marking and sale of non-DOT specification portable tanks, for transportation of chlorine or sulfur dioxide. (Modes 1, 2, 3.) |
| 7505-X | DOT-E 7505 | Platte Chemical Company, Greeley, CO. | 49 CFR 173.28(m), 173.346(a)(2), 173.358(a)(2), 173.359(a)(2), 173.359(b)(2). | To authorize use of DOT Specification 17C drums, previously used for shipment of class B poisons and reconditioned (decontaminated). (Mode 1.) |
| 7513-X | DOT-E 7513 | MG Burdett Gas Products Company, Incorporated, Reading, PA. | 49 CFR 173.315(a)(1) | To authorize shipment of pressurized liquid oxygen, in DOT Specification MC-331 cargo tanks. (Mode 3.) |
| 7543-X | DOT-E 7543 | Monsanto Company, St. Louis, MO. | 49 CFR 173.154 | To authorize shipment of a flammable solid in a DOT Specification 56 portable tank. (Mode 1.) |
| 7625-X | DOT-E 7625 | Hydrite Chemical Company, Milwaukee, WI. | 49 CFR 173.245, 173.249, 173.263, 173.268, 173.272. | To authorize transport of certain corrosive liquids, in DOT Specification 56 portable tanks. (Mode 1.) |
| 7700-X | DOT-E 7700 | U.S. Department of Argiculture, Washington, DC. | 49 CFR 175.310(d) | To authorize transport of gasoline in the baggage and or passenger compartment of helicopters. (Mode 5.) |
| 7735-X | DOT-E 7735 | Rheem Manufacturing Company, Linden, NJ. | 49 CFR 173.119, 173.264(a), 173.272(g), 173.346, 173.358, 173.359. | To authorize manufacture, marking and sale of DOT Specification 34 containers, for shipment of certain flammable liquids, corrosive materials and class B poisonous liquids. (Modes 1, 2, 3.) |
| 7768-X | DOT-E 7768 | Plasti-Drum Corporation, Lockport, IL. | 49 CFR 173.154, 173.217, 173.245b, 173.365, 178.19. | To authorize manufacture, marking and sale of non-DOT specification blow-molded, high molecular weight polyethylene drums, with removable head, for shipment of oxidizers, corrosive, flammable and poison B solids. (Modes 1, 2, 3.) |
| 7769-X | DOT-E 7769 | Brunswick Corporation, Lincoln, NE. | 49 CFR 173.302(a)(1), 175.3 | To authorize manufacture, marking and sale of non-DOT Specification fiber reinforced plastic full composite cylinder, for transportation of certain nonflammable compressed gas. (Modes 1, 2, 3, 4, 5.) |
| 7849-P | DOT-E 7849 | Welding Products of Georgia (HOLOX), Atlanta, GA. | 49 CFR 173.315(a) | To become a party to Exemption 7849. (Mode 1.) |
| 7876-P | DOT-E 7876 | Micro Image Inc., Orange, CT. | 49 CFR 173.299(a), 175.3 | To become a party to Exemption 7876. (Modes 1, 2, 3, 4.) |
| 7879-X | DOT-E 7879 | Gearhart Industries, Inc., Fort Worth, TX. | 49 CFR 173.246, 175.3, 178.42 | To authorize shipment of bromine trifluoride, in non-DOT specifiations seamless cylinders. (Modes 1, 2, 3, 4.) |
| 7957-X | DOT-E 7957 | Process Engineering, Incorporated, Plaistow, NH. | 49 CFR 173.315(a)(1), 173.33(a), 177.824(c)(4), 178.337. | To authorize manufacture, marking and sale of non-DOT specification aluminum cargo tanks, for transportation of carbon dioxide, liquefied. (Mode 1.) |
| 7963-X | DOT-E 7963 | Stauffer Chemical Company, Westport, CT. | 49 CFR 173.245, 173.360(a)(5) | To authorize transport of perchloromethyl mercaptan and thiophene-2-acetyl chloride, in monel tanks constructed in accordance with DOT Specification 51, with certain exceptions. (Modes 1, 2, 3.) |
| 7971-P | DOT-E 7971 | Walter Kidde, Division of Kidde, Inc., Wilson, NC. | 49 CFR 173.302, 173.304, 175.3, 178.53 | To become a party to Exemption 7971. (Modes 1, 2, 3, 4, 5.) |
| 8083-P | DOT-E 8083 | Matson Navigation Company, Honolulu, Hawaii. | 49 CFR 172.101, Column 7(c) only | To become a party to Exemption 8083. (Mode 3.) |
| 8086-X | DOT-E 8086 | Boeing Aerospace Company, Seattle, WA. | 49 CFR 172.101, 172.102, 173.118(b), 173.119, 173.206, 173.87. | To authorize transport of a cruise missle containing hazardous materials. (Mode 1.) |
| 8108-X | DOT-E 8108 | Allied Chemical, Morristown, NJ. | 49 CFR 173.24(c)(6), 173.245(a)(27) | To authorize use of a DOT Specification 33A polystyrene case containing four 5-pint glass bottles, for shipment of corrosive liquids. (Modes 1, 2, 3.) |
| 8129-P | DOT-E 8129 | CECOS International, Inc., Buffalo, NY. | 49 CFR 177.834(k), Part 173, Subparts D, E, F, H, Subparts K, L, M, O. | To become a party to Exemption 8129. (Mode 1.) |
| 8129-X | DOT-E 8129 | Iowa State University, Ames, IA. | 49 CFR 177.834(k), Part 173, Subparts D, E, F, H, Subparts K, L, M, O. | To authorize shipment of various waste hazardous materials packed in bottles surrounded by absorbent material overpacked in DOT Specification 37A, 17H, or 6J drums. (Mode 1.) |
| 8129-X | DOT-E 8129 | University of Maryland, College Park, MD. | 49 CFR 177.834(k), Part 173, Subparts D, E, F, H, Subparts K, L, M, O. | To authorize shipment of various waste hazardous materials packed in bottles surrounded by absorbent material overpacked in DOT Specification 37A, 17H, or 6J drums. (Mode 1.) |
| 8129-P | DOT-E 8129 | Midwest Research Institute, Kansas City, MO. | 49 CFR 177.834(k), Part 173, Subparts D, E, F, H, Subparts K, L, M, O. | To become a party to Exemption 8129. (Mode 1.) |
| 8129-P | DOT-E 8129 | ARCO Chemical Company, Newtown, Square, PA. | 49 CFR 177.834(k), Part 173, Subparts D, E, F, H, Subparts K, L, M, O. | To become a party to Exemption 8129. (Mode 1.) |
| 8129-P | DOT-E 8129 | American Scientific Products, McGaw Park, IL. | 49 CFR 177.834(k), Part 173, Subparts D, E, F, H, Subparts K, L, M, O. | To become a party to Exemption 8129. (Mode 1.) |
| 8129-X | DOT-E 8129 | Triangle Resource Industries, Laurel, MD. | 49 CFR 177.834(k), Part 173, Subparts D, E, F, H, Subparts K, L, M, O. | To authorize shipment of various waste hazardous materials packed in bottles surrounded by absorbent material overpacked in DOT Specification 37A, 17H, or 6J drums. (Mode 1.) |

RENEWAL AND PARTY TO EXEMPTIONS—Continued

| Application No. | Exemption No. | Applicant | Regulation(s) affected | Nature of exemption thereof |
|---|---|---|---|---|
| 8129-X | DOT-E 8129 | Kenn-McGee Chemical Corporation, Oklahoma City, OK. | 49 CFR 177.834(k), Part 173, Subparts D, E, F, H, Subparts K, L, M, O. | To authorize shipment of various waste hazardous materials packed in bottles surrounded by absorbent material overpacked in DOT Specification 37A, 17H, or 6J drums. (Mode 1). |
| 8129-P | DOT-E 8129 | Lion Technology Inc., Lafayette, NJ | 49 CFR 177.834(k), Part 173, Subparts D, E, F, H, Subparts K, L, M, O. | To become a party to Exemption 8129. (Mode 1.) |
| 8156-P | DOT-E 8156 | Union Carbide Corporation, Danbury, CT | 49 CFR 173.121, 173.302(a)(4), 173.302(f), 173.304(a)(1). | To become a party to Exemption 8156. (Modes 1, 2.) |
| 8156-P | DOT-E 8156 | Scientific Gas Products, Inc., South Plainfield, NJ | 49 CFR 173.121, 173.302(a)(4), 173.302(f), 173.304(a)(1). | To become a party to Exemption 8156. (Modes 1, 2.) |
| 8184-X | DOT-E 8184 | Trojan Corporation, Salt Lake City, UT | 49 CFR 173.65 | To authorize transport of flake trinitrotoluene in a non-DOT specification multi-wall paper polyethylene jute composite bag with net weight not exceeding 100 pounds. (Modes 1, 2, 3.) |
| 8220-X | DOT-E 8220 | Applied Environments Corporation, Woodland Hills, CA. | 49 CFR 173.320(a), 175.3 | To authorize use of non-DOT specification girth welded steel cylinder, for transportation of nonflammable compressed gases. (Modes 1, 2, 4.) |
| 8221-X | DOT-E 8221 | Applied Environments Corporation, Woodland Hills, CA. | 49 CFR 173.302(a), 175.3 | To authorize use of non-DOT specification high pressure cylinders of welded construction for military missile systems use only. (Modes 1, 2, 4.) |
| 8237-X | DOT-E 8237 | Sanders Associates, Inc., Nashua, NH | 49 CFR 172.101, 173.302(a)(2), 175.3 | To authorize transport of a device containing lithium batteries and a cylinder containing compressed nitrogen in a wooden box. (Modes 1, 4.) |
| 8426-X | DOT-E 8426 | Martin Tank Manufacturing, Inc., Wilmington, CA | 49 CFR 173.119(a), (m), 173.245(a), 173.346(a), 178.340-7, 178.342-5, 178.343-5. | To authorize manufacture, marking and sale of non-DOT specification cargo tanks complying with DOT Specification MC-307/312 with certain exception, for transportation of liquid and semi-solid waste materials. (Mode 1.) |
| 8445-X | DOT-E 8445 | Rohm and Haas Company, Philadelphia, PA | 49 CFR Part 173, Subpart D, E, F, & H | To authorize shipment of various hazardous substances and wastes packed in inside plastic, glass, earthenware or metal containers, overpacked in a DOT Specification removable head steel, fiber or polyethylene drum, only for the purposes of disposal, repackaging or reprocessing. (Mode 1.) |
| 8451-P | DOT-E 8451 | Ethyl Corporation, Ferndale, MI | 49 CFR 173.65, 173.86(e), 175.3 | To become a party to Exemption 8451. (Modes 1, 2, 4.) |
| 8518-X | DOT-E 8518 | Pacific Tank and Manufacturing, Long Beach, CA | 49 CFR 173.119(a), (m), 173.245(a), 173.346(a), 178.340-7, 178.342-5, 178.343-5. | To authorize manufacture, marking, and sale of non-DOT Specification cargo tanks complying generally with DOT specification MC-307/312 except for bottom outlet valve variations, for transportation of flammable or corrosive waste liquids or semi-solids. (Mode 1.) |
| 8519-X | DOT-E 8519 | Atlantic Container Line, Elizabeth, NJ | 49 CFR 176.905(L) | To authorize stowage of motor vehicles containing gasoline, in their fuel tanks, classed as a flammable liquid in the same cargo compartment with other hazardous materials on specially equipped roll-on/roll-off cargo vessels. (Mode 3.) |
| 8520-X | DOT-E 8520 | Atlas Powder Company, Dallas, TX | 49 CFR 173.114a (b)(6) | To authorize use of a "pipe test" on a material being evaluated as a blasting agent, instead of fire test prescribed in 173.114a(b)(6). (Modes 1, 2, 3, 4.) |
| 8523-X | DOT-E 8523 | Dehon Services, Paris, France | 49 CFR 173.304, 173.315 | To authorize use of non-DOT Specification IMCO Type 5 portable tanks, for transportation of flammable and non-flammable compressed gases. (Modes 1, 2, 3.) |
| 8523-X | DOT-E 8523 | Fauvet-Ginel, Paris, France | 49 CFR 173.304, 173.315 | To authorize use of non-DOT Specification IMCO Type 5 portable tanks, for transportation of flammable and nonflammable compressed gases. (Modes 1, 2, 3.) |
| 8526-X | DOT-E 8526 | National Starch and Chemical Corporation, Bridgewater, NJ. | 49 CFR 177.834(L)(2)(i) | To authorize shipment of flammable liquids and/or flammable gases in temperature controlled equipment. (Mode 1.) |
| 8526-X | DOT-E 8526 | PPG Industries, Inc., Pittsburgh, PA | 49 CFR 177.834(L)(2)(i) | To authorize shipment of flammable liquids and/or flammable gases in temperature controlled equipment. (Mode 1.) |
| 8550-X | DOT-E 8550 | Environmental Sciences Associates, Inc., Bedford, MA. | 49 CFR 173.119(m)(6), 175.3 | To authorize shipment of a hydrochloric acid/propanol mixture, classed as a flammable liquid, in non-DOT specification one-pint polyethylene bottles, not to exceed 6 bottles to one outside DOT Specification 12B fiberboard box. (Modes 1, 2, 3, 4, 5.) |
| 8551-X | DOT-E 8551 | Huber Manufacturing, Incorporated, Gulfport, MS | 49 CFR 173.119(a), (m), 173.245(a), 173.346(a), 178.340-7, 178.342-5, 178.343-5. | To authorize manufacture, marking and sale of non-DOT specification cargo tanks complying generally with DOT Specification MC-307/312 except for bottom outlet valve variations and certain other features for transportation of flammable, corrosive, or poisonous waste liquids or semi-solids. (Mode 1.) |

## RENEWAL AND PARTY TO EXEMPTIONS—Continued

| Application No. | Exemption No. | Applicant | Regulation(s) affected | Nature of exemption thereof |
|---|---|---|---|---|
| 8554-P | DOT-E 8554 | Cordeino Trucking, Dania, FL | 49 CFR 173.114a, 173.93 | To become a party to Exemption 8554. (Mode 1.) |
| 8554-P | DOT-E 8554 | Florida Explosives, Inc., Hialeah Gardens, FL | 49 CFR 173.114a, 173.93 | To become a party to Exemption 8554. (Mode 1.) |
| 8558-X | DOT-E 8558 | Trojan Corporation, Spanish Fork, UT | 49 CFR 173.53 | To authorize the transport of a pharmaceutical described as an initiating explosive in a non-DOT specification polyethylene pail, overpacked in a 15 gallon DOT Specification 37A steel drum. (Mode 1.) |
| 8565-X | DOT-E 8565 | PPG Industries, Inc., Pittsburgh, PA | 49 CFR 173.217(a)(3), 178.224 | To authorize shipment of calcium hypochlorite mixture, dry, classed as oxidizer, in a DOT Specification 21C drum having an inner ply consisting of a lamination of polyester film mounted on aluminum foil. (Modes 1, 2, 3.) |
| 8565-X | DOT-E 8565 | Pennwalt Corporation, Philadelphia, PA | 49 CFR 173.217(a)(3), 178.224 | To authorize shipment of calcium hypochlorite mixture, dry, classed as oxidizer, in a DOT Specification 21C drum having an inner ply consisting of a lamination of polyester film mounted on aluminum foil. (Modes 1, 2, 3.) |
| 8569-X | DOT-E 8569 | General Dynamics Corporation, Fort Worth, TX | 49 CFR 172.101(6)(b), 173.276, 175.3 | To authorize shipment of 6.6 gallons of hydrazine, aqueous solution in non-DOT specification F-16 emergency fuel tanks. (Modes 1, 3, 4.) |
| 8569-X | DOT-E 8569 | U.S. Department of Defense, Washington, DC | 49 CFR 172.101(6)(b), 173.276, 175.3 | To authorize shipment of 6.6 gallons of hydrazine, aqueous solution in non-DOT specification F-16 emergency fuel tanks. (Modes 1, 3, 4.) |
| 8571-X | DOT-E 8571 | EM Science, Cincinnati, OH | 49 CFR 173.119(a)(28), (b) | To authorize shipment of various flammable liquids packaged in a DOT Specification 12A corrugated fiberboard box, with two inside metal containers not over 10 liters capacity each. (Mode 1.) |
| 8592-X | DOT-E 8592 | Beech Aircraft Corporation, Boulder, CO | 49 CFR 173.315 | To authorize use of a non-DOT specification demountable cargo tank, for transportation of flammable gases. (Mode 1.) |
| 8620-X | DOT-E 8620 | Polar Tank Trailer, Inc., Holdingford, MN | 49 CFR 173.119(a), 173.119(m), 173.245(a), 173.346(a), 178.340-7, 178.342-5, 178.343-5. | To authorize manufacture, marking and sale of non-DOT specification cargo tanks complying generally with DOT Specification MC-307/312 except for bottom outlet valve variations for transportation of flammable or corrosive waste liquids or semi-solids. (Mode 1.) |
| 8627-P | DOT-E 8627 | Champion Chemicals, Inc., Houston, TX | 49 CFR 173.119, 173.245, 178.253 | To become a party to Exemption 8627. (Mode 1.) |
| 8720-X | DOT-E 8720 | Applied Environments Corporation, Woodland Hills, CA. | 49 CFR 173.302(a), 175.3 | To authorize manufacture, marking and sale of non-DOT specification welded high pressure non-refillable cylinders, for shipment of nonflammable and nonliquefied gases. (Modes 1, 2, 4.) |
| 8732-P | DOT-E 8732 | ICI Americas Inc., Wilmington, DE | 49 CFR 173.245 | To become a party to Exemption 8732 (Mode 1.) |
| 8839-X | DOT-E 8839 | Poly Processing Company, Inc., Monroe, LA | 49 CFR 173.266, 178.19, Part 173, Subpart F | To authorize manufacture, marking and sale of non-DOT specification nationally molded, cross-linked polyethylene portable tanks, for shipment of corrosive liquids and an oxidizer. (Modes 1, 2, 3.) |
| 8878-P | DOT-E 8878 | Preussag AG Metall, Boslar, West Germany | 49 CFR 173.245 | To become a party to Exemption 8878. (Mode 1.) |
| 8925-X | DOT-E 8925 | Military Sealift Command, Washington, DC | 49 CFR 46 CFR 146.29-35(f), 49 CFR, Part 107 Appendix B, Subparagraph 1, Subparagraph 2. | To authorize installation and operation of electrical dehumidification equipment in the hold of a vessel (Gulf Shipper) containing Class A, B, and C explosives. (Mode 3.) |

## NEW EXEMPTIONS

| Application No. | Exemption No. | Applicant | Regulation(s) affected | Nature of exemption thereof |
|---|---|---|---|---|
| 8877-N | DOT-E 8877 | PCR, Incorporated, Gainesville, FL | 49 CFR 173.119(m)(3), 173.245, 175.3 | To authorize shipment of certain materials described as flammable liquids, corrosive, n.o.s. (corrosive to skin only) and corrosive liquids, n.o.s., in DOT-12B65 fiberboard boxes with inside glass bottles having a capacity not to exceed one-gallon or an all-18-gauge DOT-17E steel drum. (Modes 1, 2, 3, 4, 5.) |
| 8901-N | DOT-E 8901 | Soweco, Inc., Amarillo, TX | 49 CFR 173.357 | To authorize shipment of chloropicrin, in polyethylene bottles overpacked in non-DOT specification triple-wall, corrugated fiberboard boxes. (Mode 1.) |
| 8954-N | DOT-E 8954 | Air Products and Chemicals, Inc., Allentown, PA. | 49 CFR 173.315, 176.76(b) | To authorize use of non-DOT specification vacuum insulated cargo tanks, for transportation of certain nonflammable gases. (Mode 3.) |
| 8958-N | DOT-E 8958 | Goex, Inc., Moosic, PA | 49 CFR 172.101, 173.60 | To authorize transportation of limited quantities of black powder, classed as a flammable solid, in DOT Specification 12H fiberboard boxes. (Modes 1, 2, 3.) |
| 8967-N | DOT-E 8967 | Hercules Incorporated, Wilmington, DE | 49 CFR 173.93(a)(11) | To authorize shipment of a solid propellant explosive, in a non-DOT specification fiberboard tube, overpacked in a non-DOT specification palletized metal cage. (Mode 1.) |

NEW EXEMPTIONS—Continued

| Application No. | Exemption No. | Applicant | Regulation(s) affected | Nature of exemption thereof |
|---|---|---|---|---|
| 8972-N | DOT-E 8972 | Union Carbide Corporation, Danbury, CT | 49 CFR 173.247(a)(18) | To authorize shipment of anhydrous thionyl chloride and mixtures thereof with non-hazardous inorganic salt, in DOT Specification 3E stainless steel cylinders. (Mode 1.) |
| 8979-N | DOT-E 8979 | Freeman Industries, Inc., Tuckahoe, NY | 49 CFR 173.270(a)(2) | To authorize shipment of phosphorous tribromide, in non-DOT specification lead-lined steel drums, overpacked with polyethylene bags which are overpacked in removable-head steel drums. (Mode 1.) |
| 8944-N | DOT-E 8944 | Union Carbide Corporation, Danbury, CT | 49 CFR 173.302(c)(2), 173.302(c)(3), 173.302(c)(4), 173.34(e)(1), 173.34(e)(3), 173.34(e)(4), 173.34(e)(6), Part 107 Appendix B. | To authorize the retest of DOT Specification 3AAX or 3T cylinders by acoustical emission equipment and procedures. (Mode 1.) |

NOTE—The provisions of DOT-E 8944 are not conducive to party status under Section 107.111.

EMERGENCY EXEMPTIONS

| Application No. | Exemption No. | Applicant | Regulation(s) affected | Nature of exemption thereof |
|---|---|---|---|---|
| EE 6064-P | DOT-E 6064 | Sodyeco, Inc., Charlotte, NC | 49 CFR 173.65(e), 187.24-4(a) | To become a party to Exemption 6064. (Mode 1.) |
| EE 6468-P | DOT-E 6468 | Sodyeco, Inc., Charlotte, NC | 49 CFR 173.365 | To become a party to Exemption 6068. (Mode 1.) |
| EE 8303-P | DOT-E 8303 | Sodyeco, Inc., Charlotte, NC | 49 CFR 172.101, 173.154 | To become a party to Exemption 8303. (Mode 1.) |
| EE 9019-N | DOT-E 9019 | Completion Services, Inc. Lafayette, LA | 49 CFR 173.119a, 173.119, 173.125, 173.263, 173.264, 173.277, 173.510, 46 CFR 64.9. | To authorixe use of a marine portable tank, for transportation of flammable, corrosive and combustible liquids. (Mode 1.) |
| EE 9020-N | DOT-E 9020 | Vought Corporation, Dallas, TX | 49 CFR 173.57, 173.66, 175.3, 175.30 | To authorize shipment of rocket ammunition with explosive projectile and separately packaged component parts (Class A explosives). (Mode 4.) |
| EE 9021-N | DOT-E 9021 | American Cylinder Corporation, Glen Burnie, MD. | 49 CFR 173.28, 178.65 | To authorize one time refilling and recharging of DOT Specification 3B cylinders, for transportation of a compressed gas. (Mode 1.) |
| EE 9022-N | DOT-E 9022 | NL Barold/NL Industries, Incorporated, Houston, TX. | 49 CFR 172.101 column 6(b), 175.30, 175.320(a). | To authorize transport of shaped charges in DOT Specification wooden or fiberboard boxes. (Mode 1.) |
| EE 9031-N | DOT-E 9031 | Raufoss Amunisjonsfabrikker (RA), Oslo, Norway. | 49 CFR 173.56, 173.86, 175.30 | To authorize shipment of rocket ammunition with explosive projectile and separately packaged explosive projectiles. (Mode 4.) |

WITHDRAWALS

| Application No. | Applicant | Regulations(s) affected | Nature of exemption thereof |
|---|---|---|---|
| 6525-X | Associated Container Transportation (USA), New York, NY. | 49 CFR 173.389(o)(1), 173.392(c), 176.700(h)(1), 176.700(h)(2). | To authorize shipment of mineral monazite sand, classed as radioactive material, low specific activity, n.o.s. under modified exclusive use provisions. (Modes 1, 2, 3.) |

**Denials**

8627-P Request by Nalco Chemical Company, Oak Brook, IL to authorize shipment of various flammable liquids on corrosive materials (oil well treating compounds) contained in 6 separate 60 gallon steel tanks firmly mounted on the chassis of a truck denied March 16, 1983.

8807-N Request by Natico, Incorporated, Chicago, IL to reconsider denial of their request to manufacture, mark and sell non-DOT specification tight head 55-gallon steel drums similar to DOT Specification 17E except top and bottom heads are 20 gauge steel secured by 7 ply chime, for shipment of commodities authorized in 17E drums denied March 28, 1983.

8868-N Request by Brea Agricultural Service, Stockton, CA to authorize transport of a corrosive liquid containing sulfuric acid in DOT Specification MC-306, MC-310, MC-311 and MC-312 cargo tanks without phenolic linings denied March 22, 1983.

8956-N Request by Clif Mock Company, Conroe, TX to manufacture, mark and sell certain steel cylinders for transporting samples of liquefied petroleum gas, oil well natural gas, and other petroleum hydrocarbon gases or liquids denied March 8, 1983.

8966-N Request by All Pure Chemical Company, Inc., Tracy, CA to authorize shipment of 12.5% sodium hypochlorite, 31.44% hydrochloric acid and 38.5% sulfuric acid, in polyethylene (PE) bottles, in a corrugated fiberboard box complying with DOT Specification 12B except for handholes in the side pannels of the box denied March 3, 1983.

8974-N Request for Fabricated Metals, Inc., San Leandro, CA to manufacture DOT Specification 56 portable tanks from an aluminum alloy which does not have the mechanical properties specified in 49 CFR 178.251-2(d)(1) denied March 28, 1983.

8989-N Request by C-I-L Inc., North York, Ont., Canada to authorize shipment of an initiating explosive (pentaerythrite tetranitrate) Class A explosive, in fiberboard boxes wet with not less than 25 percent by weight of water with boxes marked "P.E.T.N." denied March 14, 1983.

9008-N Request for Reynolds Manufacturing Company, McAllen, TX to manufacture, mark and sell certain vacuum tanks made to MC-307 without internal valves on each tank outlet denied March 25, 1983.

**Note.**—Inadvertently omitted from the 47 FR 244 publication of Exemptions issued during December 1982 is the following:

8762-N Appeal by O. I. Corporation, College Station, TX to authorize shipment of chromic acid solution, containing less than 35% chromic acid by weight, classed as corrosive liquid, n.o.s. contained in glass ampules packed in styrofoam containers overpacked in a fiberboard box denied December 6, 1982.

Issued in Washington, DC, on April 12, 1983

**J. R. Grothe,**

*Chief, Exemptions Branch, Office of Hazardous Materials Regulation, Materials Transportation Bureau.*

[FR Doc. 83-10389 Filed 4-20-83; 8:45 am]

**BILLING CODE 4910-60-M**

## Urban Mass Transportation Administration

### Availability of UMTA Circular 5010.1, "Project Management Guidelines for Grantees"

**AGENCY:** Urban Mass Transportation Administration, DOT.

**ACTION:** Notice.

**SUMMARY:** By this notice, the Urban Mass Transportation Administration (UMTA) announces that UMTA Circular 5010.1, "UMTA Project Management Guidelines for Grantees," is available to the public. This circular provides project management guidelines for recipients of grants for mass transportation activities

pursuant to Sections 3, 5, 6, 8, 9, and 10 of the Urban Mass Transportation Act, as amended (49 U.S.C. 1601 et seq.) and sections 103(e)(4) and 142 of Title 23 of the United States Code.

**EFFECTIVE DATE:** April 21, 1983.

**FOR FURTHER INFORMATION CONTACT:** Timothy B. Wolgast, Urban Mass Transportation Administration, Office of Administration, 400 7th Street, SW., Washington, D.C. 20590; telephone (202) 426–4022. A copy of UMTA Circular 5010.1 may be obtained from UMTA Regional Offices or by contacting Joseph F. Vocke, Office of Administration, Room 7427, at the above address; telephone (202) 426–4865.

**SUPPLEMENTARY INFORMATION:**

**Significant Features of New Guidelines**

UMTA Circular 5010.1 provides grantees with procedures and guidelines to be applied in administering UMTA grants, cooperative agreements, and loans. The guidance incorporates various statutory and regulatory requirements; Office of Management and Budget, and Department of Treasury control agency circulars; and specific UMTA program information which is instrumental in maintaining proper grantee project management responsibilities and practices.

UMTA Circular 5010.1 provides guidance and instructions on three areas: Project Management and Administration; Financial Management; and Payment Procedures. The Project Management and Administration chapter includes information on project reporting, budget revisions and amendments, disposition of project property, record retention, closeout procedures, and other special requirements important to grantees. The circular's Financial Management chapter details responsibilities and procedures on internal controls, cost allocation plans and cost standards, program income, financial reporting, and audit requirements. The Payment Procedures section discusses the various methods and forms used in making cash payments to grantees.

This circular was approved for publication while the 1982 amendments to the Urban Mass Transportation Act of 1964 were being passed by Congress and sent to the President for approval. Therefore, the circular does not include new project management guidelines for provisions contained in Title III of the Surface Transportation Assistance Act of 1982 (Pub. L. 97–424), enacted January 6, 1983. Guidelines for the implementation and management of Title III will be published by UMTA in a separate circular and will be made available in the next few weeks.

**Background**

On September 11, 1980, UMTA published the information in this circular as a Notice of Proposed Rulemaking (NPRM) in the **Federal Register** (45 FR 60306). This material was intended to be issued as a regulation, but UMTA determined that the necessary program guidance could be more effectively issued in a non-regulatory matter. The NPRM was formally withdrawn on January 25, 1982 (47 FR 3391).

Twenty-six interested parties commented on the NPRM. The comments assisted UMTA in drafting the circular. Some significant comments and UMTA's response follow: (1) Inconsistencies between language in the NPRM and that in OMB Circular A–102, "Uniform Requirements for Assistance to State and Local Governments" (1/81), upon which the NPRM was based, were noted. UNTA has revised the language in all such cases to assure consistency with A–102; (2) Inconsistencies between the NPRM and OMB Circular A–87, "Cost Principles for State and Local Governments" (1/15/81), with respect to travel costs and the submission of a cost allocation plan, were noted. UMTA has eliminated the inconsistency involving travel cost and the requirement to submit a complete cost allocation plan with each application; (3) There were comments requesting the easing of budget revision requirements, such as permitting the transfer of funds between direct and indirect costs. UMTA has revised the circular to allow the transfer of funds budgeted for direct cost items to absorb authorized increases in indirect costs for nonconstruction grants; (4) A commenter requested that UMTA clarify proposed Appendix III, Section 1(b), Payroll and Distribution of Time, as it would have applied to Section 8 technical study grants. The optional format contained in this appendix has been eliminated. Grantees who prefer to use another method, such as the one used in the UMTA regulation on Urban Transportation Planning (49 CFR Part 613, Subpart A&B) may do so; and (5) Concern was expressed about the proposed cash-drawdown procedures in Chapter III, that provided a 3-day limitation in the Letter of Credit procedures. A commenter felt it would make more sense if drawdowns could be requested on a quarterly basis to satisfy cash requirements for vendor payments. The 3-day limitation procedures have been eliminated to parallel the language in Treasury Circular 1075. However, drawdowns should not be made on a quarterly basis, and must be made as close to the disbursing date as possible in accordance with Department of Treasury policy.

Issued on: April 14, 1983.

**Arthur E. Teele, Jr.,**

*Administrator.*

[FR Doc. 83–10552 Filed 4–20–83; 8:45 am]

BILLING CODE 4910–57–M

## DEPARTMENT OF THE TREASURY

### Customs Service

**[T.D. 83–39]**

### Decision Denying Domestic Interested Party Petition Requesting Reclassification of Certain Plywood Panels; Petitioner's Desire to Contest the Decision

**AGENCY:** Customs Service, Treasury.

**ACTION:** Notice of: (1) Decision on domestic interested party petition, and (2) receipt of notice of petitioner's desire to contest the decision.

**SUMMARY:** In response to a petition from a domestic interested party requesting that certain plywood panels that have been processed, be reclassified for tariff purposes under the provision for softwood plywood, in item 240.21, Tariff Schedules of the United States (TSUS), Customs invited comments with regard to the correctness of the present classification. After consideration of the comments received and further review of the matter, Customs has advised the petitioner that such plywood panels would continue to be classified as building boards, in item 245.80, TSUS. Upon being informed that its petition had been denied, the petitioner filed a notice of its desire to contest the decision.

**FOR FURTHER INFORMATION CONTACT:** John G. Hurley, Classification and Value Division, Office of Regulations and Rulings, U.S. Customs Service, 1301 Constitution Avenue, NW., Washington, D.C. 20229 (202–566–8181).

**SUPPLEMENTARY INFORMATION:**

**Background**

On March 4, 1982, a petition was filed under section 516, Tariff Act of 1930, as amended (19 U.S.C. 1516), by the American Plywood Association, a trade association which represents American manufacturers of softwood plywood, requesting that certain imported plywood panels that have been processed (i.e., tongue and grooved, edge-worked, or shiplapped), be

reclassified as plywood with a face ply of softwood, in item 240.21, Tariff Schedules of the United States (TSU) (19 U.S.C. 1202), presently dutiable at 21 percent ad valorem. Such plywood panels have been classified by Customs under the provision for building boards not specially provided for, whether or not face finished, laminated boards bonded in whole or in part, or impregnated, with synthetic resins, in item 245.80, TSUS, at a lower rate of duty, following Customs ruling 069190 JLJ, dated February 12, 1982.

Specifically, the petitioner alleges that the provision for softwood plywood in TSUS item 240.21, is more specific than the provision for building boards in TSUS item 245.80, and therefore it should govern the classification of the imported panels. It is Customs position that edge-working changes plywood panels, dedicates them to a special use (i.e., as building boards), and thus prevents them from satisfying the definition of plywood in Schedule 2, Part 3, headnote 1(b), TSUS.

A notice of receipt of the petition was published in the **Federal Register** on August 13, 1982 (47 FR 35391), inviting public comment. Written comments were to have been received on or before October 12, 1982. Two comments were received in response to the notice. Both opposed any change in the classification of the panels, supporting Customs position that they are correctly classified as building boards in item 245.80, TSUS.

### Decision on Petition and Receipt of Petitioner's Notice of Desire To Contest

In a letter dated December 13, 1982, the petitioner was advised that Customs had decided to continue its practice of classifying such plywood panels in item 245.80, TSUS. In response, by letter dated January 5, 1983, the petitioner filed a notice of its desire to contest the decision in accordance with section 516(c), Tariff Act of 1930, as amended, (19 U.S.C. 1516(c)), and § 175.23, Customs Regulations (19 CFR 175.23).

After careful analysis of the comments received in response to the notice and further review of the matter, Customs remains of the opinion that its practice of classifying the subject panels under item 245.80, TSUS, is correct. This practice will continue provided that no decision of the United States Court of International Trade or the United States Court of Appeals for the Federal Circuit not in harmony with this practice is rendered.

**Authority:** This notice is being published in accordance with section 516(c), Tariff Act of 1930, as amended (19 U.S.C. 1516(c)), and § 175.24, Customs Regulations (19 CFR 175.24).

### Drafting Information

The principal author of this document was Jesse V. Vitello, Office of Regulations and Rulings, U.S. Customs Service. However, personnel from other Customs offices participated in its development.

Dated: March 18, 1983.

**Alfred R. De Angelus,**

*Acting Commissioner of Customs.*

[FR Doc. 83-7909 Filed 4-20-83; 8:45 am]

BILLING CODE 4820-02-M

## OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

### Motorcycle Import Relief Determination

On April 1, 1983, the President transmitted the following memorandum to the United States Trade Representative setting forth his decision to provide import relief for the heavyweight motorcycle industry.

**Frederick L. Montgomery,**

*Chairman, Trade Policy Staff Committee.*

April 1, 1983.

The White House, Washington

Memorandum for the United States Trade Representative

Subject: Motorcycle Import Relief Determination

Pursuant to Section 202(b)(1) of the Trade Act of 1974 (Pub. L. 93-618, 88 Stat. 1978), I have determined the action I will take with respect to the report of the United States International Trade Commission (USITC), transmitted to me on February 1, 1983, concerning the results of its investigation of a petition for import relief filed by the Harley-Davidson Motor Co., Inc., and Harley-Davidson York, Inc., producers of heavyweight motorcycles, provided for in item 692.50 of the Tariff Schedules of the United States (TSUS).

After considering all relevant aspects of the case, including those set forth in Section 202(c) of the Trade Act of 1974, I have determined that granting import relief is consistent with our national economic interest. Therefore, I will proclaim the USITC five-year import relief remedy with one modification. I will impose tariff increases of 45 percent *ad valorem* in the first year, declining to 35, 20, 15 and 10 percent above scheduled rates in subsequent years. Imposition of these tariff increases should allow the heavyweight motorcycle industry to adjust to the threat of injury caused by increased imports, which have raised inventories to twice their normal level.

To assure small volume producers who have not contributed to that threat of injury continued access to U.S. markets for heavyweight motorcycles, I will modify the USITC remedy by proclaiming tariff-rate quotas of 5,000 units (increasing yearly to 6,000, 7,000, 8,500 and 10,000) for imports of motorcycles manufactured in the Federal Republic of Germany, and 4,000 units (increasing yearly by 1,000) for imports from all other countries except Japan. The additional duties will apply to all imports above the tariff-rate quotas. In order to treat Japan fairly I will also proclaim a tariff-rate quota of 6,000 units (increasing 1,000 yearly) for motorcycles imported from Japan.

I also direct you to keep the issue under close review so that, should the U.S. motorcycle industry no longer need this level of relief, you may, in consultation with the Trade Policy Committee, obtain other necessary advice and propose changes in the terms of relief. If no earlier review is initiated by such conditions, you are to undertake such a review in two years. The objectives of this review would be to assess the effectiveness of import relief and Harley-Davidson's trade adjustment efforts.

Ronald Reagan.

[FR Doc. 83-10554 Filed 4-20-83; 8:45 am]

BILLING CODE 3190-01-M

# Sunshine Act Meetings

Federal Register
Vol. 48, No. 78
Thursday, April 21, 1983

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).

## CONTENTS



1

**FEDERAL ELECTION COMMISSION**

Federal Register No. 525

**PREVIOUSLY ANNOUNCED DATE AND TIME:** Thursday, April 21, 1983, 10 a.m.

**CHANGES IN MEETING:** Pursuant to 11 CFR 3.5(d)(1), the Commission determined that Commission business so required, and that no earlier announcement of these changes was possible, and accordingly added the following matters to the agenda for the open meeting for this date:

Whether or not to withdraw nonpartisan communications by corporations or labor organizations—11 CFR 114.3 and 114.4
Letter to House Administration Task Force on Elections—Travel and subsistence reimbursement

**DATE AND TIME:** Tuesday, April 26, 1983, 10 a.m.

**PLACE:** 1325 K Street NW., Washington, D.C.

**STATUS:** This meeting will be closed to the public.

**MATTERS TO BE CONSIDERED:**

Compliance. Personnel. Litigation. Audits.

**DATE AND TIME:** Thursday, April 28, 1983, 10 a.m.

**PLACE:** 1325 K Street NW., Washington, D.C. (fifth floor).

**STATUS:** This meeting will be open to the public.

**MATTERS TO BE CONSIDERED:**

Setting of dates for future meetings
Correction and approval of minutes
Eligibility reports for candidates to receive Presidential primary matching payments
Draft AO 1983-9: Robert I. Bogin, on behalf of The Curry Exploratory Committee
Finance Committee report
Routine Administrative matters

**PERSON TO CONTACT FOR INFORMATION:** Mr. Fred Eiland, Information Officer, telephone: 202-523-4065.

**Marjorie W. Emmons,**

*Secretary of the Commission.*

[S-553-83 Filed 4-19-83; 3:32 pm]

BILLING CODE 6715-01-M

2

**FEDERAL HOME LOAN BANK BOARD**

**"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT:** 48 FR 16375, Friday, April 15, 1983.

**PLACE:** Board room, sixth floor, 1700 G Street NW., Washington, D.C.

**STATUS:** Open meeting.

**CONTACT PERSON FOR MORE INFORMATION:** Ms. Gravlee (202-377-6970).

**CHANGES IN THE MEETING:** The following items have been added to the open portion of the Bank Board meeting scheduled Wednesday, April 20, 1983, at 10 a.m.:

Acquistion of non-cash assets
Interstate operations of insured institutions
[No. 33, April 19, 1983]

[S-554-83 Filed 4-19-83; 3:38 pm]

BILLING CODE 6720-01-M

3

**FEDERAL MARITIME COMMISSION**

**TIME AND DATE:** 9 a.m., April 27, 1983.

**PLACE:** Hearing Room One, 1100 L Street NW., Washington, D.C. 20573.

**STATUS:** Open.

**MATTERS TO BE CONSIDERED:**

1. Agreement No. T-4091: Terminal lease between the Board of Trustees of the Galveston Wharves and Trans Freight Lines, Inc.
2. Agreements Nos. 9787-1 and 9925-2: PACE/ACTA Modifications Seeking Intermodal Authority.

**CONTACT PERSON FOR MORE INFORMATION:** Francis C. Hurney, Secretary (202) 523-5725.

[S-552-83 Filed 4-19-83; 12:27 pm]

BILLING CODE 6730-01-M

federal register

Thursday
April 21, 1983

Part II

# Department of Health and Human Services

Public Health Service

National Toxicology Program; Fiscal Year 1983 Annual Plan

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Public Health Service

[NTP-82-119]

### National Toxicology Program; Fiscal Year 1983 Annual Plan

The Director of the National Toxicology Program (NTP) announces the availability of the NTP Annual Plan for Fiscal Year 1983 and the quarterly NTP Technical Bulletins, solicits comments on the Annual Plan and urges all interested persons to propose chemicals(s) for testing by NTP.

**Background**

The National Toxicology Program develops scientific information about potentially toxic and hazardous chemicals which can be used for protecting the health of the American people and for the primary prevention of chemically-induced disease. The NTP centralizes and strengthens the Department of Health and Human Services' (DHHS') activities in toxicology research, testing, and test development/validation efforts and provides the necessary toxicological information needed by health research and regulatory agencies. Four specific goals continue to be emphasized:

- Expand the spectrum of toxicologic information obtained on the chemicals nominated, selected, and being tested;
- Increase the numbers of chemicals tested in various short-term assays, within funding limits;
- Develop, coordinate, and validate a series of tests/protocols more appropriate for regulatory needs;
- Communicate Program plans and results to governmental agencies, the medical and scientific communities, and the public.

To accomplish these four major aims the NTP was formed by bringing together the relevant toxicological programs, people, and resources from the Public Health Service.

The four DHHS agencies whose relevant toxicology programs comprise the NTP are the National Cancer Institute, National Institutes of Health (NIH); National Institute of Environmental Health Sciences, NIH; National Center for Toxicological Research, Food and Drug Administration; and National Institute for Occupational Safety and Health, Centers for Disease Control.

The NTP Executive Committee provides linkage between DHHS research and regulatory agencies to ensure that the toxicology research, testing and test development activities carried out under the aegis of the NTP are responsive to the needs of those agencies and to the needs of the public. This unique and important aspect of the NTP brings together the research agencies doing fundamental biomedical research and the regulatory agencies. The governmental agencies that comprise the NTP Executive Committee are listed in the 1983 Annual Plan.

The NTP Board of Scientific Counselors provides scientific oversight of the NTP. The NTP Board advises the NTP Director and the NTP Executive Committee on scientific content, philosophy, and policy and evaluates the merit and overall quality of the science conducted in the NTP components. The members (enumerated in the 1983 Annual Plan) are appointed by the Secretary of the Department of Health and Human Services.

The program segments of the NTP are grouped into two categories—toxicological research and testing, and coordinative management activities. Individual NTP scientists are identified as leaders of the major program segments and subprogram activities and serve as the focus or contact persons for their particular program activities. Program and project leaders are identified in the 1983 Annual Plan.

The development and approval of the NTP Annual Plan remain central to the effective planning, coordination, and operation of the National Toxicology Program. As NTP Director, Dr. David P. Rall (also the Director of the National Institute of Environmental Health Sciences) reports to the Assistant Secretary for Health.

The National Toxicology Program's fifth annual plan consists of two parts published separately: (1) "NTP Annual Plan for Fiscal Year 1983" (NTP-82-119), describes current year research, testing and validation efforts, resources and past year program accomplishments. (This first part is printed in full following this announcement.) (2) "Review of Current DHHS, DOE and EPA Research Related to Toxicology" (NTP-83-001), lists chemicals being tested by DHHS agencies, the Department of Energy, and the Environmental Protection Agency, and describes toxicology methods currently being developed by these agencies.

Written comments on the FY 1983 Annual Plan are requested and welcome. These should be addressed to Dr. Larry Hart, Assistant to the Director, National Toxicology Program, P.O. Box 12233, Research Triangle Park, NC 27709 (telephone: (919) 541-3971 or FTS 629-3971).

Regarding chemical nomination, NTP urges all those interested in proposing chemical(s) for testing to do so, and at a minimum to give the rationale for the nomination and to recommend the type test(s) to be considered. In addition, it would be desirable (but not essential) to supplement each nomination with the following information, if known.

I. Chemical identification.

II. Production, use, occurrence, and analysis.

III. Toxicology.

IV. Disposition and structure-activity-relations.

V. Ongoing toxicological and environmental studies in government, industry, and academia.

To bridge the yearly gap between Annual Plans, NTP started a quarterly NTP Technical Bulletin in FY 1980 to keep those persons or groups interested in the NTP informed about the NTP's most current and proposed activities. The NTP Technical Bulletins augment the Annual Plans by more timely and frequent announcements of the NTP research activities and specific actions.

To receive the NTP Annual Plan for Fiscal Year 1983; the FY 1983 Review of Current DHHS, DOE, and EPA Research Related to Toxicology; or NTP Technical Bulletins, please indicate which publications you wish to receive and submit this information to: NTP Public Information Office, P.O. Box 12233, Research Triangle Park, NC 27709, (telephone: (919) 541-3991 or FTS 629-3991).

Dated: April 1, 1983.

**David P. Rall,**

*Director, National Toxicology Program.*

**Note.**—All fiscal assumptions are based on the President's proposed FY 1983 budget.

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## Executive Summary National Toxicology Program Annual Plan for Fiscal Year 1983 [1]

The National Toxicology Program (NTP) will begin its fifth year of operation in FY 1983. The NTP was established in November 1978 as a Department of Health and Human Services (DHHS) cooperative effort to coordinate and manage the Department's program to develop the scientific information necessary to protect the health of the American public from exposure to hazardous chemicals. DHHS Secretary Richard S. Schweiker granted permanent status to the Program in October 1981.

At the present time, the NTP represents a major Federal resource for chemical testing, and represents a principal Federal effort in assessing current methods or developing better methodology for determining toxic potential of chemicals. This interagency program comprises one of the largest scientific data resources in genetic toxicity and animal carcinogenicity. There are also significant toxicology research, testing and test methods development activities ongoing in other Federal agencies. Current information on many of these efforts may be found in the NTP's FY 1983 *Review of Current DHHS, DOE and EPA Research Related to Toxicology.*

Within the framework of its charge to identify those chemicals potentially toxic to humans, as well as to develop and validate new and better integrated test methods, the NTP continues to emphasize four specific goals: (1) expand the spectrum of toxicologic information obtained on the chemicals being tested; (2) increase the numbers of chemicals tested in various short-term assays within funding limits; (3) develop and validate a series of test protocols more appropriate for regulatory needs; and (4) establish a coordinated communications network to collect, evaluate, and disseminate toxicology information generated by the Program.

The NTP's predominant long-term objective centers on the development, validation, and application of better, less expensive, more specific test methodologies. However, chemical testing for toxicology continues to be a central focus and still utilizes the most resources. By broadening the protocols to better characterize the chemical toxicologic profile, the NTP is successfully implementing a comprehensive approach to assessing chemical toxicity which includes carcinogenesis, genetic toxicity, chemical disposition (absorption, distribution, metabolism, and excretion), fertility and reproductive assessment, and major organ toxicity.

Accomplishments of NTP programs during FY 1982 and program plans for FY 1983 are described in the following sections of the FY 1983 Annual Plan. This year, accomplishments and plans are described separately by agency under each scientific and management section. The name of a key staff person is given for each project and program activity. A complete listing of program leaders and contact persons, along with addresses and phone numbers, appears in the Appendix. A bibliography of recent NTP-related publications, arranged alphabetically by the last name of the first author and by type of publication, is also included in the Appendix.

*Important Accomplishments of the NTP in FY 1982 Include:*

- Implemented a more comprehensive approach to assessing chemical toxicity including genetic toxicity, chemical disposition, fertility and reproductive assessment, major organ toxicity, and carcinogenesis.

[1] Page numbers correspond to the bound version of the plan available from the NTP Public Information Office.

- Focused testing efforts on characterizing toxic properties associated with classes of chemicals with similar structures—e.g., benzidine congener dyes and phthalic acid esters.
- Continued an interagency effort on benzidine and cogener-based dyes wth regard to their chemical disposition and mutagenic, carcinogenic, and chronic toxic effects.
- Initiated studies with selected esters of ortho phthalic acid to assess genetic toxicity, dermal absorption, reproductive toxicity, and carcinogenic potential and mechanisms.
- Incorporated a set of cellular and genetic toxicology assays into prechronic testing phases for all chemicals being considered for long-term testing—gene mutations in bacterial and mammalian cells, chromosome damage, mammalian cell transformations, and DNA damage/repair.
- Completed testing on 288 chemicals in the *Salmonella typhimurium* mutagenesis assay.
- Completed testing on 48 chemicals for heritable genetic effects in *Drosophila melanogaster*, (fruit flies) and completed cytogenetics testing on 65 chemicals using Chinese hamster ovary cells.
- Began evaluating new methods for monitoring mutagenic activity in human lymphocytes and urine.
- Completed peer review of the technical reports for 21 carcinogenesis bioassays.
- Developed a protocol which will significantly modify the histopathology requirements for future two-year bioassays while retaining sensitivity for tumor detection. Addition of an interim kill near 15 months should enhance detection and characterization of non-tumor toxic lesions.
- Proposed enhancing the experimental design of the two-year bioassay (e.g., 4-doses) to provide better data for low-dose toxicology evaluation and for risk assessment while retaining power for detecting a cancer response in rodents.
- Initiated a research program investigating the utility of *in vivo* rodent liver tumor models for evaluating initiation/promotion mechanisms of chemical carcinogenesis.
- Continued long-term studies assessing etiology of cancer in occupational environments and conducted animal bioassays on materials ranging from single chemicals to mixtures using routes by which humans are exposed in the workplace.
- Added evaluation of male and female reproductive dysfunction to the 90–120 day prechronic test phase.
- Continued development of short-term prescreens of chemicals for teratologic effects and fertility assessment.
- Continued a collaborative inter laboratory behavioral teratology initiative.
- Initiated development and evaluation of a new model for percutaneous absorption of chemicals.
- Characterized an animal model (monkey) of human occupationally induced asthma.
- Evaluated pulmonary function indices as being more sensitive to low level chemically-induced lung damage than more traditional morphologic assessments.
- Implemented an immunotoxicology assay panel in prechronic testing phase for selected chemicals.
- Proceeded with implementation of the interagency toxicology data management system (TDMS) at bioassay contractor laboratories.

The NTP's completed, ongoing and planned activities in toxicology research, testing, test methods development and validation efforts, as well as other key program activities, are described in capsule form in the following pages, and in more detail in the main body of the *Annual Plan*.

*Cellular and Genetic Toxicology* (See pages 32 to 100)

During FY 1982, tests were completed on 288 chemicals in the initial testing phase for chemical mutagens, the *in vitro* microbial assay in *Salmonella typhimurium*. Testing was completed for heritable genetic effects on 48 chemicals in *Drosophila melanogaster* (fruit files) and for cytogenetic effects on 66 chemicals in the *in vitro* mammalian cell culture system (Chinese hamster ovary cells). In FY 1983, testing in *Salmonella* will continue with completion of about 300 chemical tests, with 75 tests completed in *Drosophila* and 100 tests completed in the mammalian cell culture system.

Cellular and genetic toxicology continues to be the largest single area of test methods development and validation in the Program with emphasis being placed on both *in vitro* and *in vivo* systems for measuring somatic mutations, chromosome aberrations, aneuploidy, heritible mutations, cellular transformation, and DNA damage and repair. Among new initiatives are measures for monitoring mutational events in human lymphocytes and urine.

*Carcinogenesis Testing* (See pages 101 to 136)

During FY 1982, 21 two-year bioassays were completed and the reports containing the data and conclusions were approved by the external peer review panel associated with the NTP Board of Scientific Counselors. In FY 1983, the NTP expects to complete 28 bioassays through peer review, and initiate 16 new starts in the prechronic phase of the bioassay, all with the incorporation of special studies for providing more comprehensive assessment of chemical toxicity.

A major addition to the prechronic phase of the toxicology and carcinogenesis bioassay process was inclusion of a group of five *in vitro* short-term cellular and genetic toxicology assays for measuring gene mutations (bacterial and mammalian cells), chromosome damage, mammalian cell transformation, and DNA damage/repair. A three-year program was initiated to evaluate and clarify the nature of biological responses associated with the two-year bioassay, especially initiation/promotion mechanisms, using selected *in vivo* rodent tumor models. Initiated or continued were a number of new or ongoing long-term carcinogenesis studies concerned with chemicals or mixtures of chemicals which humans may encounter in the workplace.

*Toxicologic Characterization* (See pages 137 to 141)

The 14-day and 90–120 day experiments with chemicals selected for carcinogenic evaluation provide a comprehensive approach to assessing chemical toxicity which includes genetic toxicity, chemical disposition, effects on reproduction and fertility, and other major organ toxicity. Test efforts are being focused on characterizing toxic properties associated with chemical class rather than chemical-by-chemical assessment. For example, studies are being initiated with selected ortho phthalic acid esters including evaluation of genetic toxicity, reproductive toxicity, dermal absorption, and carcinogenic potential and mechanisms of several esters. Chemical disposition studies are being done on all chemicals selected for long-term bioassays.

*Benzidine-Dye Initiative* (See pages 142 to 147)

Chemical disposition studies at the National Institute of Environmental Health Sciences (NIEHS), the National Center for Toxicological Research (NCTR), and the National Institute for Occupational Safety and Health (NIOSH) on the benzidine congeners and selected derivatives were largely completed in FY 1982. Since metabolic activation of benzidine and congener derivatives is a prerequisite for production of genetic toxicity, priority was given to developing a protocol for anaerobic metabolism of the derivatives. Short-term *in vivo* toxicity and carcinogenesis studies were initiated. In FY 1983, long term bioassays will begin on the dimethyl- and dimethoxy-benzidine congeners and a derivative of each.

*Chemical Pathology* (See pages 163 to 177)

The chemical pathology program has increased efforts in the areas of toxicologic and experimental pathology while continuing the major function of detecting and characterizing specific lesions in prechronic and chronic bioassay studies. Modifications in pathology requirements for the bioassay were proposed and revised after peer review and agency and public comment, and are being implemented to orient towards select organs and tissues examined histopathologically at 24 months while retaining the detection potential for neoplasia and increasing the ability to measure non-tumor pathology through use of an interim kill and histopathologic examination after 15 months.

*Immunological Toxicology* (See pages 182 to 185)

In FY 1982, the comprehensive panel of immunology and host resistance assays was implemented in the prechronic testing phase of the bioassay. A select number of chemicals were examined indepth for effects on the immune system. There will be continuing investigations in FY 1983 aimed at better correlating changes in immune function with altered host resistance, and at development of virus challenge models.

*Neurobehavioral Toxicology* (See pages 186 to 188)

In-depth neurological studies continued in developing and mature animals to elucidate the effects of chlordecone and 2,4-dichlorophenoxyacetic acid (2,4-D). Studies have been initiated to assess neurotoxicity in animals using naturally occurring home cage

behaviors, such as spontaneous motor activity and eating-related behaviors. Methods development/evaluation of human neurotoxicity tests to be used at the worksite are continuing as well as validation of reflex activity tests in animal and human laboratory studies.

*Pulmonary Toxicology* (See pages 192 to 195)

A panel of pulmonary function tests was determined to be more sensitive for the detection of lung damage from low levels of specific inhaled pollutants than traditional histopathologic techniques. A model of human occupational asthma developed in the monkey was further characterized, and screening of organic allergens using this non-human primate model will be initiated in FY 1983.

*Reproductive and Developmental Toxicology* (See pages 196 to 210)

Primary emphasis continued on (1) developing short-term tests in both reproductive toxicology and teratology, including both *in vivo* and *in vitro* teratologic test systems and a continuous breeding assay for fertility assessment, and on (2) using existing methodology to evaluate toxicity. In FY 1982, "conventional" teratology testing was completed on eight chemicals and was in progress on nine others. An interlaboratory behavioral teratology project using known behavioral teratogens continued. A class study remains in progress on the reproductive and developmental toxicology of the glycol ethers.

*Resources and Planning Assumptions* (See pages 12 to 16)

The President's budget for FY 1983 provides a funding level of $71.4 million. Increasing emphasis on short-term test methods development and validation coupled with a decreased emphasis on standard testing, particularly in the two-year bioassay, will continue. Major portions of these resources must still be placed on chemical testing because of the relatively high costs of the bioassay and because tests started two to three years ago are entering the pathology, data evaluation, report preparation, and peer review phases.

*Oversight and Review* (See pages 17 to 22)

The Executive Committee provides primary oversight and coordination for the Program, while the Board of Scientific Counselors provides scientific review and evaluation. During the year, the Board reviewed programs in inhalation toxicology and neurobehavioral toxicology, examined proposed modifications in the experimental design and pathology requirements for the two-year bioassay, and provided peer review and priority ranking of 57 chemicals nominated for testing. The Board on two occasions provided special peer review of chronic bioassays for the Food and Drug Administration. A Subcommittee aided by an *ad hoc* panel of experts peer reviewed in public session 21 toxicology and carcinogenesis bioassay reports.

*Organization* (See pages 25 to 27)

The toxicology Research and Testing Program (TRTP) NIEHS, was established in FY 1981 to integrate the Carcinogenesis Bioassay Program, transferred from the National Cancer Institute (NCI), and the NIEHS toxicology testing and methods development activities. Representing most of the National Institutes of Health (NIH) component of the NTP, the TRTP is composed of six branches: Cellular and Genetic Toxicology, Chemical Pathology, Systemic Toxicology, Carcinogenesis and Toxicology Evaluation, Program Resources, and Program Operations.

*Data Management and Analysis* (See pages 258 to 264)

Implementation of the Toxicology Data Management System (TDMS) began in FY 1982 with specially designed microprocessors being delivered and put in use for support of bioassay experiments at five contract laboratories. A chemical management and tracking system is being implemented. Possible statistical modifications of the basic experimental design of the two-year carcinogenesis bioassay were peer reviewed and are being revised. These modifications are aimed at improving the information obtained for low dose extrapolation while retaining the detection power of the bioassay.

*Chemical Nomination and Chemical Selection* (See pages 213 to 238)

During FY 1982, 28 chemicals were nominated for toxicological testing by the NTP, while 151 chemicals representing 10 chemical classes and one use class were nominated for mutagenicity testing. The Board of Scientific Counselors reviewed and made testing recommendations on 57 chemicals. The Executive Committee selected 26 chemicals as the NTP FY 1982 priority chemicals for in-depth toxicologic evaluation, and selected 24 chemicals for the FY 1983 priority list.

*Information Generation and Dissemination* (See pages 270 to 275)

An NTP/EPA interagency effort was initiated to establish a worldwide clearinghouse on phthalate research activities. A data form was sent to persons involved in phthalate testing or research. Also, information was sought from readers of the NTP Technical Bulletin.

*Annual Report on Carcinogens* (See pages 276 to 277)

The Third Annual Report on Carcinogens will be published in the first half of FY 1983.

**Introduction**

The National Toxicology Program (NTP) will begin its fifth year of operation in FY 1983. The NTP was established in November 1978 as a Department of Health and Human Services (DHHS, formerly Department of Health, Education and Welfare) cooperative effort to coordinate and provide information about potentially toxic chemicals to regulatory and research agencies and to strengthen the science base in toxicology. Because the Public Health Service of DHHS is responsible for safeguarding the public's health, and prevention of human exposure to toxic substances is integral to disease prevention, the establishment of the NTP was a logical outgrowth from the need for better coordination and program integration of the DHHS toxicology research and testing activities. Thus, the NTP was envisioned as a means of bringing together the Department's major toxicological research and testing activities—most of which had been developed to support different organizational missions—to mount a coordinated attack on the problems associated with toxic chemicals.

The NTP has realized already some of its potential by generating and disseminating scientific information needed for protecting the population from chemical health hazards. The NTP represents a major Federal resource for chemical testing, and represents a principal Federal effort in evaluating current methods and developing better methodology for assessing toxic potential of chemicals. There are also significant toxicology research, testing and test methods development activities ongoing in other Federal agencies. Current information on many of these efforts may be found in the NTP's FY 1983 *Review of Current DHHS, DOE and EPA Research Related to Toxicology*. The Program is a scientific data resource in genetic toxicity and animal carcinogenicity. Perhaps, most importantly, the NTP has developed an open and objective testing process which is beneficial and useful to other Government agencies, industry, the scientific community and the public.

Two recent organizational changes should increase Program stability and —effectiveness. The Program, on an experimental status since inception, was granted permanent status by DHHS Secretary Richard S. Schweiker in October 1981. This action will enable better integrated long-range planning. Second, the transfer of the NCI carcinogenesis bioassay program, including personnel and resources, to the NIEHS was approved by the Secretary in July 1981. This has enhanced the overall integration, coordination, and management of the NIH component of the NTP.

The NTP consists of the relevant toxicology activities of the National Institutes of Health's National Cancer Institute (NIH/NCI) and National Institute of Environmental Health Sciences (NIH/NIEHS); the Food and Drug Administration's National Center for Toxicological Research (FDA/NCTR); and the Centers for Disease Control's National Institute for Occupational Safety and Health (CDC/NIOSH). Resources for the program originate from the budgets of these agencies. The NTP activities to which these agencies allocate their resources are planned and accomplished as a coordinated effort under the leadership of the Program Director, Dr. David P. Rall, who also is Director of the NIEHS. For purposes of the NTP, he reports to Dr. Edward N. Brandt, Jr., Assistant Secretary for Health, DHHS.

*Objectives of the Program*—Within the framework of its charge to identify those chemicals potentially toxic to humans, the broad goal of the NTP is to coordinate and strengthen the activities of the Department of Health and Human Services in testing chemicals of public health concern, as well as to develop and validate new and better integrated test methods. Four specific goals are identified:

—Expand the spectrum of toxicologic information obtained on the chemicals nominated, selected, and being tested.
—Increase the numbers of chemicals tested in various short-term assays, within the funding limits.
—Develop, coordinate, and validate a series of tests and protocols more appropriate for regulatory needs.
—Communicate Program plans and results to governmental agencies, the medical and scientific communities, and the public.

During the first four years, the NTP has made considerable progress towards these objectives and related goals. Some of the more significant recent accomplishments are described briefly as follows:

• Although the Program allocates a majority of resources to chemical testing, more priority emphasis is given to development and implementation of new initiatives in areas of toxicology methods development.

• The Program is systematically reviewing and restructuring the sequence and approach to toxicity assessment of chemicals, and implementing major changes in the approach to testing for chemical carcinogenicity by utilizing chemical disposition, genetic toxicity, reproduction and fertility assessment, and major organ toxicity data and modifying the approach to histopathological evaluation of tissues.

• Test efforts are oriented more toward characterizing toxic properties associated with classes of chemicals rather than chemical-by-chemical assessment.

Among proposed and/or near-term research objectives are the following:

• Current methods for assessing carcinogenic potential of chemicals basically provide qualitative information. Better methods are needed to permit a general understanding of the major processes associated with carcinogenic responses and enable quantitative estimates of risk. Approximately three dozen chemicals have strong epidemiologic evidence for carcinogenicity in humans. All chemicals shown to cause cancer in humans also induce cancer in laboratory animals. The NTP proposes an initiative to characterize in animals the specific biological effects of these human carcinogens using current toxicology test methodologies. These data should provide insight on the utility of various methods for detecting or predicting carcinogenic risk. Of long-term value the results would serve as a reference data base to compare the utility of emerging test methods and to design future systems.

• A number of short-term *in vivo* research models which are organ specific have been developed which should help distinguish whether a chemically-induced carcinogenic response is through an initiation or promotion mechanism. A research program was initiated late in FY 1982 to investigate rodent liver tumor models. Investigation of these models will be expanded to include bladder tumor responses.

• With regard to applicability of NIP research results for extrapolation, there will be an intensification of efforts to validate emerging test methodologies with respect to comparability of interlaboratory results and extrapolation to humans.

• Efforts to identify the major processes involved in chemically-induced toxic effects will allow more broadened toxicologic profiles for chemicals. A current example is the FY 1982 initiative to better define the factors involved in rodent liver non-neoplastic and tumor responses which are observed in a majority of positive bioassays.

• Similarly, increased emphases are placed on chemical disposition, effects on reproduction and fertility, neurobehavioral toxicity, and other types of major organ toxicity. For example, evidence is accruing that animal and human male fertility may be a target site for certain chemicals (chlordecone, 1, 2-dibromo-3-chloropropane, 2,5-hexanedione). Current test methods will be refined to determine if the toxic action is mediated through pituitary function, testicular endocrine function, or direct effects on spermatogonia.

• Several methods have been developed to assess heritable genetic damage. Each method has limitations in that the assay detects for effects on only 10 to 18 gene loci. It is proposed to investigate the feasibility of using the same test animals to detect deleterious effects that may be under polygenic influences. Candidate indices for assessment include general tumor response, life span, fertility, and immune system profiles.

• The NTP will continue to expand and improve effects in: (1) Scientific coordination and (2) communication of the results of the Program's research, test methods development and validation, and testing. With respect to scientific coordination, NTP continues to seek additional input from the scientific community, industry, and the public into NTP research and testing activities. For instance, public briefings on chemicals and chemical classes of public health concern will continue. This has been done successfully by bringing together research and regulatory agencies with industry and the public to discuss benzidine-based dyes and phthalate esters.

With respect to enhanced communication, the NTP aims to increase and accelerate public dissemination of research and testing results. For instance, comprehensive technical reports are published, and abbreviated articles on the results (including toxicologic characterization and special studies from the prechronic phases of the long-term bioassay process) are published in recognized archival journals. This permits not only wider availability but also submits the data and interpretations to the most accepted and rigorous peer review system. Further, the NTP Technical Bulletin, published quarterly, will continue to serve as a means to alert the public and scientific community to upcoming NTP meetings and publications as well as to solicit comments on nominated chemicals and research proposals. Additionally, meeting announcements and solicitations for comments will be published in the **Federal Register**.

The Annual Plan separates annual report information (FY 1982) from planned activities (FY 1983 and beyond). In last year's Plan, programs and projects were associated with a contact person. This will be continued, and to further identify the agency responsible for a project or activity, the accomplishments and plans will be described separately by agency under each scientific and management section where appropriate.

The following chapters discuss Program resources, oversight and review, coordination and communication, organization structure, and describe in detail the NTP's ongoing and planned efforts in toxicology research, testing, and test methods development and validation as well as other key program activities such as chemical nomination and selection, information generation and dissemination, and data management and analysis.

**Resources and Planning Assumptions**

The NTP relies on voluntary allocations from the member DHHS agencies. The resources allocated to the NTP are specified in memoranda of understanding, prepared after each agency receives their funding through the Congressional appropriations process. In July 1981, DHHS Secretary Richard Schweiker transferred the carcinogenesis bioassay program from the NCI to the NIEHS; this action strengthened overall integration, coordination, and management of the NIH component of the NTP, and gave the NTP Director and central staff direct responsibility for about 85 percent of the Program's resources.

The NTP's FY 1982 obligations were $72.9 million. Using the member agencies' current NTP allocations, the President's budget for FY 1983 would provide for a funding level of $71.4 million. The estimated budget for FY 1983, compared with the actual obligations for FYs 1979, 1980, 1981, and 1982, is shown in Figure 1.

Over the first four years of the Program an increasing emphasis has been centered on short-term test methods development and validation coupled with a decreasing emphasis on standard testing, particularly in the long-term bioassay. A second major shift in program emphasis has been to broaden the experimental design protocols through inclusion of various additional toxicology studies for the prechronic phases of the long-term animal bioassay, thereby establishing the prechronic-chronic interface as a major decision point on whether or not to do a long-term bioassay. This has served two purposes: set priorities of the fewer numbers of compounds committed to chronic tests and provide more information on toxic endpoints other than cancer. Modifications to the two-year bioassay were studied and proposed in FY 1982 which would: (1) Enhance the information generated for possible use in risk estimation while retaining the detection power of the bioassay and (2) redefine significantly the list of organs and tissues undergoing histopathology while retaining detection power for cancer and enhancing the ability of the bioassay to detect non-tumor pathologic effects through addition of an interim sacrifice.

Although the Program's emphasis is changing, major resources are still focused on chemical testing, primarily reflecting the relatively high costs of the two-year animal bioassay. However, dollar allocations for testing have increased only slightly from FY

1981 to 1983 (Figure 2). Figure 3 divides the funding levels in FY 1982 for testing, methods development, and test validation for the four major program areas. The continuing large numbers of dollars for testing reflect, in large part, the costs for long-term bioassays initiated prior to NTP involvement. Starting in FY 1982, this investment is gradually scaling down with fewer bioassay starts and more funds being devoted to development of tests as alternatives to the bioassay.

Thus, in the coming years, the NTP will devote more resources and attention to the critical task of test methods development and validation. Emphasis will be placed on: (1) Completing validation of test methods now under development; (2) identifying and defining underdeveloped areas in toxicology, and beginning to develop, within resource limitations, research and test methods in newly identified areas; (3) developing the research tools and knowledge needed to study the problem of chemical mixtures, their interactions, and their toxic effects; (4) developing methodologies to permit low-dose extrapolation from test species to other species, including humans; and (5) continuing incorporation of improvements, in the prechronic and chronic testing phases of the bioassay.

**Oversight and Review**

Because of the interdisciplinary scientific tasks assigned to the NTP, and the need to integrate the programmatic activities of a variety of agencies, the NTP established two complementary oversight and review groups. The Executive committee and the Board of Scientific Counselors have helped ensure integration of NTP efforts and coordination of activities among the health research and health regulatory agencies, as well as with industry. Through these mechanisms, the NTP is assured that:

- Program planning and balance are designed with input from the health research and health regulatory agencies, as well as from the public, industry, and other non-government groups;
- Testing and test methods development and validation activities are responsive to the needs of the other agencies, are coordinated with those activities undertaken by other agencies and industry, and are complementary to efforts undertaken elsewhere;
- Research and testing efforts receive extensive peer review for scientific adequacy, merit, and relevance;
- Applied research needs are identified and can be targeted;
- Chemicals selected for testing are evaluated thoroughly; and
- Planning and decision-making processes are open, with opportunity provided for public input and comment.

The agencies, other than the NTP members, associated with the Program through the Executive committee also contribute and profit from these NTP oversight and review mechanisms. These agencies are assured of:

- Participation in the nomination, evaluation, and selection of chemicals for testing;
- Involvement in developing test protocols pertinent to their research and regulatory needs;
- Input into science policy issues that impact on their programs and activities;
- A role in overseeing test progress and participating in appropriate and necessary modifications;
- Early access to test results to aid in health and regulatory policy analysis;
- Timely information exchange, not only with the other research and regulatory agencies, but with industry as well; and
- A primary source within Government to serve as the repository for information on testing and test methods development and validation, as well as a source for consultation on issues related to chemical toxicology.

*NTP Executive Committee* provides primary oversight for the National Toxicology Program. The Executive Committee, composed of the heads of the research and regulatory agencies, serves as NTP's major advisory group and meets about four times a year. The Committee advises the NTP Director on research and testing needs and on selecting and setting priorities for the specific chemicals to be tested. This interagency group also serves as a forum for discussion of science policy issues and provides for timely information exchange among the various agencies as well as with industry and other interested groups. One of the key tasks for the Executive Committee is review and approval of the NTP Annual Plan.

Current members of the Executive Committee are:

Mr. Thorne G. Auchter, Assistant Secretary of Labor for Occupational Safety and Health Administration, Department of Labor
Dr. Edward N. Brandt, Jr., Assistant Secretary for Health, Department of Health and Human Services (non-voting)
Dr. Vincent T. DeVita, Jr., Director, National Cancer Institute
Mrs. Anne Gorsuch, Administrator, Environmental Protection Agency
Dr. Arthur H. Hayes, Jr., Commissioner, Food and Drug Administration (Chairperson)
Dr. James B. Wyngaarden, Director, National Institutes of Health
Dr. J. Donald Millar, Director, National Institute for Occupational Safety and Health
Dr. David P. Rall, Director, National Institute of Environmental Health Sciences
Mrs. Nancy Steorts, Chairman, Consumer Product Safety Commission

The Chairperson is elected by the Committee and serves a one-year term.

Through this interactive and cooperative mechanism, the NTP is assured of a continuing interface with the health research and health regulatory agencies and of receiving input into critical phases of NTP operation, including oversight of program planning and balance.

*Board of Scientific Counselors* provides scientific oversight. The Board, composed of eight non-governmental scientists appointed by the Secretary of DHHS, reviews the Program for scientific adequacy and merit and helps identify program needs. The Board meets an average of three times a year in sessions open to the public. Additionally, scientists with expertise in particular scientific areas are invited on an *ad hoc* basis to assist and supplement the Board for review of specialized segments of the Program.

Current members of the Board are:

Leila Diamond, Ph. D., Professor, Wistar Institute
Curtis Harper, Ph. D., Associate Professor of Pharmacology, University of North Carolina School of Medicine
Margaret Hitchcock, Ph. D., Assistant Professor of Pharmacology, Yale University Medical School
Jerry B. Hook, Ph. D., Professor and Director, Center for Environmental Toxicology, Michigan State University
Marjorie G. Horning, Ph. D., Professor of Biochemistry, Baylor University College of Medicine
Norton Nelson, Ph. D., Professor of Environmental Medicine, New York University School of Medicine (Chairperson)
James A. Swenberg, D.V.M., Ph. D., Chief, Pathology Department, Chemical Industry Institute of Toxicology
Alice S. Whittemore, Ph. D., Adjunct Professor of Family, Community and Preventive Medicine, Stanford University

The Board of Scientific Counselors held three open meetings during FY 1982. These meetings are summarized as follows:

*October 22–23, 1981 Meeting, Cincinnati, Ohio (NIOSH)*

The major agenda items included peer review of NTP programs at NIOSH and NIEHS in inhalation toxicology and neurobehavioral toxicology. The Board reviewed and approved concepts for one new initiative and two continuing actitivies in cellular and genetic toxicology. The Board reviewed 26 chemicals which had been nominated for testing and previously evaluated by the NTP interagency Chemical Evaluation Committee; their recommendations and priority rankings were incorporated into the literature summaries sent to the Executive Committee.

*March 10–12, 1982 Meeting, Research Triangle Park, NC (NIEHS)*

The Board, augmented by an *ad hoc* international group of scientists expert in chemical carcinogensis, mutagenesis, pathology, and biostatistics, met to review NIH/NTP proposed modifications in the experimental design and pathology requirements of the two-year carcinogensis and toxicology bioassay, and the proposed development and utilization of *in vivo* rodent liver tumor models. There was extensive discussion on these issues and the Board endorsed these new directions. Concept approval was given for research and development of the *in vivo* rodent tumor models, as well as for renewal and inclusion of inhalation exposure capabilities in contract activities of the NIH/NTP chemical disposition program.

*September 23–24, 1982 Meeting, Research Triangle Park, NC (NIEHS)*

An overview was given, as orientation for the three new Board members of the history, organizational structure and objectives of the

NTP as well as information on current activities in chemical testing, methods development and validation. A status report was presented on revisions made in the modified pathology protocol which had been originally reviewed at the March 1982 Board meeting. In part, revisions reflected responses to comments and suggestions from other Federal agencies, academia and industry. There was a discussion of problems encountered when trying to utilize a NCI/NTP historical control data base in analyzing the results of NTP bioassays, and of efforts being made to resolve these problems. A working paper was presented and discussed which dealt with guidelines for combining benign and malignant neoplasms as an aid in determining evidence of carcinogenicity. Seven contract or interagency agreement initiatives dealing with new or continuing cellular and genetic toxicology testing and methods development/validation activities were reviewed for concept by the Board; six were approved. One reproductive and development toxicology initiative was reviewed for concept and approved. The Board reviewed 31 chemicals which had been nominated for testing and previously evaluated by the NTP Chemical Evaluation Committee, and their recommendations and priority rankings were incorporated into the literature summaries sent to the Executive Committee.

*Special Reviews for the Bureau of Foods, FDA*

The Board met on March 9, 1982 in Washington, DC, at the request of the Bureau of Foods, Food and Drug Administration (FDA), to review the data from the chronic carcinogenesis bioassay of D&C Green No. 5. The Board met again on August 11, 1982 in Washington, DC, to review the data from the chronic carcinogenesis bioassay of FD&C Blue No. 2. These bioassays were submitted to the FDA to support permanent listing of the dyes. The Board was augmented by expert consultants in pathology and biostatistics for each review.

Summary minutes of the three regular and two special Board meetings held in FY 1982 are available on request. (CONTACT PERSON: Dr. L. G. Hart)

*Peer Review:* Peer review of NTP projects is a multi-level process involving review of project concepts, project proposals, and completed technical bioassay reports. Internally, the NIP Steering Committee (see Organization section) performs an initial review of the NIH/NTP research and testing proposals to determine if these should be developed further. The Board of Scientific Counselors performs external concept peer review for the Program; and reviews all NTP proposals to determine their relevance, need, and priority.

Once grant applications or contract proposals for projects are submitted to the NIH/NTP, they are evaluated for scientific merit by the Environmental Health Sciences Review Committee (ESRC). The ESRC, which was established as part of the NIH-wide peer review process, is composed of 21 members with expertise in pharmacology, toxicology, pathology, biochemistry, mutagenesis, and clinical disciplines.

When projects are completed and technical bioassay reports on the results are prepared, the Technical Rports Review Subcommittee of the Board of Scientific Counselors, supplemented by an *ad hoc* panel of expert reviewers, evaluates the reports for technical and scientific merit. Through this extensive and public review, the NTP is better assured that its program efforts are of acceptable quality and relevance. During FY 1982, the Subcommittee and panel met in open session in December, June, and September. Peer review was completed on 21 carcinogenesis bioassay reports. (See Table 10 in the Carcinogenesis Testing section). Summary minutes of the report reviews are available. (CONTACT PERSON: Dr. L. G. Hart).

The members of the Subcommittee and panel of experts during FY 1982 were as follows:

*Technical Reports Review Subcommittee Members*

- Dr. Margaret Hitchcock (Chairperson).
- Dr. Curtis Harper.
- Dr. James Swenberg.
- Dr. Alice Whittemore.

*Ad Hoc Review Panel Members*

- Dr. Norman Breslow, Professor of Biostatistics, Department of Biostatistics, University of Washington.
- Dr. Robert M. Elashoff, Jonsson Comprehensive Cancer Center, University of California at Los Angeles.
- Dr. Joseph H. Highland, School of Engineering and Applied Sciences, Princeton University.
- Dr. J. Michael Holland, Department of Biology, Oak Ridge National Laboratory.
- Dr. Frank Mirer, Assistant Director, Social Security Department, International Union, United Auto Workers.
- Dr. Robert A. Scala, Exxon Corporation.
- Dr. Bernard A. Schwetz, Director, Toxicology Research Laboratory, Dow Chemical Company.
- Dr. Stan D. Vesselinovitch, Professor, Department of Radiology and Pathology, University of Chicago.
- Dr. Mary Vore, Assistant Professor, Pharmacology Department, University of Kentucky, College of Medicine.

*Operations Management System*—The Secretary, DHHS, established this management tracking system in FY 1980 for the purpose of overseeing specific, major operational achievements. The Operations Management System (OMS) monitors progress and effectiveness of selected program initiatives by measuring actual monthly and quarterly achievements against projected goals set at the beginning of the fiscal year. The carcinogenesis bioassay and mutagenesis testing programs of the NTP, as well as the development of the Annual Report on Carcinogens, continued to be monitored in FY 1982.

In FY 1982, the NTP divided its current OMS carcinogenesis testing initiative into two distinct categories: general toxicologic characterization and two-year bioassays; these more accurately reflect current testing.

**Coordination and Communication**

Communication of Program activities and results of chemical testing and test development efforts, and coordination of related scientific programs among agencies represent two key elements essential to Program success.

*NTP Annual Plan*—Central to both elements is the development and approval of the *Annual Plan* to which the DHHS member agencies (NIH, NCTR, and NIOSH) contribute. The *Annual Plan* is the principal instrument for describing the coordination of toxicology research, test development, and chemical testing among the relevant health research and regulatory agencies. This annual document represents NTP's strategy for testing, test methods development and validation, and contains an annual report detailing the NTP's accomplishments in the preceding year. The *Annual Plan* is distributed widely and is also published in the **Federal Register**. Part II of the *Annual Plan* is printed separately and reviews current DHHS, Environmental Protection Agency (EPA), and Department of Energy (DOE) research related to toxicology, including methods development and chemical testing. To foster greater awareness regarding toxicology research of the Government, chemical toxicology activities in other Federal agencies may be included in future volumes. The *NTP Technical Bulletin*, published four times a year, serves as the major medium for more frequent communication of NTP's past, current, and upcoming activities, including abbreviated experimental results.

*Open Meetings*—The NTP Open Meetings are one of the ways NTP gives the public the opportunity to provide comment on and receive information about the Program. Specifically, the Open Meeting: (1) Gives the NTP staff a public forum to provide information on current and planned research, test development, and testing activities, (2) allows public comment on these activities and on the *Annual Plan*, and (3) encourages nominations of chemicals for testing. Past meetings have been held in Washington, DC, and most recently in San Diego, in conjunction with the Annual Meeting of the Society of Toxicology. Other sites are being considered for future meetings.

*Interagency Coordination*—The NTP is an active center for information and scientific collaboration for those individuals or groups concerned with current and common problems of chemical toxicology. As examples, two efforts begun in fiscal year 1981 dealing with chemical classes continue and are illustrative of the role that NTP performs in interagency coordination.

- The Benzidine Dye Initiative was developed to study the metabolism, toxicology, and carcinogenicity of a class of dyes derived from benzidine, 3,3'-dimethylbenzidine (DMB), and 3,3'-dimethylbenzidine (DMOB). The objectives and approaches were formulated by scientists from EPA, CPSC, OSHA, NIH/NTP, NCTR, and NIOSH in response to the needs of the regulatory agencies. The research *per se* is a collaborative effort between NIH/NTP, NCTR, and NIOSH. Through the judicious selection of chemicals for testing a set of basic principles is being established which can be applied to the entire class of

benzidine-based dyes, serve as a model for future chemical class studies, and provide scientific information required for making regulatory decisions. The activities cover three main areas of research and testing: (1) Chemical disposition and metabolism, (2) genetic toxicology, and (3) *in vivo* toxicology and carcinogenicity testing. The fiscal year 1982 accomplishments and future plans are described in the section on the Benzidine Dye Initiative. (CONTACT PERSON: Dr. J. Mennear, NIEHS)

• A key recommendation made at the June 1981 Conference on Phthalates held in Washington, DC, co-sponsored by the Interagency Regulatory Liaison Group (IRLG) and the NTP, was that the NTP should create a clearinghouse of toxicological data on this class of compounds. NTP consulted with scientists from Federal health regulatory and research agencies as well as from the Chemical Manufacturers Association, all of whom supported the clearinghouse and contributed to its development. The Environmental Protection Agency (EPA) was particularly committed to this project because of its involvement in the testing of alkyl phthalates under the Toxic Substances Control Act and together with the NTP sponsored the formation of the Clearinghouse in fiscal year 1982. Persons or organizations planning, conducting, or having completed research on the toxicological effects of these compounds are requested to contact Ms. Joan Chase, NTP/EPA Clearinghouse on Phthalates, Room 3A-06, Landow Building, National Institutes of Health, Bethesda, MD 20205, 301-496-1152, FTS 8-496-1152. In addition, a research program on phthalates was initiated by the NTP aimed at providing information complementary to that from previous NTP studies and efforts completed or ongoing by other groups. These studies are described in more detail in the section on Ortho Phthalic Acid Esters-Safety Evaluation. (CONTACT PERSON: Dr. W. Kluwe, NIEHS)

*Interagency and International Liaison*—The NTP continues liaison with foreign agency counterparts including the World Health Organization's (WHO's) International Program on Chemical Safety, the International Agency for Research on Cancer, the United Nations Environment Program's (UNEP's) International Registry of Potentially Toxic Chemicals, the International Commission for Protection Against Environmental Mutagens and Carcinogens (ICPEMC), and the National Institute of Hygienic Sciences (Japan).

During fiscal year 1982, as part of the Public Health Service's assistance to the Spanish government for investigating the toxic oil-associated epidemic, the NTP was assigned lead responsibility for providing laboratory testing and consultation with respect to animal toxicological studies of the disease. This work would be conducted in part through existing collaboration with the WHO, and working in cooperation with laboratories of CDC, FDA, and NIH. Additionally, NTP staff persons have served previously in a consultative role after public health disasters involving toxic chemicals, e.g., the dioxin episode in Seveso, Italy, and the polybrominated biphenyl (PBB) disaster in Michigan.

NTP staff continue to participate in interagency liaison groups, including the DHHS Committee to Coordinate Environmental and Related Programs, the Task Force on Environmental Cancer and Heart and Lung Disease, and the Interagency Collaborative Group on Carcinogenesis.

**Organization**

The NTP is a consortium of independent agencies within the Public Health Service which are linked by common goals: to strengthen the science base in chemical toxicology, develop and validate new or improved toxicological test methods, and evaluate substances or classes of substances that might pose threats to the public health, while eliminating or at least minimizing duplication of effort.

Currently, there are three organizational components of the Program. The National Institutes of Health component in NIEHS represents the majority of the NTP budget, and is under direct administrative and management control by the Director, Deputy Director and central NTP staff located within the NIEHS. The Centers for Disease Control (NIOSH) and Food and Drug Administration (NCTR) components are not under direct NTP management; however, each continues to cooperate and participate fully in overall NTP activities. The NTP Steering Committee, formed in 1980, has strengthened coordination and promoted interagency working relationships within the Program. Composed of the NTP Director and the operating heads of the contributing agencies, along with key support staff, the Committee meets approximately quarterly. The group plans agendas for upcoming NTP meetings, reviews ongoing programs and projects as well as proposed programs, resolves interagency problems, and makes agency allocations for chemicals approved for testing by the Executive Committee. Within the agencies, individual NTP staff members are identified as leaders of the major scientific and program support segments, and serve as the focus for their particular program activities.

The program segments of the NTP can be grouped broadly into two categories—toxicologic research and testing, and coordinative management activities. These activities are described briefly by agency as follows:

*NIEHS*—The Toxicology Research and Testing Program (TRIP) combines under NIEHS management the chemical toxicity testing efforts transferred from the NCI with the NIEHS testing, test development, and management activities. The TRIP, headed by the NTP Deputy Director, Dr. J. A. Moore, is responsible for all NIH/NTP operations and is composed of six branches:

*Cellular and Genetic Toxicology Branch*

—Develops and validates a variety of *in vivo* and *in vitro* methods to detect and define effects of chemicals on genetic components.
—Investigates somatic as well as heritable gene damage.
—Studies effects of chemicals on experimental organisms (primarily) and on human populations.

*Chemical Pathology Branch*

—Provides pathology support to all segments of the Program, especially critical to carcinogenesis bioassays.
—Develops standards for tumor and non-tumor pathology diagnoses and nomenclature.
—Develops clinical chemistry parameters for assessing cellular and organ function.

*Systemic Toxicology Branch*

—Develops methods for assessing toxic effects involving immune, pulmonary, reproductive and renal function.
—Performs studies to develop basic knowledge of chemical absorption, distribution, metabolism, and excretion.

*Carcinogenesis and Toxicology Evaluation Branch*

—Principal group for designing, conducting and interpreting carcinogenesis and related studies on chemicals.
—Works closely with other programs to develop data that elucidates general mechanisms that may be involved in a toxic effect.

*Program Operations Branch*

—Provides logistical support for coordinating and scheduling the contract testing functions, and monitors quality assurance and good laboratory practices at the testing laboratories.

*Program Resources Branch*

—Serves as resource for chemical acquisition and storage, laboratory animals breeding and allocation, and general laboratory health and safety.

The Program Resources and Program Operations Branches along with information generation and dissemination activities (managed from the Office of the Director, TRIP) and data management and analysis functions (provided by the Data Management and Analysis group of the NIEHS Biometry and Risk Assessment Program) constitute a major segment of *coordinative management* activities which facilitate and support the research and testing efforts and provide information on program plans and progress.

The heads of the six branches along with a few other key staff persons form the TRIP Management Committee. The Committee, chaired by the Director, TRIP, was established to ensure coordination and communication among the NIH components. The committee, which meets at least monthly, is responsible for planning, review and implementation of NIH/NTP activities.

*NIOSH*—The Division of Biomedical and Behavioral Science has the lead responsibility for the NIOSH occupational toxicology program. The program consists of research concerned with the toxicity of chemicals found in the workplace with emphasis in the areas of carcinogenesis, reproduction and fertility, neurobehavioral effects, cutaneous toxicity, and organ specific effects. Emphasis is given to inhalation and dermal routes of exposure.

NCTR—The National Center for Toxicological Research contributes to the NTP effort, primarily in:

—Chemical Nomination and Selection
—Reproductive and Developmental Toxicity
—Cellular and Genetic Toxicology
—Chemical Disposition
—Chemical Evaluation
—Toxicology Data Management System

Two coordinative mamagement activities, in particular, involve all NTP member agencis: Chemical nomination and selection, and chemical and laboratory test management. The former involves evaluation and priority ranking of chemicals by staff from all the agencies on the Executive Committee and coordination by staff from NCTR and NIEHS. Staff members at each agency are assigned as chemical managers for individual compounds to serve as a focus for the scientific aspects of the studies on that chemical. Laboratory management is carried out by scientists serving as project officers to ensure that each toxicological study is conducted in a proper and timely fashion (see Chemical and Laboratory Test Management section).

**Toxicology Research and Testing Overview**

Toxicology research and testing activities within the NTP are divided into four major program areas: cellular and genetic toxicology (mutagenesis); carcinogenesis; toxicologic characterization; and fertility and reproduction (reproductive and developmental toxicology). Through coordination and integration of the activities of the member agencies (NIH, NCTR, NIOSH), the NTP develops the capabilities in toxicologic research and testing necessary not only to improve testing of chemicals by means of a comprehensive approach to evaluating chemical toxicity, but also to put greater emphasis on development and validation of new assay methods, as well as to provide better information for risk estimation. Through open and active communication with other Federal agencies and the private sector, the NTP is able to minimize duplication and avoid unnecessary testing.

The NTP has broadened and strengthened the toxicology and carcinogenesis bioassay especially in the prechronic phases to provide imformation about genetic toxicity, immunotoxicity, renal toxicity, neurobehavioral toxicity, reproductive toxicity and fertility assessment, clinical chemistry, and chemical disposition. The comprehensive toxicologic data obtained are then used to better design long-term studies or to make decisions that further studies may not be necessary. Presumptive information developed may also be used to design and conduct more indepth studies of a chemical's toxic effects on specific target organs or organ systems. This has resulted in major improvements in testing efforts, related mainly to the mandate to guarantee a more complete toxicologic dossier on chemicals selected for study. Further, the NTP is selectively focusing test efforts on characterizing toxic properties associated with chemical class, e.g., benzidine-based dyes, phthalate esters, glycol ethers, etc. The Program is systematically reviewing and restructuring where appropriate the sequence and approach to toxicity assessment of chemicals, and implementing needed changes in the approach to testing for chemical carcinogenicity. This is being accomplished by utilizing chemical disposition and genetic toxicity data and by modifying the approach to histopathological evaluation. These integrated and rational approaches to testing permit a more effective use of the Government's testing resources.

The NTP's major long-term objective remains the development, validation, and application of better, more specific test methodologies. Priority areas are determined by: (1) The identification of novel means by which chemicals may exert a toxic effect, (2) circumstances where current test methods are inadequate, and (3) innovative approaches to existing methods which would provide toxicologic results in a faster or more definitive manner. In FY 1982, the NTP continued development and validation of short-term prescreens for teratogenesis and assessment of effects on fertility and reproduction: initiated a three-year program to develop and validate *in vivo* rodent tumor models for carcinogenesis; initiated development and evaluation of new models for percutaneous absorption of chemicals: began using the immunotoxicology test panel to examine relationships between carcinogenicity and immunotoxicity with chemicals identified as human carcinogens; continued development and validation of tests for better assessment of neurotoxicity in humans; and continued validation of pulmonary function tests as sensitive measures of detecting and characterizing chemically-induced pulmonary toxicity. The largest single area of test methods development and validation continues to be cellular and genetic toxicoloy, where emphasis is being placed on both *in vitro* and *in vivo* test systems for measuring somatic mutations, chromosome aberrations, aneuploidy, heritable mutations, cellular transformations, and DNA damage and repair. New initiatives are evaluating and monitoring mutagenic activity in human lymphocytes and urine.

The major research and testing initiatives for FY 1982 and FY 1983 are briefly summarized below (more detailed descriptions of specific program activities are given in the following sections).

*Cellular and Genetic Toxicology*—Tests were completed in the *Salmonella typhimurium* assay system for 288 chemicals in FY 1982. Testing for heribtable genetic effects was completed on 48 chemicals in the *Drosophila melanogaster* system and testing for cytogenetic effects was completed on 66 chemicals in cultured mammalian cells (Chinese hamster ovary). Testing will continue yearly at levels of about 300 completions in *Salmonella* and up to 75 to 100 tests completed in *Drosophila* and up to 100 tests completed in cultured mammalian cell systems. At NIEHS, newly initiated and ongoing activities include development and evaluation of an *in vivo* mouse assay for chemically-induced cytogenetic damage; development and validation of a multiple endpoint mutation system in cultured mammalian cells; development of assays for induction of aneuploidy in *Drosophila* and in yeast; an *in vitro* assay in mammalian cells for induced DNA damage; and a dual laboratory evaluation of three mammalian cell transformation systems. The final phase of evaluation for another cell system for chemical transformation, Balb/c 3T3, is in progress.

Other developmental projects include an effort to develop a standardized protocol by which frequencies of chromosome aberrations and sister chromatid exchanges (SCE's) can accurately and reproducibly be measured in human lymphocytes. Efforts to measure germinal mutations in mice include studies with the morphological specific locus assay and the search for electrophoretic variant isozymes resulting from chemical exposure. A new project beginning in FY 1982 is aimed at organ specificity of chemicals. Research with *Salmonella* tester strains, yeast (*Saccharomyces*), and fruit flies (*Drosophila*) is aimed at improving their value as test systems and gaining better understanding of mutational processes including the relationship between DNA damage/repair and mutagenesis.

At NCTR, a standardized protocol for a sequential fertility test method of the heritable translocation assay with empirically determined mis-classification error has been successfully developed for use in evaluating NTP compounds. NCTR and NIEHS are collaborating on a project using the primary hepatocyte DNA repair system to detect potential genotoxicity of up to 24 chemicals. The NIOSH/NTP efforts are concerned with: (1) Monitoring airborne particles from coal liquefaction plants as well as complex mixtures and industrial chemicals found in various workplaces for mutagenic activity, and (2) developing and using suitable assay systems for measuring mutagenic effects in biological samples from workers such as lymphocytes and urine.

*Carcinogenesis*—The NIEHS/NTP continued to use broadened protocols epecially in prechronic testing to give information on toxicity other than cancer, to help in experimental design, and to assist in determining whether or not to do long-term testing. All chemicals started in prechronic testing during FY 1982 had one or more special studies incorporated in the protocols. During FY 1982, 21 bioassays were completed through peer review. There were 27 new starts in prechronic testing, and a total of 45 bioassays in prechronic and 172 in chronic testing at the end of FY 1982. There are 16 starts projected for the prechronic phase of the bioassay in FY 1983 and 26 bioassays are expected to be completed through peer review in FY 1983.

A major addition to the prechronic phase was inclusion of a group of five *in vitro* short-term cellular and genetic toxicology assays. These assays will measure gene mutations in bacterial and mammalian cells, chromosome damage, mammalian cell transformation, and DNA damage/repair.

Mathematical simulations were used to investigate modifications in bioassay design which might improve use of the bioassay for low-dose extrapolation while retaining power to detect cancer. Modifications were proposed in pathology requirements aimed at greater efficiency while retaining the detection potential for neoplasia and also

increasing the ability to measure non-tumor pathology through use of an interim kill at 15 months into the study. In FY 1983, NTP will complete, summarize, and evaluate the data from a two-laboratory validation of the pulmonary tumor assay in Strain A mice. Initiated in late FY 1982 was a three-year program to evaluate and clarify the nature of carcinogenic responses using selected *in vivo* rodent tumor models. The study will evaluate the ability of selected chemicals to act as initiators, promotors, or complete carcinogens.

The NIOH/NTP efforts included continuation of long-term studies emphasizing the etiology of cancer in occupational evnrionments. Bioassays with materials ranging from single chemicals to complex mixtures of substances collected at the workplace were also conducted. In addition, efforts are underway to develop efficient *in vitro* and *in vivo* methods for identifying cocarcinogens found at the workplace. At NCTR, a number of bioassays were either initiated or are ongoing. Microencapsulation was studied as a mode for dosing by the oral route with volatile or unstable chemicals.

*Toxicologic Characterization*—In the NIEHS program, major testing initiatives continue to be 14-day, and 90-120 day experiments with chemicals originally nominated and selected for evaluations of carcinogenic potential; during these phases broadened protocols give information on all types of toxicity as well as allow better experimental design of long-term studies. Measures of reproductive dysfunction in rodents were added to the 90-day study—testicular pathology, epididymal weights, sperm counts and morphology in males, and vaginal cytology in females. There has been an expansion of the chemical pathology program especially in the areas of toxicologic and experimental pathology. Chemical disposition studies are now being done on all chemicals selected for long-term bioassays; special projects include benzidine-based and other dyes, halogenated alkyl and aromatic compounds, aromatic amines, and cyclic and inorganic compounds. There is a continuing activity in development and validation of test methodologies for measuring toxic effects of chemicals on several target organ systems. The immunotoxicology assay panel was implemented in prechronic testing and a number of chemicals were examined indepth for effects on the immune system. Standardization and validation of a neurobehavioral test battery used in prechronic studies was completed. In FY 1983, automated procedures will be under development to assess neurotoxicity in animals using naturally occurring home cage behaviors.

Special studies to evaluate the toxicology of chemical classes were underway in FY 1982 and will be continued in FY 1983. For instance, selected members of the psoralen class are being examined with respect to mutagenicity, carcinogenicity, pharmacokinetics and metabolism, and effects on skin enzyme levels in rodents. Studies are being initiated with selected ortho phthalic acid esters including investigations of the genetic toxicity and carcinogenic mechanisms of di(2-ethylhexyl) phthalate, and the reproductive toxicity, dermal absorption, and carcinogenic potential of several esters.

Toxicologic characterization studies at NIOSH in pulmonary toxicology indicated that a panel of pulmonary function tests were more sensitive for the detection of lung damage from levels of inhaled pollutants than traditional histopathologic techniques. There is continuing development and evaluation of human neurotoxicity tests to be used at worksites as well as validation of tests for changes in reflex activity in animal and human laboratory studies. In FY 1982 and 1983, behavioral teratologic effects will be characterized for two classes of chemicals, the glycol ethers and straight-chain carbon compounds. Efforts began to refine, validate, and apply two model systems for measuring dermal absorption of chemicals.

Chemical disposition studies at NIEHS, NCTR, and NIOSH on the benzidine congeners and selected derivatives were largely completed in FY 1982. In genetic toxicology, emphasis was given to developing a protocol for enabling anaerobic metabolism of derivatives, a prerequisite for metabolic activation. Short-term *in vivo* toxicity and carcinogenesis studies were initiated. In FY 1983 long-term bioassays will begin on the dimethyl and dimethoxy congeners of benzidine and a derivative of each.

*Fertility and Reproduction*—Primary emphasis continues on: (1) Developing short-term tests in both reproductive toxicology and teratology, including both *in vivo* and *in vitro* teratologic test systems and a continuous breeding assay for fertility assessment, and (2) using existing methodology to evaluate toxicity. In the NCTR program in FY 1982, conventional teratology testing was completed on eight chemicals and was in progress on nine others. The interlaboratory behavioral teratology validation initiative continued using known behavioral teratogens. In the NIOSH program, a short-term *in vivo* teratology assay was being validated while *Drosophila* were being evaluated as a potential teratology screening system. Attention was focused on inhalation teratology studies. A chemical class study continued on the reproductive and developmental toxicology of the glycol ethers. In the NIEHS program, fertility assessment using continuous breeding is being evaluated as a test which may take half as long to complete and at half the cost of the three generation study yet may yield comparable information on fertility effects and, perhaps, more information about the affected sex or target organ for chemical insults.

### Cellular and Genetic Toxicology

The cellular and genetic toxicology programs at the three NTP agencies in many instances have parallel objectives. The NIEHS through the Cellular and Genetic Toxicology Branch is directly involved in imporvement and validation of short-term tests for mutagens and carcinogens, the application of tests designed to detect and characterize chemicals that may pose carcinogenic or genetic risks to humans, and in basic research on mutagenesis and related genotoxic processes.

The NCTR program is focused on: (1) Modifying the heritable translocation assay (HTA) to imporve the test's precision and reliability while developing an in-house capability for performing HTA studies, and (2) using the primary hepatocyte/DNA repair system to detect potential genotoxicity of selected NTP chemicals.

The NIOSH program is concerned primarily with: (1) Monitoring airborne particles from coal liquefaction plants as well as complex mixtures and industrial chemicals found in workplaces for mutagenic activity, and (2) developing and using suitable assay systems for measuring mutagenic effects in biological samples for workers, such as urine and lymphocytes.

### NIEHS; Cellular and Genetic Toxicology Branch

The goal of the Cellular and Genetic Toxicology Branch is to provide and integrated research and testing program using short-term test systems to evaluate the genetic toxicity of selected chemicals. The program is also aimed at developing an understanding of the mechanisms of cellular and genetic toxicity to provide a better basis for further tests system development and interpretation of test results. Emphasis is currently placed on short-term tests that measure mutagenicity and aneuploidy in microbial cells as well as mutagenicity, DNS and cytogenetic damage, and oncogenic transformation in mammalian cells. Test data are used to set priorities for further testing and in the design and interpretation of long-term animal carcinogenicity mutagenicity, and toxicity studies.

An implicit goal of the cellular and genetic toxicology effort is to establish a scheme of short-term testing which can be used to predict chemical carcinogenicity and mutagenicity and thereby reduce the need for *in vivo* assays or assist in setting testing priorities for long-term animal bioassays. However, for short-term tests to be predictive, several criteria must be fulfilled. These include both a knowledge of the reproducibility of individual test results and the relationship of the endpoint measured to carcinogenicity, mutagenicity, or other *in vivo* toxic effects. The application of a group of complementary tests which meet these criteria should ultimately result in an effective system for testing chemicals. An important part of the Branch program is to produce sufficient short-term test data, particularly across chemical classes, and to relate short-term test results to carcinogenic effects in animals and man. Even with the appropriate use of available test systems, some potential carcinogens (or cocarcinogens or tumor promotors) may not be identified, particularly those that do not induce damage leading to observable gene mutations or chromosomal changes. It is therefore important that we continue to develop new methods capable of detecting carcinogens not identified by the assays currently in use and to distinguish chemicals which "promote" tumor development. In order to accomplish these goals, it is important that the program

remains involved in and responsive to basic research developments together with their potential applications.

A substantial portion of Branch resources are committed to studies of chemically-induced mutations. These mutation studies can be divided into two categories: (1) Somatic cell; and (2) germ cell mutation studies. The major difference between the two is that mutations arising in germ cells can be transmitted to subsequent generations, while somatic cell mutations can only be expressed in the affected individual. *In vitro* test systems are considered relevant for somatic mutation because they measure mutagenicity in mitotically dividing cells. However, the information gained from tests using *in vitro* systems also has implications for heritable mutation risk because a chemical that is mutagenic *in vitro* has the potential to be mutagenic in germ cells *in vivo*. (By the same argument, germ cell mutagens are likely to be somatic cell mutagens.)

The portion of the program concerned with assay validation and testing is performed through extramural contracts, and interagency agreements while basic research, test development or modification, and data management and analysis activities are generally performed intramurally.

The key extramural contract activities include microbial (*Salmonella*), *Drosophila*, and mammalian cell mutagenesis testing; *in vitro* cytogenetic testing (chromosome aberrations and sister chromatid exchanges) and the development and evaluation of an *in vivo* mouse assay for chemically-induced cytogenetic damage; development and validation of a multiple endpoint mutation system in cultured mammalian cells; the development of assays for induction of aneuploidy in *Drosophila* and in yeast; an *in vitro* assay in mammalian cells for induced DNA damage; a dual laboratory coded compound evaluation of three mammalian cell transformation systems including Syrian hamster embryo (SHE) cells, SHE cells infected with Simian adenovirus (SA7), and retrovirus infected rat cells (the latter two systems measure chemical enhancement of viral transformation); and the final evaluation of the BALB/c-3T3 transformation assay.

A coordinated effort was initiated in fiscal year 1981 to assess the genetic toxicity of 19 chemicals which were priority candidate bioassay chemicals for 1982. Other developmental projects include an effort to develop a standardized protocol by which the frequencies of chromosome aberrations (CA's) and sister chromatid exchanges (SCE's) can be accurately and reproducibly measured in human lymphocytes with particular emphasis on understanding the sources of variation that may affect the measurement of these endpoints. Efforts to measure chemically-induced germ cell mutations in mice involve both the morphological and biochemical specific locus assays. Other developmental projects include identification of mutagens produced in cooked foods and an attempt to develop an assay for specific sequence transpositions in mammalian cells.

Intramural research efforts involve both prokaryotes and eukaryotes. Studies on *Salmonella typhimurium* tester strains include attempts to increase our understanding of the test system, to improve the sensitivity and efficiency of protocols currently in use and to use the *Salmonella* test as a tool to study *in vitro* and *in vivo* metabolism of mutagenic chemicals. Studies with the yeast *Saccharomyces cerevisiae* are directed at the meiotic process in an effort to better understand the genetic events of meiosis at molecular and enzymological levels; to determine the role of DNA repair mechanisms in mutational processes and to understand meiotic and mitotic recombination and DNA repair processes. Studies in *Drosophila melanogaster* are directed at characterization of the relationship between DNA repair and mutagenesis using mutagen sensitive mutants, many of which are defective in DNA repair. Such repair-defective mutants have also been combined with certain naturally occurring transposable elements to allow the study of interactions that occur in double mutant combinations. Alterations in gene structure and expression, which may result from chemical and physical toxic/carcinogenic agents, are also being analyzed in mammalian cells by recombinant DNA techniques with particular attention to potential gene or sequence transpositions. Finally, a new project has been added that is directed at the organ specificity of chemical carcinogens. Using liver and bladder cells, organ and species specificities of the chemical activation of several carcinogen classes are being investigated. Details of these respective projects are described in the accompanying project reports.

In summary, the Branch is directly involved in improvement and validation of short-term tests for mutagens and carcinogens, the application of tests designed to detect and characterize chemicals that may pose carcinogenic or genetic risks to humans, and in basic research on mutagenesis and related genotoxic processes.

**Extramural Program**

*Fiscal Year 1982 Accomplishments and Fiscal Year 1983 Program Plans*

*Somatic Mutation and Cellular Transformation*

• *In Vitro* Microbial Test Systems

*Microbial Mutagenesis Testing*—The *Salmonella typhimurium* test developed by Ames has been generally proposed as an initial screening test to identify mutagenic chemicals. *Salmonella typhimurium* tester strains, TA–98, TA–100, TA–1535, and TA–1537, are being used to test environmental and commercial chemicals for mutagenicity using a preincubation modification of the Ames *Salmonella* microsome assay in three laboratories (Case Western Reserve University, Dr. W. Speck; Microbiological Associates, Dr. S. Haworth; and SRI International, Dr. K. Mortelmans). All chemicals are incubated with tester strains in suspension prior to addition to soft agar and plating for detection of induced mutants. Exogenous metabolic activation is provided by liver S–9 preparations from Aroclor 1254-induced Sprague-Dawley rats and Syrian hamsters. All chemicals are tested blind at five doses, in triplicate, in each *Salmonella* strain. Also, all chemicals are retested at least one week following the first test. Results are entered directly into minicomputers at the test laboratories for transfer to the data-base system. Results have been received from these laboratories on a total of 692 test samples to date encompassing 545 unique chemicals. In fiscal year 1982, 308 tests were completed on 288 unique chemicals. These results are listed in Table 1.

Chemicals positive for mutagenicity or producing equivocal responses in *Salmonella* are analyzed for identity and purity and are tested in the *Drosophila* sex-linked recessive lethal test, as are a selected number of negatives. Equivocal chemicals are also tested in the *in vitro* cytogenetics assay along with selected *Salmonella* positives and negatives. Additionally, the *Salmonella* results are used along with other toxicology data by the NTP to assist in making decisions regarding further testing of the chemicals, and by NTP chemical managers to provide additional information pertinent to the evaluation of chronic studies. The *Salmonella* data is also used in the selection of chemicals for additional *in vitro* and *in vivo* genetic toxicology studies.

Numerous requests for information and data on specific chemicals tested have been received from Government personnel and from the private sector. All information requested has been provided, where possible.

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In FY 1983, 330 tests are scheduled to be completed in *Salmonella*. Most of the chemicals to be tested will be selected from the listing in Table 2. Undoubtedly, some of these chemicals will not be tested due to unavailability, high cost or for other reasons while other chemicals may be added in response to urgent agency needs. (CONTACT PERSON: Dr. E. Zeiger).

*Salmonella/Microsome Testing—Evaluation of Predictive Value of Carcinogenic Potential of Chemicals*—This cooperative study, aimed at evaluating and validating microbial mutagenicity assays for their reproducibility and predictive value in assessing carcinogenic potential of chemicals, was completed in FY 1982. An overall evaluation is being compiled on intralaboratory variation, variation among the four laboratories, comparison of activation systems, and comparison with *in vivo* and other microbial test results. This evaluation will be completed in FY 1983. (CONTACT PERSON: Dr. E. Zeiger)

*Modification of the Salmonella Test for Chemicals that may be Metabolized to Mutagens under Reductive Conditions*—The standard protocols which use *in vivo* metabolic activation for mutagenesis studies are based on the assumption that the substances to be tested require aerobic metabolism for their activation. However, many substances, such as azo-containing dyes (including benzidine dyes), may be metabolized only by reductive pathways. These pathways occur in the mammalian liver *in situ* and in the mammalian gut through the action of the normal gut flora.

Therefore, azo-containing chemicals which may be metabolized to mutaghens *in vivo* may appear to be non-mutagenic when tested using the standard metabolic (aerobic) activation protocols.

The objectives of this contract are the development of *Salmonella* test protocols for detection of chemicals requiring reductive/anaerobic metabolism for expression of mutagenic activity, and the testing of chemicals for mutagenicity using these protocols. Among the chemicals tested will be a series of benzidine congener-based dyes. Urine samples from rats given benzidine dyes will also be tested.

Dr. Charles King, The Michigan Cancer Foundation, is investigating modifications of the *Salmonella* preincubation protocol which permit reductive metabolism followed by oxidative metabolism to measure the mutagenicity of benzidine-containing dyes. In addition, rat cecal flora preparations are being used in an attempt to develop an alternate activation system which is representative of the metabolism that occurs in the gut.

This contract has recently been initiated and the majority of effort so far has been the definition of different metabolic activation systems and the investigations of chemical methods for purification of benzidine-based dyes. The sensitivity of various mutagenicity protocols to benzidine, dimethylbenzidine, dimethoxybenzidine and some model benzidine metabolites in rat urine is being determined in preparation for a survey of urine from rats administered benzidine dyes.

*FY 1983 Program Plans*

After the protocols have been standardized, a number of benzidine congener-based dyes will be tested. In addition, urine samples from rats administered a number of benzidine congener dyes will be tested for mutagenicity. (CONTACT PERSON: Dr. E. Zeiger)

*Estimating Toxicity in Salmonella Mutagenesis Assays*—A limitation of the *Salmonella* mutagenicity assay is its limited ability to measure the toxicity of a test chemical. The number of revertants formed is directly related to the dose of the chemical only if the chemical is not toxic to the cells. If the compound is both mutagenic and bactericidal, then the number of revertants observed may be a function of both properties. For a mutagenic compound, high toxicity may distort the mutagenic response of the cells and make potency calculations unreliable. The objective of this work is to develop reliable methods to determine the toxicity of a chemical in the *Salmonella* assay and to develop methods to use this information in the interpretation of results.

Two approaches were taken to estimate the toxicity of a chemical to the cells. In the standard *Salmonella* assay, strains with known point mutations in the histidine operon form colonies upon reversion to prototrophy. The *his*$^+$(mutant) macrocolonies appear against a thin film of *his*$^-$ microcolonies. These microcolonies are attributable to the small quantity of histidine present in the medium. These auxotrophs grow to form microcolonies until histidine is depleted unless the test compound is toxic. The number of *his*$^+$ revertant macrocolonies is related to the mutagenic properties of the chemical. The number and size of the background microcolonies is a function of its toxicity.

In the first approach, the number of microcolonies that survive treatment with a test chemical is being measured with an automatic colony counter. The greater the toxicity, the fewer and larger the colonies. Toxicity data are derived directly from the "mutagenicity plate" and the decision to obtain toxicity information need not be made until after the experiment is performed.

This toxicity assay employs a second plate designed to mimic the environment of the plate in which revertants are counted (mutagenicity plate). Two sets of strains, isogenic to the five *Salmonella* tester strains, have been constructed. One set consists of histidine double mutants unable to revert to histidine independence; these are called "filler cells". These "filler cells" are used to mimic the $10^8$ bacteria that are normally plated in the mutagenicity assay. The other set consists of specially constructed *his*$^+$ bacteria that are plated at a concentration of about 500 colony forming units in the presence of the $10^8$ "filler cells." The "filler cells" stop growing or die upon depletion of minimal histidine and simulate the background growth of the mutagenicity test. The *his*$^+$ bacteria form colonies simulating histidine revertants. Survival is calculated from the number of *his*$^+$ colonies at the end of the experiment. This "toxicity plate" is run in parallel with the "mutagenicity plate".

The importance of the "filler cells" in the toxicity test was demonstrated in a series of experiments in which the concentration of the "filler cells" was altered. The survival of the *his*$^+$ cells varied with the varying concentrations of the "filler cells". Generally, survival increases with increasing concentrations of "filler cells". This result suggests that measurements of toxicity in which 400 cells are plated and survivors counted may not accurately estimate the toxicity observed on the "mutagenicity plate".

Experiments have been designed to determine whether toxicity greatly affects the number of revertants observed. Preliminary results suggest that below a threshold toxicity the number of revertants are not seriously affected by toxicity. However, above the toxic threshold the number of revertants rapidly decreases. (CONTACT PERSON: Dr. W. Caspary)

• *In Vitro* Mammalian Test Systems

*In Vitro Mammalian Cell Mutagenesis*—This study was designed to evaluate the L5178Y mouse lymphoma cell system as an *in vitro* assay for detecting mutagenic chemicals. The evaluation includes protocol development, determination of reproducibility of responses under field conditions, development of quality control standards, development of response categories based on mathematical definitions and development of a data management system including statistical support to aid in the interpretation of results.

Two laboratories tested the same compounds under code. Based on this work, a reliable biological assay protocol was established. Cultures are exposed to the test chemical for four hours at preselected doses, then washed and the cells are placed in 20ml of growth medium at a density of $3x10^5$ cells/ml to allow recovery, growth and expression. At the end of the first day of expression the cells are counted. The cells, are then adjusted to a density of $3x10^5$ cells/ml and placed in 20 ml of growth medium. At the end of the second day of expression the cells are counted. Ten milliliters of cells are seeded in soft agar plates with selection medium (trifluorothymidine) and the resistant (mutant) colonies are counted after a ten- to twelve-day incubation period (total mutant counts). To determine the actual number of cells capable of forming colonies, 600 cells from the cell suspension are also cloned in normal (nonselective) agar plates. The colonies are counted after ten to twelve days incubation (total viable clones).

The measured mutant frequency, defined as the mutant count divided by the product of the cloning efficiency and the number of cells plated for mutant count, is the critical experimental parameter to be derived from this assay. The cloning efficiency, which is the probability that a cell grows in the agar plate, is defined as total viable clones/600 cells where 600 cells are plated for viable count.

The assay protocol requires that doses be done in duplicate, positive controls in triplicate, and solvent controls in quadruplicate. Experiments must be repeated to assess the reproducibility of the cellular response, though the doses used may be different in the replicate experiment. Agreement of responses within and between laboratories was greater than 90%.

A major effort was also initiated to establish a data management system for the mouse lymphoma system. This consists of the development of quality control criteria, experimental response categories, test response categories and statistical support to aid the interpretation of data.

The quality control criteria are based on an analysis of over 400 experiments performed at SRI International and Litton Bionetics. Quality control criteria are those minimum criteria that must be met before an experiment is evaluated further for its response. Experiments that meet these minimum criteria may be rejected upon further evaluation.

The response categories are defined in terms of the significance of an individual dose and the significance of the trend of the dose response. For a response to be considered *positive*, both factors have to be significant. A *questionable* response lacks one of these factors. A *not positive* response lacks both factors. Significance is defined in terms of a statistical model developed to aid in the interpretation of the data. The response categories for a test are based on an evaluation of the results of the replicate experiments.

The statistical approach is based on an estimate of the variance of the mutant frequency, the measured parameter obtained from this assay. This estimate is made by developing a mathematical model of the biological protocol. The mathematical model

relates the mutant progenitor frequency (MPF), which is the number of cells with genetic damage at the TK locus after exposure to the test chemical, to the mutant frequency (MF):

$$MF = r_s \times r_c MPF$$

where $r_s$ is the ratio of suspension growth of the mutant and mutant progenitor population to that of the wild type population and $r_c$ is the ratio of cloning efficiencies of these populations. The estimated variance is then applied to making statistical interpretations of the mutation assay data.

Test results for chemicals tested in the L5178Y mouse lymphoma cell system during FY 1982 are given in Table 3. (CONTACT PERSON: Dr. W. Caspary)

*Mouse Lymphoma L5178Y Forward Mutation Assay*—Based on the results of studies on the mouse lymphoma system, the successful development of a working protocol and an effective data management system, the program issued a new RFP to test chemicals and to build a data base from results of this mammalian mutagenesis assay. Recently, it has been reported that the occurrence of small colonies from mutagen-treated cultures represents the induction of chromosomal damage. At present, however, evidence is not conclusive that measurements of small colonies are necessarily a measure of chromosomal mutation. The ability to measure chromosomal damage with an assay that is demonstrated to measure point mutations would be beneficial and cost effective. The purpose of this contract initiative is to test the ability of the mouse lymphoma cell system as a reliable indicator of gene and chromosomal mutation.

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It is projected that testing will be completed on 70 chemicals in the L5178Y mouse lymphoma cell system in FY 1983. Most of the chemicals will be selected from the listing in Table 4. (CONTACT PERSON: Dr. W. Caspary)

*In Vitro Cytogenetics in Mammalian Cells*—Chromosome aberrations (CA's) and sister chromatid exchanges (SCE's) are used as indicators of genotoxic effects of chemical agents. While the literature is extensive on the nature of cytogenetic events and the effects of particular chemicals, there have been few attempts to develop a highly reliable and reproducible system for detecting chemically-induced cytogenetic damage. A protocol using Chinese hamster ovary (CHO) cells has been developed in a dual laboratory study over the past two years. Several coded compounds were examined using this protocol with comparable results obtained in the two laboratories. To enhance the reliability of the system, several control and test experiments are being done to determine the best statistical approach to the data. It is clear that variability within an experiment is very low, thus greatly enhancing the sensitivity of the assays.

An essential feature of this program is the examination of a large number of chemicals. Testing was completed on 67 samples, consisting of 66 unique chemicals, in FY 1982. Results are given in Table 5. The use of the assay has now been extended to a third laboratory.

*FY 1983 Program Plans*

It is anticipated that testing will be completed on 100 samples. Most of the chemicals to be tested in CHO cells for detection of chromosome aberrations and sister chromatid exchanges will be selected from the listing in Table 6. In addition, the results of previous testing will be published. (CONTACT PERSONS: Dr. E. Zeiger and Dr. M. A. Resnick)

*Development and Validation of a Multiple Endpoint Mutation System in Cultured Mammalian Cells*—Because they can both produce human genetic disease, two major types of effects of concern in genetic toxicology are gene and chromosome mutations. Genotoxic chemicals usually induce both types of effects but the extent to which gene mutations or chromosome mutations are induced by any individual chemical is not predictable at this time.

Typically, induction of gene mutations in mammalian cells is detected in one of a number of different cell lines and the induction of chromosome mutations is usually detected using the same or different cell lines in laboratories specializing in cytogenetics. As a result, it is difficult to determine the relative frequencies induced and the effective doses. Yet a comparison between gene and chromosome mutations as a function of chemical dose is needed as a reference when moving from results obtained with cells in culture to predicted effects in treated animals. Such an extrapolation is necessary when only one type of mutagenic effect can be measured *in vitro* but it may be important to estimate the sum of both effects.

Two contracts were recently awarded to develop, refine and test a protocol (or series of protocols) using mammalian cells in culture to determine the frequencies of chemically-induced gene and chromosomal mutations. The possibility of determining other genetically-related endpoints such as sister chromatid exchange (SCE), DNA damage and repair, DNA adduct formation and aneuploidy are being considered. Once an acceptable protocol is developed, a number of coded chemicals will be tested.

Allied Corporation (Dr. G. Brewen) is investigating two cell lines, a human epithelial cell, HSBP, and Chinese hamster ovary (CHO) cells; Bioassay Systems Corporation (Dr. K. Loveday) is using a different CHO line. Both laboratories will standardize the culture and treatment conditions for each endpoint. The majority of efforts has been to define the optimum culture and treatment conditions for the different cell lines and to develop protocols for synchronizing the cells. Preliminary experiments have been run to determine the responses of the cells to a standard mutagen.

*FY 1983 Program Plans*

Optimization of the cell systems will be continued and a number of mutagens will be used to induce gene mutations (at the HGPRT, and possibly the OUA locus), chromosome aberrations (CA's), SCE's and aneuploidy. Measurements of DNA damage and repair and DNA-adduct formation will be made. In addition the effects of liquid holding on the mutagenic and other responses will be determined. (CONTACT PERSON: Dr. E. Zeiger)

*In Vitro Mammalian Cell Transformation*—For many classes of chemicals there is a high degree of relationship between the ability of the chemical to induce neoplastic transformation in certain mammalian cells in culture and the concomitant induction of tumors *in vivo*. Several cell culture systems including primary cultures, continuous lines, and virus infected cells have been used to detect potentially carcinogenic chemicals. Included among these are the BALB/c3T3 cell line currently being evaluated by the NTP; the C3H10T½ cell line which is being evaluated through the Division of Cancer Cause and Prevention, NCI; and the BHK cell line which is being studied in Europe. Three other systems which have been evaluated to some degree include: primary Syrian hamster embryo (SHE) cells; and two viral mediated transformation systems: SHE cells infected with Simian adenovirus 7 (SA7), and rat cells infected with Rauscher leukemia virus (RLV). However, sufficient across-chemical and across-system data do not exist to permit an evaluation of which system or systems may be most useful and to determine what characteristic advantages or limitations each system may have in the identification of potential carcinogens. Therefore, we have initiated a multiple laboratory coded compound evaluation of these latter transformation assays.

The initial objectives of this project involve the development of a standardized protocol, indetification of the sources of intra-and interlaboratory variability, and establishment of interlaboratory reproducibility of the respective test systems. Results of previous contract supported studies and published results have shown that these assays detect chemical carcinogens. This project is an effort to systematically evaluate and compare the three assays for oncogenic transformation and to determine which system or systems may be most applicable. In the SHE assay, cells are collected, frozen, characterized for their response to known carcinogens, and then exposed to concentrations of a test chemical. The exposures are based upon preliminary tests for toxicity; after 7 to 10 days the treated cultures are examined for foci of transformed cells. In the SHE/SA7 assay, the cells are prepared from pooled 13-day gestation embryos. Transforming virus is obtained from standardized stocks with a defined plaque forming unit/focus forming unit (PFU/FFU) ratio and the cells are infected with virus prior to or after treatment with doses of the test chemical. These doses are selected on the basis of acute toxicity. The treated cultures are examined for foci of transformed cells 7 to 10 days after exposure. In the retrovirus infected rat cell system (RLV), infected (2FR450) and uninfected (2FRN) cell lines were recovered from passage 7 frozen cells. The cells are first exposed to chemicals to determine acute toxicity. Subsequently, selected doses are applied and the cells are tested for neoplastic

transformation by the aggregation (survival) assay which detects the preferential ability of transformed cells to survive under the test conditions.

For the first year of this project, the major goals included: (1) Standardization of test protocols; (2) identification of key test reagents and materials; (3) selection of optimal doses of reagents and materials following preliminary testing; (4) acquisition of sufficient quantities of critical reagents (from identical sources by the respective contract laboratories; and (5) testing of representative chemicals, positive and negative for transformation, for toxicity and transformation to establish interlaboratory reproducibility of the method. Each contract laboratory has the responsibility of focusing on key components of the system, e.g., identification of suitable frozen cell pools, identification of optimal serum and medium stocks. Progress has been made in all areas, although some technical aspects require further evaluation before final protocols can be defined. Preliminary toxicity and transformation assays of the standard chemicals are being performed in the test laboratories and the results of these independent tests will be the basis for determining the degree of interlaboratory reproducibility.

*FY 1983 Program Plans*

One of the major technical issues have been resolved and a standardized test protocol has been adequately developed and validated, all of the laboratories will begin to test coded chemicals. The results of these studies will be used to determine whether *in vitro* transformation systems offer significant advantages in time and cost over animal bioassays for carcinogens. In addition, the systems will be evaluated for their ability to provide information for mechanistic inferences on the toxicity of chemicals. It is important that the use of such test systems include the application of standardized protocols which provide for a high degree of interlaboratory reproducibility and an understanding of the biological limitations of the test systems. (CONTACT PERSON: Dr. R. W. Tennant)

*In Vitro Transformation of BALB/c-3T3 Cells*—The purpose of this project is to develop and standardize methods for performing *in vitro* transformation assays with BALB/c-3T3 cells. The BALB/c-3T3 neoplastic transformation assays is used to measure the ability of chemical agents to induce alterations in a population of cells (derived from mouse embryo fibroblasts) from a pattern of controlled monolayer growth to one exhibiting foci of disorientation and piled up growth against a background monolayer. Toxicity is used to determine the high dose (10–20% cell survival) at which a chemical will be tested. Dishes for transformation are plated with cells expanded from frozen stock at $10^4$ cells per 60 mm Falcon plate. Twenty-four hours later, the test chemicals are added to the appropriate plates in the final volume of 0.1 or 0.2 ml. After a three-day treatment, the medium is removed and the plates are washed and replenished with fresh medium and incubated for an additional four weeks. The medium is changed twice weekly during the incubation period. At the end of the incubation period, the plates are fixed with methanol and stained with 2–3% Giemsa or May-Grumwald-Giemsa and then scored for foci of transformed cells.

A number of factors that affect the quantitative assessments of transformation were examined. The results showed that the survival of cells in mass culture is invariably greater at toxic doses than one would expect from extrapolation of direct cloning data. Also, the number of cells surviving till the end of treatment was dependent on the source of insult and was not reflected in the direct cloning data. These observations suggest that the use of direct cloning data to estimate the number of cells at risk in the transformation assay grossly underestimates the actual population of cells exposed to the test chemical.

A study was conducted to correlate anchorage-independent growth and *in vivo* tumorigenicity with progression of Type III foci in cell passage. It was found that the transformed population (Type III foci) acquired the ability to grow in soft agar at the earliest passage. However, although most Type III cell populations grew tumors in irradiated syngeneic animals, the cell populations did not exhibit quantitative correlation of growth in soft agar with tumorigenicity. Tumorigenicity of transformed populations contrary to growth in soft agar, was dependent on cell passages in culture. This suggests that populations of clone I–13 contain premalignant cells, which develop tumorigenic potential after extensive passage in cluture.

Due to the fact that growth in soft agar was not found to be a consistent marker of oncogenicity for BALB/c-3T3 cells, another proposed marker, basal cathepsin C activity, was examined. However, this marker was not found to correlate with either the ability of populations to grow in soft agar or to grow tumors in animals.

In comparative tests run between cells of the I–13 clone and other cells, there were varied results. Cells from the I–11 clone showed no spontaneous background transformation frequency, but were less sensitive to chemical treatment. Clone I–11 cells also showed little response when their enhancement with promoter was attempted. A comparison of the metabolism of methylcholanthrene (MCA) by I–13 and C3H-10½ cells showed differences in kinetics between the two populations. However, no simple relationship between the rate of MCA metabolism and transformation of cells by MCA could be obtained.

The testing of seventy coded samples has been completed using the BALB/c-3T3 system and the data obtained are currently being analyzed.

Additionally, studies were designed to investigate the effects of various activation systems. Preparations of rat liver 900 x g supernatant fraction (S–9) proved toxic. Experiments with primary rat hepatocytes were designed so that only minimal modifications would be made on the established standard protocol for the transformation assay without metabolic activation. The target BALB/c-3T3 cells were plated at $10^4$ cells/plate either prior to or after plating of primary rat hepatocytes. Treatement with chemicals was carried out for 1–3 days. The remainder of the procedure was the same as that used in assays without metabolic activation. None of the procarcinogens tested (N-2-fluorenylacetamide, 2-aminofluorene, dinitrosopiperazine and nitrsos-2,6-dimethylmorpholine) appeared to be activated by the hepatocytes to transform BALB/c-3T3 cells in a consistant manner.

A second approach was designed in which protocols followed were similar to those used in mammalian mutagenesis assays. Two sets of experimental conditions were tested, differing primarily in the density of target cells. Under one condition, BALB/c-3T3 cells were plated at or near confluence. Primary rat hepatocytes were then plated on top of the target cells. This plating condition facilitates maximum contact between BALB/c-3T3 cells and hepatocytes, where the monolayer or BALB/c-3T3 cells serves as a feeder layer for attachment of hepatocytes and maintenance of their metabolic capabilities. Alternatively, BALB/c-3T3 cells were plated at a moderately high density ($2\times10^5$ plate), but still being in the exponential growth stage, they were unable to undergo division during the chemical treatment period. Under both conditions, the cells were trypsinized and replated at a low density ($10^4$/plate) after the chemical exposure period to allow for development of foci as in a standard transformation assay. The results suggested that for the transformation of BALB/c-3T3 cells, primary rat hepatocytes were not very effective in the activation of carcinogenic nitrosamines. (CONTACT PERSON: Dr. W. Caspary).

• Special Applications—*In Vitro* and *In Vivo* or *In Vitro* Mammalian Testing

*Mutagens Formed from the Cooking of Foods*—The objectives of this interagency agreement with the Department of Energy at Lawrence Livermore National Laboratory are to identify the mutagens produced in foods cooked under approximately normal household conditions and determine the mechanism(s) of mutagen formation, assess the spectrum of genetic toxicity caused by these mutagens using *in vitro* and *in vivo* short-term tests, devise strategies to limit or prevent mutagen formation and to estimate the normal dietary intake of these mutagens.

Hamburger is fried under normal cooking conditions, extracted and the extracts tested for mutagenicity using the *Salmonella* plate test with S–9 preparations from mice, rats, and hamsters pretreated with various inducers. Extracts exhibiting the highest levels of mutagenicity are separated in an attempt to isolate and identify the mutagenic components. Similar work is being done with other fried meats, fried eggs and beef extracts. Mutagenicity studies are being performed in *Salmonella* and in cultured CHO cells. Metabolism studies are being done *in vitro* using S–9 fraction in the incubation vessel.

A series of extraction procedures have been developed for hamburger which greatly increase the yield of extracted mutagen. The hamburger mutagens require metabolic

activation and revert only those *Salmonella* strains which are reverted by frameshift mutagens. Studies on the kinetics of hamburger mutagen formation showed that the cooking temperature, rate of heat transfer and level of dehydration all affect the level of mutagenicity. Following a Japanese report which identified imidazoquinoline (IQ) and methylimidazoquinoline (MeIQ) as beef mutagens, studies were performed, using preparative TLC followed by GC/MS and HPLC. A number of mutagenic fractions have been identified; the presence of IQ in one of the fractions has not been confirmed. Cold IQ and radiolabelled IQ have been synthesized and chemistry and mutagenicity studies have been initiated. Methyl-imidazoquinoline will be synthesized in the near future. Extracts will be spiked with IQ and its location in the fractions identified.

A number of metabolites of $^{3}$H-IQ have been separated from an *in vitro* S-9 system. The metabolism of IQ is mediated by cytochrome P/448. Only one of the metabolites, as yet undefined, is a direct mutagen for TA1538. Purification and identification of these metabolites is underway.

Trp-P-2 and IQ are both potent mutagens in *Salmonella*. Trp-P-2 is a potent mutagen in mammalian cells (CHO), inducing gene mutations, SCE's CA's and micronuclei, but IQ was only weakly positive for these endpoints, and only in repair-deficient CHO cells. These results are in contradiction to the relative *Salmonella* results and studies are underway to resolve this problem. CHO cells will be treated with the direct mutagen metabolite of IQ.

Boiling beef to produce stock results in the formation of a product that is mutagenic to *Salmonella* in the presence of liver S-9. The highest level of mutation is found with extracts prepared at pH4 and pH9. Results from proteolytic digests of beef extracts implied that soluble amino acids or polypeptides could influence the formation of mutagens. Enhancement of mutagenic activity at pH4 is optimal after addition of tryptophan and creatinine $PO_4$ and results from reactions with components of less than 500 molecular weight in the soluble portion of the beef extract. Addition of ferrous sulfate further stimulates mutagen formation. The mutagens in boiled beef and Difco beef extract have been separated chromatographically and also have been reacted with nitrite. Results are consistent with the presence of at least two mutagenic components, one of which may be IQ.

Extracts of fried eggs were also mutagenic, although the extraction and purification procedure that was optimal for fried beef was not optimal for fried egg. Studies are underway to identify the optimum extraction procedure for fried eggs and to determine why the mutagenic activity of egg extract appeared to be suppressed by the beef extraction procedure. (CONTACT PERSON: Dr. E. Zeiger)

*Rapid in Vitro Test Project*—This project was designed to provide genetic toxicity data to aid in setting priorities for chemicals to be entered into the long-term carcinogenicity bioassays and for use by NTP experimental disign groups. An *in vitro* testing capability was developed to utilize five broad classes of genetic toxicity assays. Use of NTP resources for implementation of this project was coordinated in a manner that utilized both ongoing and new contracts to perform the assays. One-year interagency agreements were initiated with the Environmental Protection Agency and the National Center for Toxicological Research to perform the following assays among three of the five classes indicated:

*Class I:* Gene mutations in mammalian cells: The L5178Y mouse lymphoma cell TK$^{+}$/$^{-}$ mutation assay

*Class II:* Mammalian cell transformation assay:

a. The BALB/C-3T3 *in vitro* transformation assay;

b. The enhancement of DNA virus transformation by chemical carcinogens using Syrian hamster embryo (SHE) cells and Simian adenovirus (SA7) assay.

*Class III:* DNA damage/repair:

a. The *in vitro* unscheduled DNA synthesis (UDS) in rat liver primary cell culture assay;

b. The *in vivo—in vitro* unscheduled DNA synthesis (UDS) in rat liver primary cell culture assay.

Twenty-five to thirty chemicals have been assigned and scheduled for testing in the assays cited above. The chemicals include those 19 chemicals selected in FY 1982 for testing in the prechronic phase of the long-term carcinogenesis bioassay. The testing of these same 19 chemicals has also been coordinated by the project officer in two other classes of genetic toxicity tests which are performed through ongoing Branch contract projects.

These two classes are:

*Class IV:* Gene mutations in bacteria: The *Salmonella*/microsome test.

*Class V:* Chromosome damage in mammalian cells: The *in vitro* cytogenetics assay in Chinese hamster ovary (CHO) cells for detection of chromosome aberrations and sister chromatid exchanges.

Results on the 19 bioassay-candidate chemicals are expected to be completed in FY 1982.

*FY 1983 Program Plans*

Emphasis will continue to be placed on providing genetic toxicity test information in a timely manner on chemicals to be considered for the long-term carcinogenesis bioassays, and for use by NTP experimental design groups. A capacity for testing 25–30 chemicals/year will be implemented through both existing and new contracts, and coordinated so that the test chemicals can be evaluated in the five classes of *in vitro* short-term tests listed above. These five test components comprise a broad range of potential mechanisms of genotoxicity. The choice of these systems does not constitute an "NTP battery" but rather represents a selection of available tests. New test systems will be used to supplement or replace these existing tests when data sufficient to justify such changes become available. The results of this project will provide important and useful information on the genetic toxicity of chemicals of priority interest to the Program. (CONTACT PERSON: Dr. J. W. Spalding)

*DNA Damage and Repair—In Vitro Unscheduled DNA Synthesis (UDS) in Rat DNA Liver Primary Cell Culture*—The induction of DNA repair measured as unscheduled DNA synthesis (UDS) in non-dividing cells has been shown to be a useful indicator of the genetic toxicity of chemicals. Several different cell types and cell lines, including those of human origin, have been utilized for the measurement of UDS. The UDS assay, which employs primary cultures of rat hepatocytes, offers the advantage of a short-term test using a metabolically competent target cell, thus eliminating the need for exogenous activation preparations or the presence of other cell types.

*In vivo—In vitro UDS in Primary Rat Hepatocyte Culture*—The *in vivo—in vitro* hepatocyte DNA repair assay Carcinogenesis *1*, 621–625, 1980) represents an important modification and extension of the *in vitro* rat hepatocyte DNA repair assay, since it involves the treatment of whole animals rather than the administration of chemicals directly to cells in culture. The *in vivo—in vitro* assay permits the administration of the test chemical to the animal in a manner analogous to the route of exposure in humans. Direct administration of the chemical to the animal also has the advantage that important factors related to uptake, metabolic activation, distribution, detoxification and elimination which are absent from *in vitro* systems are included. After appropriate treatment intervals, primary hepatocyte cultures are prepared from the treated animals, and the incorporation of $^{3}$H-cultured cells serves as an indication of the degree of an induced DNA repair response. While the number of chemicals tested to date in this assay is small, it has been demonstrated that this *in vivo—in vitro* assay is responsive to the genotoxicity of some classes of chemicals, e.g., the nitroaromatics, to which the *in vitro* UDS rat primary hepatocyte culture assay does not respond.

*FY 1983 Program Plans*

It is planned to evaluate 30 test chemicals per year in both the *in vitro* and *in vivo—in vitro* UDS rat primary hepatocyte culture assays. These assays will provide another test component for the evaluation of chemicals being considered for long-term bioassays and for use by NTP experimental design groups. In addition, the responsiveness of the two DNA damage/repair assays to different classes of chemicals with genotoxic potential will be compared relative to each other and to other assay systems. (CONTACT PERSON: Dr. J. W. Spalding)

• *In Vivo Mammalian Test Systems.*

*Rodent Bone Marrow Cytogenetics*—Through collaboration between two laboratories, methods are being developed for the routine screening of chemicals for the induction of chromosome aberrations (CA's) and sister chromatid exchanges (SCE's) in mice. It is known that CA and SCE both are endpoints associated with the genetic effects induced by many chemical mutagens and carcinogens. As such, these endpoints are potentially important as predictors of

chemical genotoxicity, particularly when conducted in whole mammals where factors such as metabolism, distribution, excretion, etc., are more reflective of the human situation than are *in vitro* studies. The studies provide direct evidence of genotoxic effects in laboratory mammals, which can be compared to similar effects in exposed humans. Further, the studies are being carried out in the mouse strain ($B6C3F_1$) used in the NTP carcinogenesis bioassay program, and, hence, will permit a more direct comparison of induced somatic-cell genetic effects with carcinogenic effects. In addition to providing a potential screen for carcinogens, comparisons may permit a better understanding of the relationship between induced cytogenetic effects and induced cancer. The primary objectives of this study are to develop and assess a testing protocol for the simultaneous determination of CA and SCE and to test approximately 40 chemicals using the protocol.

Although the basic methods for conducting these tests (*Mutat. Res. 87*, 143–188, 1981; *Mutat. Res. 87*, 17–62, 1981) are available and have been used extensively, there remains a need for an acceptable protocol of demonstrated utility for use in routine testing. The protocol under development will use current technology to apply accepted techniques for determining the frequency of CA and SCE in the bone marrow cells of $B6C3F_1$ mice.

In the preliminary phases of the study, male mice, 8–10 weeks old, are treated by intraperitoneal injection with the test compounds. Chromosomal aberrations are determined in bone marrow cell preparations. Sister chromatid exchange frequencies and cell proliferation kinetics are determined with 5-bromodeoxyuridine (BU) substituted chromosomes. Bone marrow cell proliferation kinetics are being investigated after administration of Mitomycin C, 7, 12-dimethylbenzanthracene, and cyclophosphamide. These same reference mutagens are being used to investigate the effect of the time-of-administration of the test agent relative to BU administration. A computerized data management system has been developed and is being used for storage of experimental details and storage and analysis of data.

It is anticipated that by the end of FY 1982, a testing protocol will be available and can be assessed using coded chemicals in the two laboratories. Following the successful outcome of that assessment, the laboratories will begin screening chemicals for cytogenetic effects.

*FY 1983 Program Plans*

In FY 1983 the testing protocol will be assessed through testing in both laboratories of five coded chemicals of known cytogenetic activity. Following the successful completion of this phase, ten NTP selected chemicals will be tested for cytogenetic activity. (CONTACT PERSON: Dr. M. D. Shelby)

• Special Applications—Human Genetic Monitoring.

*Human Lymphocyte Cytogenetics*—Determination of cytogenetic damage in peripheral lymphocytes offers a practical means of detecting exposures of humans to genotoxic agents. The basic technique has been used for many years to detect human exposure to ionizing radiation. It has been applied to a lesser extent in connection with exposures to chemical agents. The protocols for the cytogenetic studies that have been performed on persons exposed to chemical agents have been varied, usually precluding cross comparison of results. They also often have been flawed in one respect or another so that definite conclusions could not be made. Thus, the development of a standard protocol for cytogenetic monitoring is needed, as is background information on the frequencies of chromosome aberrations (CA's), particularly chromatidtype aberrations, and sister chromatid exchanges (SCE's), their variability, and the sources of variability. Such information is needed for the proper design and interpretation of cytogenetic studies of populations exposed to potential chromosome damaging agents. (Guidelines for Studies of Human Populations Exposed to Mutagenic and Reproductive Hazards, Arthur D. Bloom (Ed.) March of Dimes Birth Defects Foundation, 1981, 163 pp.).

A project has been undertaken in which two laboratories are collaborating: (1) To develop and standardize a protocol by which the frequencies of CA's and SCE's in human lymphocytes can be accurately and reproducibly determined; and (2) to investigate the variation of these frequencies as affected by the protocol and, to the extent possible, by the circumstances of the individuals from whom blood samples are obtained.

It has been demonstrated that blood samples can be stored at 4°C, shipped by airfreight and cultured within 24 hours without a significant loss in growth potential of the lymphocytes. A reduced quality of chromosome differentiation for SCE analysis was noted in shipped samples. This appeared to be a result of shipping/handling and not of storage since the phenomenon was not observed in cells maintained at 4°C for 24 hours at the site of collection. Reproducibility of scoring both SCE and CA on common slides has been demonstrated at the two laboratories. Determinations of first, second, and third division cells in 48 hour cultures (the fixation time normally chosen to ensure scoring of first division cells) produced somewhat surprising results in that an average of 18% of cells are in their second mitosis at this time.

*FY 1983 Program Plans*

Once the protocol has been defined, agreed upon and demonstrated to provide reproducible results in the two participating laboratories, the second phase of the study will begin. Phase two is intended to investigate and to the extent possible, identify sources of variation in the frequencies of CA and SCE. Variables to be investigated include age, sex, and race. Cytogenetic analyses will be conducted on approximately 150 individuals in FY 1983. (CONTACT PERSON: Dr. M. D. Shelby)

*Germ Cell Mutation*

• Heritable Effects—Nonmammalian Assays.

*Drosophila Mutagenesis Testing*—Standard sex-linked recessive lethal and reciprocal translocation tests in *Drosophila melanogaster* are being used in three laboratories (Bowling Green State University, Dr. R. Woodruff; Brown University, Dr. S. Zimmering; and University of Wisconsin at Madison, Drs. R. Valencia and S. Abrahamson). Chemicals are selected based on results obtained from previous mutagenicity tests using *Salmonella*. Chemicals are administered in feed for the sex-linked recessive lethal test. If the results are negative, the test is repreated using injection; if the results are again negative, the chemical is considered nonmutagenic in *Drosophila* for the endpoint. If the results are positive, the chemical is tested in the reciprocal translocation test using the means of administration which gave the positive result. In the reciprocal translocation test, sperm is stored to enhance the ability to recover chromosome breaks induced by the chemicals. Results are entered on data forms and transferred to a computerized data base system. Results have been received on a total of 52 test samples to date, which includes 47 unique chemicals. Results for 48 chemicals tested in FY 1982 are shown in Table 7.

*FY 1983 Program Plans*

Testing will continue on these contracts with testing expected to be completed on 75 chemicals. Most of the chemicals tested in *Drosophila* will be selected from the listings in Table 8. In addition, the results from initial testing will be published. (CONTACT PERSON: Dr. J. Mason)

*Aneuploidy Test Systems*—Three systems are being developed for the monitoring of chemically-induced aneuploidy, a genetic endpoint not monitored by other mutagenesis test systems. Two of these systems measure germinal or meiotic events in *Drosophila* and the yeast *Saccharomyces cerevisiae*, and a third follows mitotic aneuploidy in yeast. For purposes of comparison, these systems will also have the capability of monitoring chemical effects on recombination and mutation induction. These assay systems in combination with other short-term tests expand the opportunities to evaluate chemically-induced genetic damage. The use of whole animal and single cell systems will allow interspecies comparisons in terms of germinal events. Since the relevance and the mechanism of mitotic and meiotic aneuploidy may differ, development of the two systems within the same organism will prove useful.

*FY 1983 Program Plans*

The development stages are nearly complete and during the coming year testing of chemicals, known or suspected to induce aneuploidy, for purposes of validation will begin. (CONTACT PERSON: Drs. M. Resnick and J. Mason)

• Heritable Effects—Mammalian Assays.

*Mouse Morphological Specific Locus Study*—Exposure of humans to mutagenic chemicals poses the risk of induced mutations in germ cells, the transmission of these mutations to subsequent generations and an increase in frequency of genetically determined diseases in the human population. Determining the risk of such

health effects must presently be approached through whole mammal assays since tests involving lower organisms or mammalian cells *in vitro* have the disadvantages of not addressing heritability of induced mutations, germ cell stage specificity, and special metabolic, physiological and transport factors that might exist during the reproductive cell cycle. The morphological specific-locus method is, at present, the most practical and reliable means available in mammals for detecting induced heritable mutations.

The test employs two strains of mice to detect mutations at seven loci that affect visible characteristics (coat color, eye color, and ear shape). In the standard test (Cold Spring Harbor Symp. Quant. Biol. *16*, 327–336, *1951*), C3Hx101 hybrid males homozygous for the wild-type alleles at the seven loci are treated with the test agent. Treated males are mated to T-stock females that are homozygous for recessive mutant alleles at the seven loci. Offspring are expected to be heterozygous at the seven loci and appear as wild-type having inherited dominant wild-type alleles from their fathers. Variant animals will appear if the male germ cell carried a mutant allele (either spontaneous or induced). Offspring are scored at weaning and variants are tested by breeding studies to determine the genetic basis for their variation.

The two basic objectives of this project are: (1) To conduct an in-depth study of chemically-induced mutation processes in mammalian germ cells using N-ethyl-N-nitrosourea (ENU) as a model mutagen; and (2) to investigate five environmentally significant chemicals for germ cell mutagenicity. In the past year, major emphasis has been on the use of ENU to investigate germ cell mutagenesis. A dose response curve has been determined for ENU-induced mutations in spermatogonia at eight doses from 0 to 250 mg/kg. There is a strong indication that the curve is not linear for points below 100 mg/kg, falling below a straight line fit to the control value. Fractionated dose experiments have shown that 10 injections of 10 mg/kg ENU yield a much lower frequency of mutants than a single injection of 100 mg/kg indicating an efficient repair of ENU-induced damage. Experiments are underway to investigate further male post meiotic germ-cell stages, effects on female germ cells, and age effects. Dosimetry studies using tritiated ENU show a much higher level of ethylation in the liver than in the testes. In testicular DNA, there appears to be a linear relationship between dose administered intraperitoneally and ethylation over a dose range from 10 to 100 mg/kg.

*Fiscal Year 1983 Program Plans*

Major efforts anticipated during the next year are:

(1) The completion of the spermatogonial dose response curve with ENU, i.e., additional data will be obtained at low-dose points;

(2) Experiments to determine the stage sensitivity of male germ cells to ENU will be completed; and

(3) The germ cell mutagenicity of 1,2-dibromo-3-chloropropane and hexamethylphosphoramide will be investigated. (CONTACT PERSON: Dr. M. D. Shelby)

*Mouse Biochemical Specific Locus Study*—The problem of heritable health risks resulting from exposure to mutagenic chemicals and the use of animal models to investigate this risk was introduced in the report on the mouse morphological specific locus study. The biochemical specific locus assay offers a second animal model by which to investigate the ability of chemicals to induce heritable mutations in mammalian germ cells. The biochemical specific locus assay has two particularly desirable features.

First, the assay detects changes in specific enzymes and offers the opportunity to relate chemically/induced mutations to changes in enzyme structure and function and ultimately to effects on health or fitness. Second, the potential availability of a large number of loci for analysis means that fewer animals than for the morphological specific locus test might be required to obtain a given amount of information.

The objectives of this study are: (1) To investigate chemically-induced mutation processes in mouse germ cells by studying cell stage specificity in both sexes and establishing a dose-response curve in spermatogonia using the mutagen N-ethyl-N-nitrosourea (ENU); and (2) investigating three environmentally significant chemicals for germ cell mutagenicity.

In this assay (Genetics *97*, 113–124, 1981; *Proc. Natl. Acad. Sci.* USA *78*, 3138–3141, 1981), induced mutant frequencies are determined by treating one parent (C57B1/6J or DBA/2J), usually the male, with ENU or a test chemical and then mating to the alternate strain to obtain progeny. Blood and kidney samples are taken from the $F_1$ progeny and tissue preparations of these samples are subjected to starch gel electrophoresis. After staining, the electrophoretic patterns of 21 proteins are observed on the gels and altered mobility patterns or missing bands are noted as variants. Breeding tests with the animals from which the altered proteins were obtained, along with additional electrophoretic analyses, are used to confirm or refute the mutational basis of the variants. At this early stage of the project, ENU treatments have been carried out and matings begun for: (1) Postmeiotic germ cells in both C57B1/6J and DBA/2J males; (2) the 200 mg/kg spermatogonial dose point; and (3) 250 and 100 mg/kg treatments in females. Insufficient progeny have been screened to draw conclusions from any of these studies. However, among 250 mg/kg treated C57B1/6J females, litters were obtained from matings beyond three weeks post-treatment. The 100 mg/kg females produced litters from matings during the first week following treatment. No electrophoretic variants have been obtained from these 100 mg/kg females but one apparent dominant coat color female mutant was detected among the progeny. The nature of this variant will be determined when she is old enough to mate. A stain specific for the esterase, Es-10, is being adapted for use in the screening system and, if incorporated, will increase the number of loci screened to 22.

*Fiscal Year 1983 Program Plans*

Several ENU studies initiated in fiscal year 1982 will be completed including those on the spermatogonial dose response curve and male and female germ cell stage sensitivities. Ethylene oxide and ethylene dibromide will be investigated for germ cell mutagenicity. (CONTACT PERSON: Dr. M. D. Shelby)

*Mouse Heritable Translocation Testing*—The thorough assessment of human genetic risk associated with exposure to mutagenic chemicals is complex and remains subject to many questions. Not only is such an assessment dependent upon extrapolation from results obtained in non-human test organisms but must also take into consideration a variety of genetic events that are known to be induced by chemical mutagens (e.g., gene mutations, chromosomal damage, and aneuploidy). All such events are known to be associated with human genetic disease. Genetic risk assessments are further complicated by the fact that some classes of genetic damage affect the first generation following the occurrence of the damage while in other cases effects may not be manifest for a few or many generations.

Heritable translocations resulting from the exchange of segments between non-homologous chromosomes are known to result in serious human health effects as in Downs and the *cri du chat* syndromes. The fact that serious genetic disease can result from heritable translocations, together with the fact that radiation and a number of chemicals are known to induce heritable translocations in mammalian germ cells, clearly demonstrates the need for testing chemicals for the ability to induce heritable translocations.

The purpose of this study is to gather additional information on the heritable genetic effects of chemicals being tested in the morphological specific locus assay. Six chemicals will be investigated over a two-year period using the same strains, chemicals, and treatment regimens used in the specific locus assay.

Heritable translocations are detected by treating male mice with test chemicals, mating the treated males and then testing $F_1$ males for fertility. Partially or completely sterile $F_1$ males are confirmed as translocation carriers by additional matings and cytogenetic analyses (*Mutat. Res. 76*, 191–215, 1980).

*FY 1983 Program Plans*

A heritable translocation study on inhaled ethylene oxide began in late FY 1982 and will be completed in FY 1983 along with the testing of three additional chemicals. (CONTACT PERSON: Dr. M. D. Shelby)

*Collaborative Activities*

*Proposed International Study on Short-term In Vitro Tests for Detecting Chemical Carcinogens*—The NTP is represented on the International Program on Chemical Safety (WHO) *Ad Hoc* Working Group on the Application of Short-Term Tests to Predict Mutagenic and Carcinogenic Potential, and will participate in a proposed international study on short-term *in vitro* and *in vivo* tests.

The objective of the proposed study is to identify and select one or more *in vitro* tests in eukaryotes which, in a battery testing approach, will complement bacterial gene mutation assays by reliably detecting chemical carcinogens that are not readily detected with bacterial systems. This is to be accomplished through the testing of eight selected carcinogens, (hexamethyl-phosphoramide, safrole, ortho-toluidine, benzene, acrylonitrile, di(2-ethylhexyl)phthalate, phenobarbital, and diethylstilbestrol), and two chemicals (benzoin and caprolactam) for which there is good evidence of noncarcinogenicity. It is recognized that such complementary assays cannot be selected strictly on the basis of the proposed study. Therefore, utilization of other major sources of data such as the International Program for the Evaluation of Short-Term Tests for Carcinogens (IPESTTC) and the EPA Gene-Tox Program is anticipated. Since much of the groundwork for the proposed study has been covered in the IPESTTC, and to keep the study to a manageable size, the specific assays will be selected from those: (1) Which were conducted in the IPESTTC; and (2) with additional endpoints which have a demonstrated or anticipated likelihood of detecting the carcinogens under test.

Letters of invitation to participate in the study have gone out to laboratories around the world and most invited participants have responded. Arrangements have been made for the acquisition and shipping of chemicals. The *in vitro* phase of the study is to begin in the summer of 1982 and will require one year to complete. The *in vivo* phase of the study in which two carcinogen/putative noncarcinogen pairs (2-acetylaminofluorene/4-acetylaminofluorene and benzo(a)pyrene/pyrene) will be tested, will begin after the *in vitro* testing phase is underway and should also require approximately one year to complete. (CONTACT PERSON: Dr. M. D. Shelby).

*International Collaborative Study on Genetic Drift in the Ames Tester Strains*—As part of a thirty-eight laboratory international study, stocks of five *Salmonella typhimurium* tester strains used by the Cellular and Genetic Toxicology Branch were compared with reference cultures for their reponse to the mutagen4-nitroquinoline-N-oxide. This comparison was done using multiple experiments and a standardized protocol.

For the analysis phase of this study, the Branch in concert with the Biometry and Risk Assessment Program is one of three groups analyzing the data generated by the thirty-eight laboratories (the other analysis groups are in England and Italy). In this analysis we are evaluating the in-house vs. reference culture response in each laboratory, and across all laboratories; the day-to-day variation within and between laboratories; laboratory-to-laboratory variability; and the degree of variability within experiments for each laboratory and between laboratories. Preliminary analyses were presented at The Environmental Mutagen Society Annual Meeting in Boston, MA in March, 1982 and at The European Environmental Mutagen Society Meeting in Helsinki, Finland, June, 1982, along with the analyses of the British and Italian investigators.

Preliminary analyses show that disagreements or differences between laboratories are probably due to the way the laboratory performs the test and not to the genetic constitution of the *Salmonella* strains used in the different laboratories. Even when a fixed protocol is used as in this study, the analyses indicate that the performance of the protocol may be as important as the protocol itself. Additional analyses are in progress. These findings have a number of implications for the conduct and interpretation of results from the *Salmonella* test and can aid in the resolution of disagreements between laboratories. (CONTACT PERSON: Dr. E. Zeiger).

*Support Activities*

*Development of a Computerized Data Base Management System for the Cellular and Genetic Toxicology Branch*—The NIEHS/NTP testing projects generate large volumes of data and experimental information on all chemicals tested for genetic toxicity. A computerized data base management system is needed to capture this information in an interactive mode in the testing laboratory, store, process, and analyze the data, and provide summary analyses to the experimenter and to the Branch project officers. This system will also allow the staff to follow the course of testing with time in a large number of laboratories regardless of the genetic toxicity test system being used.

The PROPHET system, developed and managed by Bolt, Beranek and Newman under contract to the Division of Research Resources/NIH, was selected for collection and retrieval of *Salmonella, Drosophila* and cytogenetics data. Work has been completed by the contractor on a laboratory data entry terminal to be used for data collection and on the data base structure and software required to store this data in PROPHET. The data entry terminals are in place in the *Salmonella* testing laboratories and are being used to transmit data directly to PROPHET thereby obviating the need for data forms. Once in PROPHET the data is checked for completeness and made available to the Branch project officer in an easily readable form for approval. After approval, the data is stored in readily accessible tables for future reference, and summary management tables are updated with the new information. *Drosophila* and cytogenetics data are being entered into the PROPHET system at NIEHS.

Analytical Techniques required to perform mutagenicity and quality control determinations are being developed by NTP scientists for addition by the contractor into PROPHET. Finally, the contractor has developed additional interactive and batch report generation routines to facilitate the mangement of the mutagenicity results.

Presently work is progressing on the development of an in-house data base management system on the VAX computer. It will contain data from all the testing projects in the Branch and will allow for immediate retrieval and management of the data. (CONTACT PERSON: Mr. R. M. Rowley)

**Intramural Program**

*FY 1982 Accomplishments and FY 1983 Program Plans*

*Salmonella Mutagenesis Reserch*—Research with *Salmonella typhimurium* tester strains can be divided into two major projects: (1) Studies on the *Salmonella* strains and protocols in order to increase understanding of the test and improve the sensitivity and effeciency of the protocols currently in use, and (2) use of the *Salmonella* test as a tool to sutdy the *in vitro* anb *in vivo* metabolism of mutagenic chemicals.

Studies designed to improve understanding of the test include: (1) Kinetics of generation and appearance of spontaneous and induced mutant colonies; (2) factors affecting the mutation response: (3) identification of sources of variability or error in the test; (4) enhancement of the sensitivity of the protocols and improvement of the efficiency of currently used protocals; and (5) characterization of the factors needed to define a positive mutagenic response. Examples of these studies are the development of a rapid plate test for characterization of the phenotypes of the various tester strains; the identification of chemicals which interfere with the appearance of histidine revertant colonies on the plate test in the absence of toxicity as normally measured in the test; and the demonstration that the test can differentiate between the two mutagenic enantiomers of styrene oxide.

We have shown that prostaglandin endoperoxide synthetase (PES) can metabolize dihydrodiol derivatives of polycyclic aromatic hydrocarbons to mutagens and tht this metabolism was more selective than that effected by liver microsomal enzymes. These studies have been extended to the metabolism of aromatic amines where PES was also more selective than liver microsomal enzymes.

The study with purified cytochromes has extended to include rat liver cytochrome P448's synthesized in response to different inducers. The ability of these different cytochromes to metabolize aromatic amines and other substances to mutagens is being studied. (CONTACT PERSON: Dr. E. Zeiger)

*Genetic Studies in Drospphila*—The characterization of the relationship between DNA repair and mutagenesis in *Drosophila melanogaster* is being studied in several ways. First, X-linked mutagen-sensitive mutants have been isolated and characterized, many being shown to be defective in DNA repair. Two mutants at one locus decrease spontaneous mutation frequency but mutants at nine other loci show no effect. A fine structure map of the *mei-41* locus is being constructed to ascertain the allelism relation ship between *mei-41* and *mus-104*, and to confirm the large size of *mei-41* that has been indicated by mutational analysis. Many *mei-41* alleles are temperature sensitive and are being mapped with the intention of localizing the coding region of the gene. It should be possible to confirm the size of the locus further by the mapping of MR-induced *mei-41* mutations.

Also, DNA repair-defective mutants have been combined with certain maturally occurring transposable elements to allow the study of the interactions which occur in the double mutant combinations. Chromosome transmission is affected.

In addition, a mutant which increases mutation frequency (a mutator) has been identified and mapped. The mutator appears defective in repair of double strand breaks. Its presence results in the recovery of many X-ray induced mutations, most of which appear to be terminal deficinecies. Based on both cytological and genetic evidence, the broken chromosomes which are recovered are considered to be deficient for a telomere. The comparison of the effects of neutrons and high LET particles with X-ray and chemicals is being made to determine their effect on the induction of chromosom damage, mutation and telomore loss in the mutants. (CONTACT PERSON: Dr. J. Mason)

*Molecular Mechanisms of Recombination and DNA Repair in Yeast*—Meiosis is a fundamental developmental stage which occurs in nearly all eukaryotes. Although there is considerable information on the genetic and morphological changes that take place, relatively little is known about DNA metabolic events, DNA repair, or mechanisms of mutation. The purpose of this research is threefold: (1) To better understand the genetic events of meiosis at the molecular and enzymological level; (2) to determine the role of DNA repair mechanisms in the process of meiosis and in dealing with external insults; and (3) to relate meiotic and mitotic recombination and DNA repair processes. Using the yeast Saccharomyces cerevisiae, we have examined the mitotically Using the yeast *Saccharomyces cerevisiae*, we have examined the mitotically defined excision, postreplication and double-strand break repair pathways in meiosis. There is only one excision-repair pathway available to cells undergoing meiosis; however, in its absence cells lacking this pathway can still tolerate a considerable amount of damage due to an ability to replicate past the damage. We have shown that the damage does not cause recombination; on the contrary it suppresses normal meiotic recombination several-fold implying that unexcised damage can have considerable genetic effects on meiotic cells. In the absence of DNA damage cells undergoing meiosis do not require the excision repair pathway' however, the mitotically defined DNA double-strand break repair pathway is essential at the beginning of meiosis. In mutants lacking the *RAD52* gene product, cells begin to die as they enter meiosis. The enzyme involved is an alkaline deoxyribonuclease and based on physical studies of meiotic DNA, it processes intermediates in molecular recombination.

Studies are underway to characterize the *RAD52* controlled gene products and understand their role in normal meiotic recombination and damage-induced recombination. Recent work has demonstrated that recombinational events associated with DNA double-strand breaks occur in a directed fashion. Further molecular characterizations will be accomplished using various recombinant DNA techniques, immuno-precipitation procedures, 2-D protein gel analysis and mathematical modeling approaches.

Some of the repair processes described above may also be relevant to mutation induction. We are examining the nature of mutagenic events at the molecular level. Replication by yeast crude extracts on DNA templates which have been damaged by various agents is being examined to determine factors which may allow synthesis past damage. During the course of these studies, it should be possible to determine the coding nature of damaged DNA. (CONTACT PERSON: Dr. M. A. Resnick)

*Molecular Analysis of Genotoxic/Carcinogenic Events in Mammalian Cells*—The mechanism of chemically or physically-induced genetic toxicity/carcinogenesis by gene rearrangement and/or structural alternations and how these events relate to normal cell differentiation processes is of considerable importance in contemporary biomedical research. The ability to detect such events in a sensitive and precise manner, and the ability to identify chemical and physical agents with the potential to cause such effects, are fundamental goals of the Cellular and Genetic Toxicology Branch. This project is aimed at providing basic information concerning such processes and providing data on which reliable assay systems can be based.

The goal of this project is to analyze, by recombinant DNA techniques, sequence transpositions and alternations in gene structure and expression which result from chemical and physical toxic/carcinogenic agents. Molecular clones of the "transposon-like" endogenous ecotropic viral genomes of BALB/c and RFM/Un mice have been constructed and characterized. Subgenomic regions have been subcloned to provide molecular probes to specifically detect the ecotropic provirus and any long terminal repeat (LTR) containing genetic regulatory elements. Detailed analysis of a large population of cloned genomes of the BALB/c endogenous retrovirus has revealed a significant variability in the U3 region of the LTR. These findings are intriguing due to the important multi-functional role of this region, including "transposon-like" integration and regulation of gene transcription. Ongoing and future studies involve the molecular cloning of the reintegrated or transposed proviral genomes when identified in cultured and primary radiation-induced myeloid leukemia cells. Analysis of alterations in gene expression due to the relocation of these elements will be performed using cloned DNA probes from adjacent cellular regions.

The long-range goal of this project is to clarify the role which chemical and physical environmental agents have in initiating the transposition or structural alteration of genes and regulatory elements and how these events result in genetic toxicity. An immediate goal is to identify and characterize transpositions of genetic elements which may be causually related to radiation-induced myeloid leukemia. The initial model will be based on the "transposon-like" endogenous provirus of RFM/Un mice.

Recombinant DNA techniques will be used to generate molecular probes from endogenous retroviral genomes. Primary (germ line provirus) and secondary (transpositions and reintegrations) loci will be molecularly cloned from normal cells and radiation-induced myeloid leukemia cells. Restriction endonuclease mapping, nucleic acid sequencing and characterization of specific RNA transcript will be employed.

*FY 1983 Program Plans*

Recombinant DNA clones of the endogenous ecotropic viral genomes of BALB/c and RFM/Un mice have been constructed and characterized. Subgenomic regions have been subcloned to provide molecular probes to specifically detect the ecotropic *env* gene and the viral LTR. Detailed mapping of the LTR region of a population of clones has revealed that a particular segment of the "U3" component of the LTR appears to be a 'hyper variable' region. The LTR is known to be involved in "transposon-like" integration and regulation of viral gene transcription and promotion of transcription of adjacent cellular genes. Continued work is to be aimed at the mechanism of generating this diversity and its biological significance. Ongoing and future studies will focus on the molecular cloning of the primary and secondary loci and characterization of gene expression patterns in adjacent regions in normal and neoplastic cells. (CONTACT PERSON: Dr. L. R. Boone)

*In Vitro Systems to Study Organ and Species Specificities of Chemical Carcinogens*—*In vitro* approaches for studying organ, species, strain and cell-type variations in the metabolic activation of chemical carcinogens have been developed (Carcinogenesis, *2*, 851, 1981; *Banbury Report*, in press; Nature *276*, 277, 1978). Rat, mouse, hamster, bovine and canine species have been most widely used with liver, lung and urinary bladder being the primary organs studied (Carcinogenesis, *2*, 851, 1981; *Envir. Health Perspect.*, in press). Both intact cells and cell homogenates from each tissue are used for metabolic activation as these systems can differ from each other and from *in vivo* activation of the carcinogen (*Environ. Health Perspect.*, in press). Two metabolic activation systems have been coupled with the two target cell systems, Chinese hamster V-79 and *Salmonella typhimurium*, to measure multiple endpoints including cytotoxicity, sister chromatid exchange (SCE) induction and mutation. Measurement of multiple genetic endpoints has proven to provide better predictability of a chemical's genotoxic activity than measurement of any single endpoint (*Mutat. Res.*, in press).

The methodologies for measuring Chinese hamster V-79 cell mutagenesis have been previously reported (PNAS, *75*, 2864, 1978); ouabain and/or 6-thioguanine will be used as the selective agents. *Salmonella* mutagenesis will be measured as described by Ames (*Mutat. Res.*, *31*, 347, 1975), with the modification where intact cells are used for metabolism (*Environ. Health Perspect.*, in press). This project was initiated in FY 1982, and the results to date indicate the following: (1) Intact liver and bladder cells can be used for carcinogen activation with V-79 cells or *Salmonella* as targets: (2) bladder epithelial cells from cows and rats are metabolically

active and can activate hydrocarbons, aromatic amines, and nitrosamines to mutagens: (3) species differences in the metabolic activity of bladder cells appear to exist with preliminary studies indicating cow>rat>dog; (4) for the aromatic amines, *Salmonella* mutagenesis is a more sensitive endpoint while for nitrosamines, V-79 mutagenesis is more sensitive; and (5) the extent of mutagenic activity observed when S-9 or intact cells (from liver or bladder) are used for metabolic activation depends on the chemical and no general pattern has yet emerged.

*FT 1983 Program Plans*

This project is directed specifically at investigating the role of the liver and bladder in the initation of bladder tumors in various species including humans. Know bladder-specific carcinogens will be studied. Bladder cells and cell homogenates, and liver cells and cell homogenates will be used for metabolic activation with V-79 cells and *Salmonella* as the targets for detecting the production of mutagenic intermediates. Furthermore, by employing both intact cells and cell homogenates for metabolic activation, these two most commonly used metabolic activation systems will be compared.

The studies will provide basic information on the mechanism of initiation of bladder cancer in various species. From such studies, a short-term screening system for detecting bladder carcinogens should emerge. Additionally, by comparing the two most commonly used metabolic activation system, their relative merits can be assessed and hopefully better *in vitro* activation systems can be devised. (CONTACT PERSON: Dr. R. Langenbach)

*NCTR Heritable Translocation Assay Program*

The initial objectives of the NCTR/NTP Heritable Translocation Assay (HTA) Program have been: (1) To identify components of the test procedure which may be modified to improve test precision and reliability, and then make and evaluate appropriate modifications; and (2) to develop an in-house capability for performing HTA studies which can provide quality data for use in regulatory evaluation of mutagens, specifically those of interest to the National Toxicology Program (NTP). An HTA test capability has now been achieved at the NCTR which can contribute not only to the testing and evaluating of compounds of interest to NTP but also to answering questions related to the extrapolation of animal model data to humans and the identification of significant human health risks.

*Experimental Design:* Two projects have been implemented: (1) "Selection of stocks of mice for use in HTA studies at the NCTR" (E-243); and (2) "Validation of the NCTR HTA test procedure" (E-244).

The first project (E-243) consists of two phases. The first phase, which was completed in FY 1980, involved comparative evaluation of the breeding performance of six stocks of mice identified by a literature review as potentially appropriate for use in HTA studies. These six stocks are:

0D—CD-1 random bred
0F—(AE×BALB/c) $F_1$ hybrid
0G—(SEC×C57BL/10) $F_1$ hybrid
0H—(A *×SEC) $F_1$ hybrid
0N—(C57BL/6N×C3H) $F_1$ hybrid
0R—(C57BL/6J×BALB/c) $F_1$ hybrid

The specific aim of this study was to determine the theoretical misclassification error rate associated with the potential use of any of the above six stocks as "tester" females in a sequential fertility test protocol (Generoso, *et al, Chemical Mutagens*, Vol. 5, 1978). The variability of litter size for "tester" females used in fertility test protocols has been shown to have a significant effect upon the misclassification error rate and, consequently, the overall test error rate. In general, the greater the standard deviation from the mean, the greater the misclassification error, (Bishop and Kodell, *TCM*, Vol. 1, 1980).

Fifty single pair matings of females from each of these stocks with CD-1 males were established for a 10-month mating period and all litters recorded upon birth. The mean and standard deviation of litters 2-4 produced by each female stock were calculated and used in published equations (Bishop and Kodell, *TCM*, Vol. 1, 1980) to determine the theoretical false negative misclassification error (b-error) using our protocol strategy where false positive misclassification errors (a-errors) are controlled below one-half percent by appropriate selection of the "decision value" (Weimann and Lang, *Mutat. Res.*, 1978).

The second phase of this project, where five experiments have been conducted to date, involves comparison of response of the different stocks in Dominant Lethal Tests (DLT). The specific aims of this study were to determine whether the frequency of fetal death induced by selected chemicals differs significantly with the stock of $F_o$ female and/or male used (Generoso, *et al, PNAS*, 1979) and whether (by comparison with HTA data collected in the second project) this difference correlates positively with HTA test results and thereby might be used in selecting $F_o$ stocks for maximizing (or moderating) test sensitivity.

Experiments one and two each consisted of treating 48 0D male mice with isopropylmethane sulfonate (IMS) or ethylmethane sulfonate (EMS), respectively, and mating each male for an appropriate post-treatment interval to three females from either the 0D, 0F, 0G, 0H, 0N or 0R stocks (8 males/24 females/stock). Experiments three, four and five each consisted of treating 16 0D, 16 0N and 16 0R males with IMS, EMS, or triethylene melamine (TEM), respectively, and mating each of them for an appropriate post-treatment interval to three females from either the 0N or 0R stocks (8 males/24 females/male-female stock combination). Concurrent control groups of equal size and design were run for each experiment. Mean fetal death rates were calculated for each stock combination and compared by an analysis of variance and a Duncan's multiple range test after "clustering" by the method of Whorton (*TCM, 1*, p. 353-360, 1981).

The second project (E-244) consists of two positive control HTA studies of basically identical design but using different chemical mutagens, TEM for the first study and cyclophosphamide for the second study. The first study was to have been completed by June 1982.

In each study 120 0D males are treated with the chemical and mated (3 females/male) to females from either the 0N or 0R stock. $F_1$ males are weaned and then 500 of them are randomly selected for testing by the "sequential fertility test" method (Generoso, *et al, Chemical Mutagens*, Vol. 5, 1978) using our specific decision strategy (Weimann and Lang, *Mutat. Res.*, 1978; Bishop and Kodell, *TCM*, Vol. 1, 1980) to identify probable translocation heterozygotes. Upon completion of the fertility test, all 500 males are screened by the "Cytogenetic Test Method," (Adler, *TCM*, Vol. 1, 1980) for multivalent meiotic chromosomes characteristic of translocation heterozygotes and/or by analysis of banded mitotic chromosomes prepared from stimulated peripheral blood cells (Barren, *et al, Nutat. Res.*, 104, 1982).

Comparison of the translocation frequency detected by our "sequential fertility test" methd with that confirmed by cytogenetic evaluation will be used for empirical determination of the misclassification error for our fertilty test procedure. In addition to validating an HTA test procedure which the NCTR can use in future evaluation of NTP compounds, findings from this project will allow us to identify and correct logistical problems which might be associated with handling such large populations of animals.

*FY 1982 Accomplishments*

*Selection of Stocks of Mice for Use in HTA Studies at the NCTR*—A final report and draft manuscript of the results of this experiment have been prepared and submitted for NCTR internal review. Theoretical misclassification errors were calculated for the six stocks of mice. Evaluation of the breeding data on the six stocks of mice resulted in identification of 0N as the preferred stock to use as "tester" female because of the relative minimal probability of $F_1$ male misclassification (0.0012). Additionally it was observed that the relative order of male stock sensitivity for EMS and TEM was similar. This is in agreement with the results of Generoso *et al, PNAS*, 1979.

*Validation of the NCTR HTA Test Procedure*—The positive control study with TEM was completed in June 1981. The results of this study are presented in Table 9. Of the 400 $F_1$ male progeny of untreated $F_1$ hybrid females mated to CD-1 males injected i.p. with 0.18 mg/kg TEM and screened for translocation heterozygotes (TH's) by both fertility and cytogenetic test methods, 97 were classified suspect TH. Of these, 27 were completely sterile and 54 were partially sterile with both tester stocks. For the (C57BL/6NxC3H) and (C57BL/6]xBALB/c) $F_1$ hybrid tester stocks, the frequency of cytogenetically normal males which were classified as suspect TH (i.e., false positives) was 0.033 and 0.025, respectively. The frequency of cytogenetically confirmed translocation carriers which were missed by the fertility test with (C57BL6NxC3H) and (C57BL/6]xBALB/c) $F_1$ hybrids (i.e., false

negatives) was 0.05 and 0.025, respectively. *Thus, a standardized protocol for a sequential fertility test method of the HTA with empirically determined misclassification error has been successfully developed for use in evaluation of NTP compounds at the NCTR.* The mathematical model proposed by Bishop and Kodell (*TCM*, Vol. 1, 1980) is being adjusted based upon the empirical results of this study. A final report and a manuscript describing the overall results of this study are in preparation and expected to be completed in FY 1982. (CONTACT PERSON: Dr. J. B. Bishop)

*FY 1983 Program Plans*

*Selection of Stocks for Use in HTA Studies at the NCTR*—All final reports and manuscripts for this experiment were completed in FY 1982. The manuscript will be submitted for publication in FY 1983. No additional dominant lethal studies are planned at this time.

*Validation of the NCTR HTA Test Procedure*—A final report and manuscript describing the results of this experiment will be completed in FY 1982. The manuscript will be submitted for publication in FY 1983. In addition, at least one additional manuscript, the statistical considerations for adjustment of the mathematical model of Bishop and Kodell, will be prepared in FY 1983.

An experimental protocol designed to assess potential immunodeficiencies in the $F_1$ animals is being prepared and will be submitted during FY 1982. If funded, this study will be implemented and completed in FY 1983.

In addition, a manuscript will be prepared in FY 1983 which outlines a proposed model for risk assessment with the HTA, reviews available animal model and human epidemiological data that can be used to estimate significant human health effects from translocations, and describes a procedure for incorporating this and future information of a similar nature into the model. (CONTACT PERSON: Dr. J. B. Bishop)

*Utilization of the Primary Hepatocyte/DNA Repair System to Detect Potential Genotoxicity of NTP Chemicals*

It is known that DNA is the target for various cytotoxic, mutagenic, and carcinogenic chemicals. It is thought that a majority of chemical carcinogens or their metabolites are electrophiles that react with cellular nucleophiles such as nucleic acids and proteins. One result of nucleic acid binding is DNA repair. This is accomplished by excision of the adduct and subsequent polymerization and ligation of the DNA strand. One method for detecting DNA repair is the use of autoradiographic techniques to measure labelled thymidine incorporation into DNA of mammalian cells outside of the normal phase of DNA synthesis (unscheduled DNA synthesis, UDS). A variety of cell systems have been developed to detect UDS, ranging from rodent to human cells in culture, and these systems have been advocated for inclusion into a battery of assays to assess hazardous chemicals. One such system is the primary hepatocyte/DNA repair system. This system is useful because the cells are non-proliferating and inhibition of scheduled DNA synthesis is not required. Further, the cells are capable of metabolically activating many precarcinogens and premutagens to their active forms allowing measurement of UDS in the same cells that activate the test chemicals.

The objective of this cooperative project with NIEHS/NTP is to test 24 coded NTP-selected chemicals in the primary hepatocyte/DNA repair system. The standard protocol uses primary hepatocytes isolated following *in situ* perfusion of rat livers with collagenase; the cells are plated in Willians' medium E and attached to coverslips for 1–2 hours. This attachment allows for selection of only viable cells. The coverslip cultures are incubated either in petri plates or Leighton tubes, depending upon the volatility of the test chemical. The hepatocytes are exposed for 18–24 hours at 37°C to a series of concentrations (dependent upon solubility) of the test chemical in Williams' medium E containing $^3$H-thymidine. After incubation, the test medium is removed and the cells are washed and fixed; the coverslips are dried and then attached to microscope slides. The slides are dipped in diluted NTB2 autoradiographic emulsion, dried and the emulsion is then exposed at 4°C in the dark for about one week. The cells are stained with Giemsa and the grains in the emulsion over the nuclei and cytoplasm are counted with an electronic counter.

An appropriate positive control agent (2-AAF or 7,12-DMBA) is used to monitor the metabolic state of the hepatocyte preparation. Additionally, the repair capacity is also monitored by using 200–300 erg/mm UV-irradiation. Depending upon the nature of the chemical being evaluated, the negative control is the solvent used to dissolve the chemical and if the solvent is organic, e.g., DMSO, ethanol, or acetone, the final concentration will not exceed one percent. Dosage selection for the UDS assay is based on the cytotoxic information obtained either from the NTP or based on preliminary cytotoxicity testing (e.g., dye exclusion, isotopically labelled leucine incorporation into protein, or morphological evaluations). A concentration which exhibits a cytotoxic response (or the highest soluble concentration, in the absence of cytotoxicity) is selected as the highest concentration for the UDS assay and the remaining four doses are selected over a 2-logarithm range.

The cells are examined microscopically and silver grains representing incorporation of $^3$H-TdR during UDS are observed and counted using oil immersion (100x) optics. The net nuclear grain count (nuclear grain counts—cytoplasmic grain counts) are determined for 50 randomly selected cells on each coverslip. The mean net nuclear grain count is determined from triplicate coverslips for each treatment condition. The test agent is considered positive if the results demonstrate a concentration-related, statistically significant increase in UDS over negatige control values and/or a reproducible, statistically significant increase in UDS at one concentration. A negative conclusion is reached in the absence of a positive response, as defined above, when the test compound has been tested to cytotoxic levels or to the limits of solubility.

*FY 1982 Accomplishments*

This project was begun December 31, 1981, and is scheduled to continue to December 31, 1982. Fourteen of the 24 chemicals have been delivered and solubility characteristics have been determined for 10 of these 14 chemicals. In addition, cells have been exposed to six of these chemicals in two separate experiments and have been carried to the nuclear grain counting phase. We are presently counting grains and developing the data on these six chemicals and exposing cells of the other four for which we have solubility data. We expected to complete all but data analysis for the 14 chemicals by the end of July 1982. (CONTACT PERSON: Dr. D. Casciano)

**NIOSH**

*Mutagenic Monitoring for High Risk Workers*

*Background Information and Objectives:* It is known that many chemical agents and mixtures are produced during coal gasification and liquefaction processes (DHS–NIOSH Publication No. 79–113). In the near future, coal gasification and liquefaction may become important energy industries owing to the Nation's attempt to alleviate natural gas and oil shortages. As these industries and plants proliferate, thousands of workers will be employed and, inadvertently, they may be exposed to the by-products associated with these operations. Any of these by-products which are mutagenic may represent a genetic hazard. To protect workers from any potential mutagenic hazard, mutagenic monitoring of plant personnel and the workplace environment are necessary. By monitoring, mutagenic agents may be detected early and identified. Awareness of this potential occupation-related hazard and adoption of proper procedures to safeguard workers from exposure to this class of industrial by-products would benefit directly the health of workers and/or their offspring. The information obtained could also be used in the future to determine whether there is any relationship between the results of mutagenic monitoring and epidemiological findings.

The objectives of this project are to determine whether: (1) The mutagenic activity of air particles form coal liquefaction plants are higher than the activity of particles from the outside environment; (2) mutagenic activities, if any, of urine samples collected from plant workers are higher than those collected from a control population; (3) the frequencies of sister chromatid exchanges (SCE's) and chromosome aberrations (CA's) in peripheral lymphocytes of workers are higher than those of the control group; and (4) there is any relationship among the objectives (1), (2), and (3).

*Experimental Design:* Two coal liquefaction pilot plants, if possible, will be used for ths study. Air particles from both plants will be collected with high volume samplers by pulling air through glass fiber filters. Solvent extracted organic materials will be tested for mutagenic activity with the *Salmonella*/microsome pre-incubation test and for induction of SCE with the cultured Chinese hamster ovary (CHO) cells assay system. Thirty workers who have been working in the plant for at least one month

and 30 unexposed local individuals near each plant will be selected as a source of blood (10 ml per participants) and urine (400–600 ml) samples.

A questionnaire will be administered to all participants. This questionnaire will be used to elicit the information necessary for matching the control group to the worker group and to properly assess the results of the bioassays.

The collected blood samples will be analyzed for the frequencies of SCE's and CA's. Appropriate numbers of cells will be scored to determined statistically significant increases in SCE and CA frequencies. Urine samples will be concentrated with an XAD–2 column. The solvent eluted concentrates will be tested for mutagenic activity with the *Salmonella*/microsome assay system. All experiments will be repeated one month after concluding the first experiment. A third experiment will be conducted if the results of the first and second experiments are not in qualitative agreement.

*FY 1982 Accomplishments*

The project protocol developed by the contractor, Litton Bionetics, has been reviewed by outside experts and approved by the NIOSH Human Subject Review Board. The approved protocol is now ready for submission to coal liquefaction plan officials to seek entry permission for the studies.

*FY 1983 Program Plan*

Sampling of air particles and collection of biological specimens will be completed if entry permission can be obtain before the first quarter of FY 1983. Mutagenic and cytogenic analyses of the collected specimens will be initiated in FY 1983. (CONTACT PERSON: Dr. T. Ong)

All chemicals known to induce cancer in humans cause cancer in laboratory animals with the possible exception of arsenic. Thus, reducing exposure to chemicals known or suspected to cause cancer in humans or animals will reduce chemically-induced cancer in humans. This public health stance of preventive oncology stands as one of the primary goals of the NTP: identify with certainty in well-conducted experiments those chemicals most likely to be hazardous to humans. From a preventive health view, the NTP underscores the concept that chemicals found to cause cancer in animals must be considered capable of causing cancer in humans.

The NTP strives to accomplish this by evaluating those large volume chemicals known to have a high index of human exposure. This scientific appraisal process comprises an integrated toxicological characterization approach: chemical disposition (absorption, distribution, metabolism, excretion), genetic toxicology, fertility and reproductive assessment, systemic toxicology (14-day and 90-120 day exposures), specific studies as needed (immunological, biochemical, and inhalation toxicology), clinical pathology where applicable (hematology, urinalysis, endocrine function, and clinical chemistry), and long-term (two-year) carcinogenesis bioassays.

The "standard" two-year carcinogenesis bioassay remains as the most definitive method for detecting chemical carcinogens in animals. The standard protocol as developed by the NCI typically uses two rodent species (usually Fischer 344 rats and B6C3F$_1$ mice), both sexes, and administration of multiple dose levels (concurrent controls, low dose, and high dose) of a chemical to groups of 50 animals, beginning at weaning and ending after two years. These experiments are designed primarily to determine whether selected chemicals produce cancer in animals.

Chemicals tested in the NTP carcinogenesis bioassay program are chosen primarily on the basis of human exposure, available (or lack of) toxicology data, level of production, and chemical structure. Selection per se is not an indicator of a chemical's carcinogenic potential.

Negative results, in which the test animals do not have a greater incidence of cancer than control animals, do not mean necessarily that a test chemical is not a carcinogen, inasmuch as the experiments are conducted under a limited set of conditions. Positive results demonstrate that a test chemical is carcinogenic for animals under the conditions of the test and indicate that exposure to the chemical is a potential hazard to humans. The determination of the risk to humans from chemicals found to be carcinogenic in animals often requires a wider analysis which at present extends beyond the purview of these studies.

The results of the bioassay also serve as the reference base for the validation of short-term carcinogenesis assays. Two additional objectives have been identified as priority items: (1) To expand the bioassay experimental protocols to extend and better characterize the toxicologic profile of chemicals; and (2) to investigate, develop, and validate accurate, less costly, and more rapid methods for detecting carinogenic potential.

Under the NTP, the carcinogenesis bioassay procedure(s) has been and continues to be changed to meet the objective of a broadened toxicologic characterization of chemicals, and further, to lead or stay abreast of advancing scientific developments. Prior to NTP involvement, the prechronic phases of the bioassay—which include single dose (acute), 14-day repreated dose, and 90- to 120-day repeated dose studies—were conducted to determine gross toxicity and general target organ effects at different dose levels as a primary basis for setting appropriate doses for the two-year bioassay studies. Now, the NTP has begun to gather routinely other information related to target organ effects: chemical disposition, fertility and reproduction, urinalysis, clinical chemistry, and hematology also are obtained from the prechronic studies—especially the 90-day study; certain other specific studies as applicable are included in the chronic two-year studies as well. Once those parameters that may be altered through exposure to the tested chemicals are identified, then suspect chemicals are referred to specific organ system groups for more detailed study of the functional, biochemical, and morphologic effects of the test compounds. Also, wider analysis of the quantitative and comparative absorption, distribution, metabolism, and excretion patterns may be desired. All chemicals selected for chronic bioassay will be profiled for chemical disposition patterns. Further, a group of five *in vitro* short-term cellular and genetic toxicology assays were added to the prechronic phases in FY 1982. All chemicals started on test in FY 1981 and FY 1982 had an expanded design including other select studies. The goal is to ensure that all major toxic effects will be identified for each chemical being considered for long-term bioassays.

These data, together with other prechronic bioassay information, are used by the experimental design groups for preparing appropriate study protocols and are used by staff for assisting in establishing priorities for chemicals queued into the long-term carcinogenesis bioassay. A key decision that must be made at this juncture between the completion of the prechronic phase and the beginning of the chronic study centers directly on whether indeed the lifetime bioassay should be done at all.

With this composite information base, the doses for the chronic study are selected. The high dose, termed the estimated maximum tolerated dose (EMTD), represents the highest dose of a chemical or substance given during a chronic study that can be predicted not to alter the treated animals' normal longevity from toxic effects other than carcinogenicity. The low dose ordinarily equals one-half EMTD. Other empirical factors include weight gain/food consumption data; for instance, a decrease in weight gain near 10–20% (not associated with a tumorigenic response) is often used as a general indication that the EMTD was achieved.

Thus, while the lifetime animal bioassay remains the best procedure for determining the carcinogenic potential of chemicals, NTP does not ordinarily use a standardized design. Rather the design is adapted to the special testing needs identified for the particular chemical. The NTP tailors its testing protocol to each chemical, based on the results from the prechronic testing phases, on available literature, and on structure-activity relationships. These new protocols permit better, more specific information to be generated for the tested compounds, which increases the effectiveness of the tests for potential human risk estimations. Such protocols also will be useful as guidelines for testing undertaken by other agencies and by industry. As examples, the NTP continues to pursue actively other design methodologies—increase the number of dose levels, "unbalanced" distribution of animals among dose groups, interim kills, modified protocols for histopathology, and so on.

While the majority of NIP Long-term bioassays are being managed and conducted by the NIEHS component of the Program, a number are being carried out by the NCTR component and are described in subsequent pages of this section.

Long-term studies by the NIOSH component specifically emphasize study of the etiology of cancer in the occupational environment. A number of long-term carcinogenesis bioassays are in progress on materials ranging from single chemicals to

mixtures administered by various routes analogous to likely routes of human exposure in the workplace.

**NIEHS**

*FY 1982 Accomplishments*

*Testing—Prechronic and Two-Year Bioassays*

During FY 1982, 21 bioassays were completed and the reports of the findings were approved by the *ad hoc* scientific peer review panel associated with the NTP Board of Scientific Counselors (Table 10). Under the conditions of these carcinogenesis bioassays, 12 (57%) were considered positive, 7 (33%) negative, and 2 (10%) equivocal. Since the NIP has become actively involved in the bioassay technical report review process, 59 experimental studies initiated by the NCI or the NTP have been completed and peer reviewed (with final reports issued or in press). Of these, 32 (54%) were positive, 22 (37%) were negative, and 5 (9%) were equivocal for carcinogenicity. Single copies of the NTP Technical Reports are available or will be available (for those in press from the NTP Public Information Office, (P.O.) Box 12233, Research Triangle Park, NC 27709.

There were 27 new chemical starts in the prechronic phases of the bioassay process in FY 1982, and a total of 45 bioassays in the prechronic phases at the end of the fiscal year (Table 11). There were 172 bioassays in the chronic testing phase at the end of the fiscal year (Table 12). This includes bioassays in the histopathology/diagnosis phase.

Since FY 1980, all new bioassays have been under direct NTP management while testing activities initiated prior to FY 1980 continued to proceed through the prime contract mechanism. Direct management and supervision of each chemical test was initiated to enable better monitoring and quality control of the testing program, especially with the inclusion of the various special studies. The process is described in the Chemical and Laboratory Test Management section. In conjunction with NTP initiation of direct arrangements with testing laboratories, a number of scientific support contracts awarded in FY 1980 continued in FY 1981 and FY 1982. These include pathology support, health and safety activities, chemical repositories, chemical analytical services, animal production and literature support.

A gradual phase out of the prime contract began in FY 1982 and is scheduled to be completed in the third quarter of FY 1983. Management of the bioassay subcontractors and support functions now carried out by the prime contractor will be assumed directly by the NTP.

To do the expanded toxicological characterization studies included in bioassays started under the NTP, the NTP continues a contracting mechanism (a master agreement) under which laboratories and their personnel are qualified for standard bioassays and in each of the various special study areas. The pool of qualified laboratories currently stands at 19. (CONTACT PERSON: Dr. M. Vernon)

*Other Long-Term Studies*—Standard two-year bioassays with six-week-old animals were initiated in FY 1982 concurrently with two bioassays where exposure began *in utero* and continued during the neonatal period. The chemicals being tested are phenytoin and ethylene thiourea; a third bioassay with polybrominated biphenyl mixture (Firemaster FF1) will be initiated in FY 1983. The objective is to determine whether extending long-term chemical exposure of animals to the gestational and neonatal periods will result in altered sensitivity to the induction of carcinogenesis and/or other types of toxic effects. (CONTACT PERSON: Dr. R. Chhabra)

*Test Methods Development and Validation*

*Prechronic Testing Phase*—Starting in FY 1982, during the prechronic phase, all chemicals undergo cellular and genetic toxicology testing in at least five *in vitro* short-term assays: (1) Gene mutations in bacteria—*Salmonella typhimurium*/microsome; (2) gene mutations in mammalian cells—mouse lymphoma (L5178Y, thymidine kinase); (3) chromosome damage in mammalian cells—cytogenetic damage and sister chromatid exchange in Chinese hamster ovary (CHO) cells; (4) a mammalian cell transformation assay—(BALB/c-3T3); and (5) a direct measure of DNA damage/repair (which does not necessarily result in mutation or transformation)—unscheduled DNA synthesis (rat hepatocytes). (CONTACT PERSON: Dr. J. W. Spalding)

*Animal Bioassay Methodology*—The NTP in March 1982 presented to the Board of Scientific Counselors a series of biomathematical simulations aimed at improving the basic experimental design of the two-year bioassay to provide information useful for low-dose extrapolation while retaining the power of the bioassay for detecting carcinogenic effects. Three and four-dose designs were examined. The optimal design involved four groups (control plus low, medium, and high dose). The estimated maximum tolerated dose (EMTD) would be the high dose, the middle dose one-half the EMTD, and the low dose 10-30% of the EMTD. The most appropriate designs are being considered for possible future implementation for long-term carcinogenicity bioassays, and are also discussed in the Data Management and Analysis section. (CONTACT PERSON: Dr. C. Portier)

Two studies planned for initiation in FY 1982, one focusing on the possible influence of the Sendai virus on chemically-induced carcinogenesis in mice, and the other aimed at evaluating strains other than the B6C3F1 mouse for carcinogenesis is bioassays, were deferred due to resource limitations.

*Short-Term Carcinogenesis Assays*—In-Life portions of the pulmonary tumor studies in Strain A mice at Oak Ridge National Laboratories will be completed by the end of FY 1982

A three-year research program using short term *in vivo* liver carcinogenesis models to help clarify the nature of the hepatocarcinogenic responses frequently associated with two-year rodent bioassays began at the end of FY 1982. A major objective of this program is to assess the ability of selected chemicals to act as initiators, promotes, or complete carcinogens in these models. Initial emphasis is to be directed toward aspects of model development including assessment of chemical dosimetry. The research will include attempts to quantitatively assess response through the use of preneoplastic markers and correlate these results with histomorphologic tumor endpoints. Initial selection of chemicals will focus on those known to induce liver tumors in rodents, taking into account their genetic toxicity. Current program plans estimate 24–36 chemicals will be tested in *in vivo* liver tumor models. (CONTACT PERSON: Dr. R. Maronpot)

*FY 1983 Program Plans*

*Testing—Prechronic and Two-Year Bioassays*

During FY 1983, the NTP plans to start 16 chemicals in the prechronic phase of the bioassay process (Table 13). It is expected that 26 two-year bioassays will be completed and the resultant draft reports will be peer reviewed in FY 1983 (Table 14). All new bioassays will include broadened protocols with various special studies integrated into the experimental design. (CONTACT PERSON: Dr. J. Douglas)

*Test Methods Development and Validation*

*Short-Term Carcinogenesis Assays*—Final summarization and evaluation of the data from the pulmonary tumor studies in Strain A mice will be completed in FY 1983. These results should help to determine the feasibility of using this short-term assay in carcinogenicity testing of chemicals. (CONTACT PERSON: Dr. R. Maronpot)

**NCTR**

*FY 1982 Accomplishments and FY 1983 Program Plans*

*Testing—Prechronic and Long-Term Bioassays*

*Rotenone*—Femal Wistar rats were used in an experiment entitled "Tumorigenic Potential of Rotenone and its Specificity for Mammary Tissue", at doses of 2.5 and 25 μM/Kg with 72 animals in each dosed and control group. The 25 μM/Kg doses proved toxic so groups at 5.0 μM/Kg were added. Animals were injected 5 days a week for a period of 8 weeks and monitored for an additional 15 months. The animals were then sacrificed.

Evaluation of gross necropsy data and microscopic pathology data revealed no dosed related lesions, either grossly or microscopically. A final report and manuscript are in preparation. (CONTACT PERSON: Dr. W. Allaben)

*Gentian Violet and Sulfamethazine*—Gentian violet and sulfamethazine are NTP selected compounds and are being evaluated as comprehensive bioassessment studies. The toxicological investigations are intended to examine the FDA's proposed Sensitivity of Method (SOM) requirements and established tolerances for use as an additive in chicken and swine feed with regard to their subsequent potential toxicity as residues in chickens and pork used for human consumption. Because of this, the

investigation of each chemical includes several phases.

The gentian violet study status is as follows: The 90-days MTD (rat and mouse) subchronic study final report is in progress. Metabolism studies, some under contract, will be completed in FY 1982. The dosing of the mice lifespan was completed in July, 1982. The rat multigeneration study is scheduled for completion in July, 1983.

The sulfamethazine study status is as follows: The 90-day MTD (rat and mouse) final report is in progress. Metabolism studies, some under contract, will be completed in FY 1983. A restarted mouse lifespan study is scheduled to be completed in July, 1984. A restarted rat multigeneration study will be completed in December, 1984. (CONTACT PERSON: Dr. N. Littlefield)

*Antihistamines*—Bioassays of the antihistamines were initiated following compound identity, and purity tests and stability trials. At present all data from the subchronic phase are being reviewed and final reports are being prepared. Details of the studies are as follows:

*Pyrilamine*

*14-Day Repeated Dose Study:* Dose levels used were: Mice—3200, 1600, 800, 400 and 200 ppm (free amine); Rats—6400, 3200, 1600, 800 and 400 ppm (free amine). Pyrilamine maleate was 99.9% pure and found to be sufficiently stable in rodent feed to use feed as the vehicle of administration. All animals gained weight during the experiment with a trend for less gain in the higher two doses in both rats and mice. There were no clinical observations noted that were considered dose related.

Gross pathology of sacrificed rats and mice showed no remarkable lesions for mice and rats. Microscopic pathology revealed no significant findings for mice. In rats there were mild fatty metamorphoses of the liver and mild lymphoid accumulations in the lung distributed equally in control and high dose animals.

*90-Day Subchronic Study:* Dose levels were: Mice—6000, 3000, 1500, 750 and 375 ppm; Rats—12,000, 6000, 3000, 1500, 750 ppm. The only clinical observations that occurred regulary were hair loss and hunched and skinny appearance occurring only in the 12,000 ppm dose group in rats. There was a general dose related decrease in weight gain throughout the study with much greater effects at the high dose in both rats (12,000 ppm) and mice (6000 ppm). Statistical analyses have not been performed as yet.

Gross pathologic evaluation of rats and mice showed no unusual dose related lesions. Histopathologic evaluation of all tissues has been completed and a final report is in progress. (CONTACT PERSON: Dr. W. Allaben)

*Doxylamine*

*14-Day Repeated Dose Study: Dose levels were: Rats and Mice—2000, 1000, 500, 250, 100 ppm (free amine). Only the highest dose level had any effect on weight gain in either species. Gross pathology of sacrificed animals showed no remarkable lesions.*

*90-Day Subchronic Study:* Dose levels were: Mice—1500, 750, 325, 162 and 80 ppm; Rats—6325, 2530, 1012, 405 and 162 ppm. The subchronic study has been completed and the data are presently being verified and analyzed for preparation of the final report.

*Tripelennamine*

*14-Day Repeated Dose Study:* Dose levels used were: Rats and Mice—6000, 2400, 1200, 600, 300, 150 ppm (free amine). Tripelennamine was found to be sufficiently stable in rodent feed to use feed as the vehicle of administration. Gross pathology of sacrificed rats and mice showed no remarkable lesions.

*90-Day Subchronic Study:* Dose levels were set at: Rats—150, 300, 600, 1200, 2400 ppm; Mice—300, 600, 1200, 2400 and 4800 ppm. A dose response relationship between dose and reduction in weight gain was observed in male and female rats. Less toxicity was observed in mice. Pathology data are presently being evaluated for preparation of a final report. (CONTACT PERSON: Dr. C. D. Jackson)

*Thenyldiamine*

*14-Day Repeated Dose Study:* Dose levels used were: Rats and Mice—4000, 2000, 1000, 500, 250 ppm (free amine). A dose dependent decrease in weight gain was observed in rats of both sexes. Gross pathology of sacrificed rats and mice showed no remarkable lesions.

*90-Day Subchronic Study:* Dose levels were: Rats—125, 250, 500, 1000 and 2000 ppm; Mice—250, 500, 1000, 2000, 4000 ppm. Analysis of generated data collected during the study are being analyzed for final report. (CONTACT PERSON: Mr. G. Cronin)

*Methapyrilene (Neutral)*

*14-Day Repeated Dose Study:* Dose levels were: Mice—2000, 4000, 8000, 16000, 24000 ppm (free amine); Rats—400, 800, 1200, 1600, 2000 ppm (free amine). In mice a linear dose-response was observed with 2000 ppm producing a 4% reduction in weight gain and 16000 ppm reducing weight gain by 40% in both males and females. Pathology data are being analyzed at present.

*90-Day Subchronic Study:* Dose levels were: Mice—500, 1000, 2000 and 8000 ppm; Rats—100, 200, 400, 800, 1200 ppm. All experimental data are presently being analyzed in preparation of the final report. (CONTACT PERSON: Dr. C. D. Jackson)

*Methapyrilene (Acid)*

*14-Day Repeated Dose Study:* Dose levels were: Mice—1000, 2000, 4000, 8000, 16000 ppm (free amine); Rats—200, 400, 600, 800 and 1000 ppm (free amine). The drinking water was acidified with HC1 to pH 2.0. All experimental data presently are being analyzed in the preparation of a final report. (CONTACT PERSON: Dr. C. D. Jackson)

*Caffeine—Acute Toxicity Studies*—At each of five (5) dose levels, six (6) animals per sex per species were given a single dose of caffeine in (a) aqueous sodium ($Na^+$) benzoate solutions or (b) trioctanoin suspensions. The doses used were: Rats (mg/kg)—50, 100, 200, 400, 800; Mice (mg/kg)—125, 250, 500, 750, 1500. The animals were held for observation for 14 days after dosing. Twice daily checks were performed for observations. Water and feed were given *ad libitum.*

All amimals dosed with caffeine/$Na^+$ benzoate that died did so within 24 hours of dosing. The $LD_{50}$ was calculated to be 400 mg/kg for female and male rats and 180 mg/kg for female and male mice. All animals dosed with caffeine/trioctanoin suspension that died did so within 24 hours after receiving the caffeine dose. The $LD_{50}$ was calculated to be 400 mg/kg for female and male rats and 370 mg/kg for female and male mice.

*14-Day Repeated Dose Study*—Six animals per sex per species at each of five (5) dose levels were given doeses of caffeine continuously in water for 14 days. Control animals received water only. Dose levels were: Rats (ppm)—0, 100, 200, 400, 800, 1600; Mice (ppm)—0, 50, 100, 200, 400, 800.

*90-Day Subchronic Study*—Data from acute and 14-day continuous feeding studies were used to establish dose levels for the subchronic study as follows: Rats (ppm) 0, 188, 374, 750, 1500, 3000; Mice (ppm) 0, 94, 188, 375, 750, 1500. The rats went on dose on October 13, 1981 and the mice one week later. The animals were fed Purina 5010M meal throughout the study; caffeine was administered via the drinking water. Both food and water consumption were measured. A final report is being prepared. (CONTACT PERSON: Dr. W. Allaben)

*Test Methods Development and Validation*

After extensive feasibility studies 1,8-Cineole and cinnamaldehyde were microencapsulated. This cost-saving method allows administration of volatile or unstable chemicals to test animals by the oral route. Animals were on repeated studies during the summer of 1982. (CONTACT PERSON: Dr. H. Schumacher)

The following Table 15 provides information about the testing schedule of different NTP compounds under test at NCTR.

**NIOSH**

*Testing—Long-Term Studies With Emphasis on Occupational Carcinogenesis*

The following NTP programs and projects emphasize the study of the etiology of cancer in the occupational environment and include: (1) The assessment of the carcinogenic potential of complex mixtures encountered by workers; (2) modification of carcinogenesis by known and potential promoters and cocarcinogens such as dusts, irritants, heat, and sunlight that may be part of the work environment; and (3) other factors which influence the carcinogenicity of workplace chemicals such as work practices, medications, and personal habits. This combination of applied and basic research is intended to identify needs for epidemiological studies and to elucidate the etiology of the carcinogenic process in various workplace environments.

*FY 1982 Accomplishments*

A number of long-term carcinogenesis studies, not formally part of the bioassay program, were initiated, completed, or in progress during FY 1982. Studied were materials ranging from single chemicals to mixtures administered by various routes

analogous to likely routes of human exposure in the workplace. Studies included: (1) Synthetic machine oils, (2) pyrolysis effluents from different foundry mold binders, (3) various substitutes for silica sand in foundry molds, (4) interaction of either ethanol or disulfiram with 1,2-dichloroethane, (5) fibrogenicity and pulmonary carcinogenesis, (6) individual chemicals—ethylene oxide, propylene oxide, N,N'-dimethylformamide, (7) mixtures—diesel exhaust, coal dust, fibrous glass, short asbestos fibers, a new postal ink formulation, and two azo dyes (Acid Black 52 and Disperse Yellow 3), and (8) asphalt and coal tar fumes and their interaction with simulated sunlight. (CONTACT PERSON: Dr. B. Johnson)

*Inhalation or Intratracheal Studies*—The chronic toxicities of ethylene oxide (ETO) and propylene oxide (PO) were evaluated in a two-year inhalation study (7 hours/day, 5 days/week). Eighty male weanling Fischer 344 rats and 12 adult male Cynomolgus monkeys were exposed at 0, 50 and 100 ppm ETO and 100 and 300 ppm PO. The purpose of the rat exposures was to conduct a rodent bioassay while the monkeys were utilized to evaluate effects of these epoxides on major organ systems. Preliminary findings in rats exposed to ETO indicated dose-response effects for decreased body weight gain and survival. The frequency of chromosomal aberrations and prevalence of sister chromatid exchanges in peripheral lymphocytes exhibited dose-response increases in monkeys exposed to ETO. PO decreased weight gain in rats in a dose-response relationship; however, no clastogenic responses to PO were observed. Other results, including histopathology and sperm analyses, are still being analyzed.

An inhalation study is being performed under contract with Litton-Bionetics to determine the long-term biological effects of dimethylformamide (DMF) in rats and mice. A 90-calendar-day study to determine the maximum tolerated dose of DMF for rats and mice was completed in FY 1982. The results of this pilot inhalation study enabled the initiation of a chronic study at 500 ppm and 250 ppm concentrations with the same animal species. Rats and mice will be exposed to DMF for 24 months and allowed to live for an additional six months or until there is 75% mortality in the low dose or control group, whichever comes first. Animals will be exposed to DMF for 6 hours/day, 5 days/week. The animals will be observed for hepatotoxicity, gastrointestinal disorders and development of neoplasms. The metabolic profiles of DMF will be monitored using blood. These indices may result in markers that may be used in mass diagnostic screens for appropriate industrial workers and should provide data applicable to the evaluation of DMF as an agent identified with worker health effects. Occupational lung disease, cancer and neurotoxic illness are of primary concern. Workers overexposed to DMF have exhibited a myriad of symptoms— cyanosis, confusions, dizziness and gastrointestinal disorder leading to colicky pain. DMF has also been incriminated in causing liver and pancreatic damage in humans. Kommineni in 1973 reported that intraperitoneal injections of DMF induced epithelial and nonepithelial neoplasms of the gastrointestinal tract in rats. The observation is of major interest in relation to the supposed conversion of colonic adenomatous polyps to carcinomas in humans.

A study was completed in FY 1982 whose purpose was to determine the type and extent of pulmonary fibrosis induced experimentally in hamsters by intractracheal instillations of quartz, fibrous glass, hydrated alumina, or a 1:1 mixture of quartz and ferric oxide. The objective was to determine a dose of each material which would induce a pronounced pulmonary fibrosis without compromising the life expectancy of the hamster. These and related data would then be used in a subsequent study to assess the role of particulate materials as potential pulmonary cocarcinogens. Four dose levels of each of the materials were administered in 15 weekly intratracheal instillations to groups of 25 hamsters beginning at 11 weeks of age. Survival and microscopic evidence of pulmonary fibrosis were determined and results compared to similar data from a group instilled with saline alone and a cage control group. Dose-related decreases in survival were evident for the groups instilled with the two highest doses of quartz or quartz and ferric oxide. A correlation between the incidence and severity of alveolar septal fibrosis and the dose of instilled material was evident in most groups, being strongest in those groups exposed to quartz or quartz and ferric oxide. These materials induced the most intense pulmonary fibrotic response. (CONTACT PERSON: Dr. T. Lewis)

A continuing study assessed the pulmonary and/or systemic effects in rats of three mineral slags, novaculite, and a plagioclase feldspar by intratracheal instillation. The mineral slag testing is a follow-up to previous NIOSH work with coal and copper slags (FY 1973 project VOT–8379). Six groups of Fischer 344 rats (85 per group) were injected with 20 mg of either a mineral slag (two copper, one nickel), novaculite, plagioclase feldspar, or Min-U-Sil (a positive fibrosis control). A seventh group received distilled water (vehicle control). During FY 1981 serial sacrifices of rats in each group were completed at 6 and 12 months post injections. Histologic evaluation of the 6-month rats showed both the Min-U-Sil and novaculite to be fibrogenic. During FY 1982, the 18-month and terminal sacrifices were completed. Histological evaluation of collected tissues is in progress. (CONTACT PERSON: Dr. L. Stettler)

*Other Studies*—Another FY 1982 project was to determine the effect of fluoride (either ingested or injected) on the ability of mineral fibers (asbestos, chrysotile) to induce mesotheliomas in rats and mice. Experiments with animals have shown that fluorides potentiate the biological activity of quartz ($SiO_2$). It is reasonable to suggest that fluorides may also potentiate the biological effects of silicates, e.g., chrysotile. Untreated commercial chrysotile, chrysotile pretreated with hydrogen fluoride (HF), and chrysotile in combination with $CaF_2$ will be injected intraperitoneally into rats and mice. In addition, NaF will be administered in drinking water to other groups of rats and mice injected intraperitioneally with untreated chrysotile. All animals will be sacrificed at 24 months, and their tissues examined grossly and microscopically. The incidence of tumors in each group will be calculated and statistical comparisons made between groups. Results of these studies will be used to reevaluate the existing health standards for various types of asbestos, other mineral fibers and fluroides. During FY 1982 this project was peer reviewed and rewritten to incorporate the ideas and advice from the reviewers. Additional literature was reviewed to obtain information on the rates of reaction of HF on silicates. The experimental phase of the project was initiated. (CONTACT PERSON: Dr. D. Groth)

*Test Methods Development and Validation*

*Short-Term Carcinogenesis Assays*—A comprehensive literature review was completed and submitted to CRC Critical Reviews in Toxicology on the available *in vitro* short-term tests for detecting promoter/cocarcinogenic activity. Contracts were awarded to three laboratories to compare results on 25 coded chemicals, including promoters and cocarcinogens, in the V–79 metabolic cooperation system. FY 1983 efforts will include a multiple award contract to study these same chemicals in the 10T½ cell system potentially forming Type III foci. In-house efforts are employing neonatal epidermal cells from four mouse strains in culture to investigate early markers of tumor promotion/cocarcinogenesis, such as ornithine decarboxylase and DNA activities. (CONTACT PERSON: Dr. J. Bohrman)

*FY 1983 Program Plans*

*Testing—Other Long-Term Studies*

Two long-term carcinogenesis studies, not formally included in the bioassay program, will be initiated in FY 1983 to examine: (1) The cause of increased risk of oropharyngeal and lung cancer experienced by newsprint pressroom workers, and (2) the cocarcinogenic/promoting activity of roofing asphalt fumes. Other long-term studies ongoing or initiated in FY 1982 will continue. (CONTACT PERSON: Dr. R. Niemeier)

*Human Studies*

A newly designed project for FY 1983 has as its objective to devise and evaluate innovative control techniques for use by roofers to reduce their risk to the carcinogenic hazards of asphalt and coal tar pitch materials. While certain hazards are subject to permanent controls, many hazards depend upon job site, suggesting the need for worker involvement and use of innovative control techniques at each job site. The purpose of this project is to apply NIOSH-proven methodology in worker training/reinforcement approaches to a more difficult situation and to use this as a model for further applications in carcinogen-exposed working populations. (CONTACT PERSON: Dr. R. Mason)

**Toxicologic Characterization**

Most chemicals selected for testing by NTP are chosen because the potential exists for human exposure and too little is known about their toxicologic profile. In the toxicologic

characterization program two principal areas of activity are defined: (1) General toxicology which identifies the toxicity of a chemical by species, sex, dose, and essential organ function; and (2) characterization of specific toxicologic effects—immunological, neurobehavioral, pulmonary, fertility and reproductive, and others.

The testing activities of the NIP toxicologic characterization program are composed primarily of intermediate-term (14-day), and subchronic (90–180 day) experiments. These efforts are often in tandem with or the same as the prechronic testing phases of the animal bioassay and have been described in the Carcinogenesis Testing section. All chemicals selected for testing in the two-year bioassay undergo short-term cellular and genetic toxicologic testing to determine potential for inducing gene mutations, chromosome damage, germ cell sensitivity, DNA damage and cellular transformation as well as dose-response information. Also, all are studied to delineate their absorption, metabolism, distribution, and excretion patterns to improve the reliability and precision of dose setting for chronic studies. Routinely gathered, especially in prechronic studies, is information related to target organ effects, fertility and reproduction, urinalysis, clinical chemistry and hematology. Chemical pathology—including tumor pathology, toxicologic pathology, experimental pathology and histology and electron microscopy—is an essential component of toxicologic characterization and is fully described in a separate section of the Plan.

Research activities in toxicologic characterization are concerned primarily with development and validation of better test methods, and with more in-depth characterization of the toxic effects and the mechanisms of effects identified in the various testing phase or by others. Specific disciplinary and target organ areas include: biochemical toxicology and renal toxicology which are described in this section, chemical disposition, chemical pathology, cutaneous toxicology, immunological toxicology, neurobehavioral toxicology and pulmonary toxicology which are described in ensuing sections.

NIEHS

*FY 1982 Accomplishments*

*General Toxicology*—Broadened protocols continued to be used which included measurements of organ weights, broadened pathology in acute and subchronic experiments, hematology, selected organ function assessment (including liver, kidney, immunologic, fertility, and neurobehavioral effects), and chemical disposition. Additions to the general toxicology screen during FY 1982 included efforts to develop and evaluate clinical chemistry procedures for organ function assessment. Also added were measures of reproductive dysfunction at the end of the 90-day subchronic phase—testicular pathology, epididymal weights, sperm counts and morphology in male animals and vaginal cytology in female animals. Efforts continue to be implemented to develop toxicity priniciples for certain chemical classes, especially chlorinated dibenzofurans, psoralems (see Cutaneous Toxicology section), phthalates (see section on Ortho Phthalic Acid Esters—Safety Evaluation), and benzidine derivatives (see section on The Benzidine Dye Initiative).

Although not a major FY 1982 accomplishment, the completion and evaluation of the 90-day study results remains a major decision point in the NTP. At this point, results from the 14-day and 90-day studies along with other information may indicate that a two-year bioassy need not be done or that the standard experimental bioassay design should be modified or that detailed special studies (e.g., reproductive toxicology), which would be done separately, are necessary to validate a presumptive toxic effect and to better characterize the toxic potential of the particular chemical. Some select areas that could be included in special studies are metabolism, clinical chemistry (hematology and urinalysis), pharmacokinetis, neuro-behavioral toxicology, organ function, immunology, and endocrinology (these special studies may be integrated into the prechronic or chronic testing phases, or both). The purpose of the special studies varies. These may, for example, focus on target organ toxicity, perhaps unrelated to carcinogenicity, or on problems of comparative toxicology, metabolism, pathology, and physiology which would strengthen an evaluation of the animal selected for the carcinogenesis bioassay. (CONTACT PERSON: Dr. J. Moore)

The acute and chronic toxic effects of 1,2-dibromo-3-chloropropane (DBCP) on the liver, testis, epididymis and stomach of male, F344 rats were studied. Acute injury of the testis and epididymis occurred coincident with depletion of reduced glutathione, although target organ concentrations of reduced glutathione were not generally affected. These data suggested that a threshold for acute DBCP injury existed commensurate with saturation of hepatic detoxication systems. The effects of the purported DBCP metabolites, 3-chloropropan-1,2-oxide (epichlorohydrin) and 3-chloropropan-1,2-diol (α-chlorohydrin), on the testis and epididymis were similar to those of DBCP, suggesting that DBCP may be toxic to the gonads secondary to metabolism to epichlorohydrin or α-chlorohydrin. A single administration of DBCP causes dose-dependent progressive seminiferous tubular atrophy and both immediate and prolonged infertility in male rats. No evidence of dominant lethal mutations was demonstrated with either single or 5 daily exposures. (CONTACT PERSON: Dr. W. M. Kluwe)

*Biochemical Toxicology*—The objectives of this study are to identify and characterize changes which occur in subspecies of cytochrome P-450 in rat liver after treatment with polychlorinated biphenyls (PCBs), 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD) and other environmental chemicals, and to assess the implications of these changes. Present work includes purification and characterization of a subspecies of cytochrome P-450 from livers of rats treated with 3,4,5,3',4',5'-hexachlorobiphenyl (HCB) and comparison with P-450PB and P-$450_{MC}$ isolated from phenobarbital (PB) and 3-methylcholanthrene (3-MC) treated rats and development of a radioimmune assay to better quantitate amounts of these enzymes in tissues. This work will also attempt to assess the contribution of these cytochrome enzymes to the formation of mutagenic products.

The P-450 system is the principle enzyme system which catalyzes metabolic conversion of foreign chemicals including carcinogens to the ultimate labile carcinogen. Many endogenous compounds (lipids and hormones) are also metabolized by this electron transport system. Present investigations are particularly oriented toward changes in the metabolism of potential carcinogens and mutagens after exposure to environmental chemicals. Changes in lipid metabolism will also be investigated and may be important factors in PCB and TCDD-induced toxicity. (CONTACT PERSON: Dr. J. Goldstein)

*FY 1982 Accomplishments*

(1) Three subspecies of cytochrome P-450 have been purified (10-19 nmol/mg) from livers of 3-MC, HCB and PB treated rats. Cytochrome P-$450_{HCB}$ differs from the major cytochrome isolated from phenobarbital or 3-MC treated rats in its immunochemical properties, molecular weight (52,000), peptide maps, and spectral properties. Its oxidized spectrum peaks at 392 nm (high spin) and its CO-reduced spectrum at 448 nm. Ouchterlony double-diffusion plates indicate the three proteins are immunologically distinct.

(2) The catalytic activities of the three enzymes have been compared after reconstitution with cytochrome c reductase and lipid. Catalytically, P-$450_{HCB}$ differs from P-$450_{PB}$ and P-$450_{MC}$ in that it has low catalytic activity toward the substrates, benzphetamine, benzo[a]pyrene (aryl hydrocarbon hydroxylase) or ethoxyresorufin. However, it has high catalytic activity toward the precarcinogen, 2-acetylaminofluorene (AAF). Both P-$450_{MC}$ and P-$450_{HCB}$ metabolize AAF, but P-$450_{HCB}$ produces more of the mutagenic N-OH metabolite. P-$450_{HCB}$ also has high activity toward amines such as acetanilide and aniline. Km's and Vmax's for each substrate have been estimated.

(3) Specific antibodies have been developed for P-$450_{MC}$ and P-$450_{HCB}$ by the use of immunoabsorbents. A radioimmunoassay (RIA) has been developed which shows less than 0.50% cross reactivity. This RIA indicates that all 3-MC type inducers tested (3-MC, 3,4,5,3',4',5'-HCB and TCDD) induce both P-$450_{MC}$ and P-$450_{HCB}$ by 50–100 fold. Neither cytochrome is a major constitutive enzyme.

(4) The monospecific antibodies have been titrated against each of the reconstituted catalytic activities. Anti-P-$450_{MC}$ is very active against the catalytic site.

(5) Mutagenesis experiments have been initiated. P-$450_{HCB}$ is more active than the other two P-450s toward AAF (N-hydroxylation). Determination of activity toward other precarcinogens is underway.

*Renal Toxicology*—The mechanisms of chemical nephrotoxicity, particularly that caused by halogenated aliphatic hydrocarbon compounds, are being studied with the aid of both *in vivo* and *in vitro* techniques. Of major

concern are species differences in toxic response, organ-specific chemical detoxication and toxification reactions, dose-response relationships and acute versus chronic toxic response. Methodology for detecting and quantifying nephrotoxic response to single and to multiple chemical exposures continues to be developed and assessed.

*FY 1982 Accomplishments*

The acute nephrotoxic effects of the nematocide, 1,2-dibromo-3-chloropropane (DBCP), were dependent on the depletion of hepatic, but not renal, reduced glutathione concentrations. These results suggest that conjugation of DBCP metabolites with hepatic glutathione is a detoxication reaction. The renal effects of DBCP were dissimilar from those caused by its purported metabolites, 3-chloropropan-1,2-diol, 3-chloropropan-1,2-oxide and oxalic acid.

Several indices of renal cell function (e.g., intracellular potassium concentration, gluconeogenesis, accumulation of organic ions, rate of respiration) can be studied *in vitro* using tissues from naive animals incubated in the presence of nephrotoxic chemicals. Using such techniques it was shown that rat renal cells exposed *in vitro* to 1,2-dibromoethane, 1,2-dibromo-3-chloropropane or hexachloro-1,3-butadiene responded similarly to renal cells derived from animals treated *in vivo* with these same chemicals, indicating that *in vitro* exposures can be used to study the nephrotoxic effects of these compounds.

Acute chemical nephrotoxicoses often are manifested as polyuria, glucosuria, proteinuria and enzymuria, suggesting that renal injury can be diagnosed by noninvasive urinalysis techniques. Upon continued treatment with mercuric chloride ($HgCl_2$), however, such functional parameters return to normal ranges despite continued evidence of residual or recurring morphological abnormalities in the kidney. (CONTACT PERSON: Dr. W. M. Kluwe)

*FY 1983 Program Plans*

*General Toxicology*—The role of glutathione in detoxication during prolonged exposure to DBCP will be studied. In addition, rats will be treated with multiple doses of DBCP for 70 consecutive days to determine the dose-dependencies, inter-relationships and reversibilities of infertility and tissue injuries. Recovery will be followed for up to 90 days. (CONTACT PERSON: Dr. W. M. Kluwe)

*Biochemical Toxicology*—Antibody experiments with whole liver microsomes will be used to identify which pathways are mediated by the respective enzymes. Mutagenesis experiments with additional substrates are in progress. RIA experiments will be used to determine whether environmental chemicals affect these enzymes in extrahepatic tissues and in the embryo. The immunoprecipitation and *in vitro* translation of the 3-MC inducible messages will be examined to determine whether these messages are expressed co-ordinately. We will examine and attempt to isolate additional enzymes including the constitutive enzymes from control animals. (CONTACT PERSON: Dr. J. Goldstein)

*Renal Toxicology*—The mechanisms of chemical nephropathy will be studied, particularly those of halogenated aliphatic hydrocarbon compounds. Comparisons will be made of morphological (light and electron microscopic) and biochemical (e.g., DNA and protein synthesis, enzyme activities) alterations at early times post-exposure to develop cause and effect relationships in toxic response. *In vitro* cell preparations (isolated renal tubules) will be developed both for mechanistic studies in rodents and for rapid inexpensive interspecies comparisons.

Urinalyses will continue to be studied as indicators (qualitative and quantitative) of nephrotoxicity in rodents both in acute and chronic exposure regimens. Of particular interest will be low molecular weight proteinurias.

Existing NTP toxicity reports will be reviewed to associate chemicals with target organs. Assessments will be made of the propensities of chemical classes to injure specific organs, including kidney. Sex and species differences in toxic reponse, and dose-response relationships will also be examined for these chemical classes. For those chemicals with a history of demonstrated human toxicity, response of the rodent models and man will be compared. (CONTACT PERSONS: Dr. W. M. Kluwe)

**NIOSH**

*FY 1982 Accomplishments*

*General Toxicology*—In FY 1982, studies were conducted to evaluate the comparative cardiac toxicity of inhaled amines on a structure-activity basis. Selected amines are being used to determine the effect of chain length and extent of substitution on the amino nitrogen of the amine on subsequent cardiac toxicity. One hundred and twenty day inhalation studies with allylamine and triethylamine were initiated and completed. Data analyses have been initiated.

*FY 1982 Program Plans*

*General Toxicology*—In FY 1983 the camparative cardiac toxicity of ethylamine will be evaluated, thereby completing the toxic evaluation of the ethylamines (diethylamine and triethylamine having being studied previously). This effort is part of NIOSH's initiative in cardiovascular disease and evaluates the effects of amines on the heart and blood vessels by monitoring clinical chemistry, electrocardiographic, and gross and histopathologic indices. (CONTACT PERSON: Mr. D. Lynch)

**The Benzidine-Dye Initiative**

The benzidine-dye initiative is a program designed to study the toxicology and carcinogenicity of a class of dyes which are derived from either benzidine; 3,3'-dimethylbenzidine (DMB) (o-Tolidine), or 3,3'-dimethoxybenzidine (DMOB) (o-Dianisidine). This group of dyes includes some 82 discrete chemicals which are available in the United States. During 1978 the combined domestic production and import volumes of these dyes totaled 4.1 million pounds. Exposure of the general public to these materials is through contact with finished products (paper, fabrics, leather) to which the dyes have been applied, packaged dyes for home use, and the use of arts and crafts products such as spray paints, enamels, and lacquers. The Dyes Environmental and Toxicology Organization (DETO) has estimated that approximately 1,000 workers are exposed to these materials during dye manufacturing and that perhaps as many as 15,000 workers are exposed in the various dye application industries.

Benzidine is recognized as a human carcinogen, causing cancer of the urinary bladder. Both DMB and DMOB have been reported to induce tumors in rats, prompting the International Agency for Research on Cancer to classify these agents as animal carcinogens. There is no evidence to show that either DMB or DMOB are human carcinogens. Earlier research has demonstrated that many benzidine and benzidine congener-based dyes are metabolized to their respective parent aromatic amines by laboratory animals. These observations suggest that the dyes may be animal carcinogens.

Because of the high cost and time required for long-term bioassays, no attempts will be made to routinely test all benzidine and benzidine congener dyes in the NTP bioassay program. Instead, an interdisciplinary chemical class toxicology program was designed and testing begun in FY 1981. The objective of this program is to develop an integrated body of scientific knowledge concerning the pharmacokinetics, genetic toxicology, and the *in vivo* toxicity and carcinogenicity of the benzidine congeners *per se* and selected prototypical dyes. Through the judicious selection of chemicals for testing it will be possible to establish basic principles which can be applied to the entire class of benzidine-based dyes.

This program was developed in response to the needs of the EPA, CPSC, and OSHA. The scientific objectives and approaches were formulated by scientists from the EPA, CPSC, OSHA, NIH/NTP, NCTR, and NIOSH. As designed, the program will provide the scientific information required for making regulatory decisions about the benzidine and benzidine congener-based dyes, serve as a model for future chemical class studies, and conserve program resources. (CONTACT PERSON: Dr. J. Mennear, NIEHS)

*FY 1982 Accomplishments*

The benzidine-dye initiative involves activities conducted at NIEHS, NCTR, NIOSH, and three contract laboratories. These activities are divided into three discrete yet closely integrated areas of research work: (1) Chemical disposition and metabolism (NIEHS, NCTR, and NIOSH), (2) Genetic toxicology (NIEHS and a contract laboratory), and (3) *in vivo* toxicology and carcinogenicity testing (NIEHS and contract laboratories) (Table 16).

*Chemical Disposition Studies*—Employing electron-capture gas chromatography and high pressure liquid chromatography methods developed during FY 1981, the metabolism of selected bisazobiphenly dyes was studied in F344 rats. The dyes were administered by gavage and urine was collected and assayed for the parent aromatic amines and their respective metabolites. Nine dyes—four

DMB-based (Direct Red 39, Direct Blue 14, Direct Blue 53, and Direct Orange 6), for DMOB-based (Direct Blue 8, Direct Black 114, Direct Blue 10, and Direct Violet 32), and one dichlorobenzidine-based (Direct Red 46) were studied. The results indicate that the dyes are all significantly metabolized to the parent amines by the rat as evidenced by the presence of the metabolites of the amines in the urine collected after dosing. (CONTACT PERSON: Dr. L. Lowry, NIOSH and Mr. C. Nony, (NCTR)

Detailed metabolism, distribution and excretion studies with $^{14}C$-labeled benzidine, DMB, and DMOB were completed. The results of these studies indicate that all three compounds were readily absorbed from the gastronintestinal tract of the rat. These compounds were extensively metabolized and metabolites (n-acetylated derivatives and sulfate and glucuronide conjugates) were excreted in both urine and feces. (CONTACT PERSON: Dr. H. B. Matthews, NIEHS)

Direct Blue 6 (a benzidine-based dye) and Acid Red 114 (a DMB-based dye were synthesized from $^{14}C$-labeled parent aromatic amines. The results of absorption, distribution, metabolism and excretion studies showed that neither of these dyes was well absorbed from the gastrointestinal tract. However, both dyes were subject to the azo reductase activity of the intestinal flora with the resulting production of free parent amine which is readily absorbed and metabolized as described above. The nonreduced dye remaining in the gastrointestinal tract is largely excreted unchanged in the feces. (CONTACT PERSON: Dr. H. B. Matthews, NIEHS)

Direct Blue 15, the 3,3'-dimethoxybenzidine congener of Direct Blue 6, has also been found to be susceptible to the azo reductase activity of the gastrointestinal tract. The resulting parent amine is absorbed and metabolized as described earlier. (CONTACT PERSON: Mr. L. Lowry, NIOSH)

The methodology and results of these studies are discussed in greater detail in the Chemcial Disposition section of the Plan.

*Genetic Toxicology*—Standard protocols employed for the *in vitro* assessment of mutagenic activity routinely provide for the metabolic activation of the agent being tested. For the most part the metabolic activation system catalyzes oxidative metabolism. Some chemicals, such as the benzidine congener dyes, are believed to require both reductive and oxidative metabolism for biologic activity to occur. Reductive metabolism frees the parent aromatic amine (benzidine, DMB or DMOB) from the chromophore and subsequent oxidative metabolism activates the aromatic amine. In the absence of a redutive metabolizing system it is possible that the mutagenic activity of the benzidine congener dyes (if any) would go undetected.

During FY 1982 a contract was awarded to develop *in vitro* test protocols for the detection of chemicals requiring reductive/anaerobic metabolism for the expression of their mutagenic activity. Also, this contract will assess the mutagenic activities of urine samples collected during the dye metabolism studies. (CONTACT PERSON: Dr. E. Zeiger, NIEHS)

Detailed methodology and progress are presented in the Cellular and Genetic Toxicology section of the Plan.

*In Vivo Toxicology and Carcinogenicity Testing*—Research was initiated on comparative studies of the toxicity and carcinogenicity of DMOB and Direct Blue 15, and DMB and Acid Red 114 in rats. These chemicals are being administered in the drinking water with doses of the parent aromatic amine (DMOB, DMB) selected to be molar equivalents of the amine content of the respective dye. Thus, if the rats completely enzymatically reduced and absorbed the dye administered, they would receive the same amount of parent amine as those animals being treaded with the amine *per se*. This approach will allow us to compare the relative potencies of the dyes and their parent amines. The studies will include 14-day repeated dose studies, 13-week subchronic studies and two-year bioassays. In addition, selected clinical chemistry measurements and urinalyses (for chemical metabolites) will be done.

The 14-day repeated dose studies were completed for all four chemicals and the results were used in the selection of does to be used in the 13-week studies. The rats appeared to tolerate the dyes better than they tolerated equimolar doses of the parent amines. This is probably a reflection of the fact that the dyes are not completely reduced within the gastrointestinal tract (see Chemical Disposition section) and the intact dye remaining is simply excreted in the feces. (CONTACT PERSON: Dr. J. H. Mennear, NIEHS)

Research was initiated on the toxicity of Direct Blue 213, a copper chelate of Direct Blue 15. A hypothesis being tested during this phase of the research effort is that copper chelation protects the azo bonds from reduction by enzymes in the intestinal flora. Since the intact molecule is a highly ionized, water soluble azo derivative, it is not expected to be well absorbed from the gastronintestinal tract. If this is true, it is likely that a two-year bioassay study will not be required. A final decision will be made on this point when both chemical disposition and 13-week subchronic studies are completed. The acute toxicity study (single gavage dose) of Direct Blue 218 was completed and the doses for the 14-day repeated dose study were selected. The results of the acute study did not afford evidence of whether or not the chemical is susceptible to azo reductase, but it did give evidence of absorption of the intact dye molecule. At necropsy the internal organs of both mice and rats were stained blue. (CONTACT PERSON) Dr. J. H. Mennear, NIEHS)

Earlier workers had reported that the administration (dosed feed) of three benzidine derived dyes (Direct Blue 6, Direct Black 38, and Direct Brown 95) produced hepatocellular carcinomas in rats. The carcinomas were diagnosed as early as four weeks. The rapidity of the onset of these tumors suggested that the carcinogenicity was due to more that simple metabolism of the dyes to benzidine. NTP staff are currently reviewing the data and selected pathology slides from this earlier study. During FY 1982 the comparative toxicity and carcinogenicity of Direct Blue 6 and equimolar doses of benzidine were assessed in female rats. The test chemicals were administered in drinking water at concentrations which approximated the daily doses used in the earlier study. Animals were on the treatment regimen for up to 90 days.

Based upon animal survival, body weight gains, clinical chemistry values, and histopathological lesions, the conclusion was reached that benzidine is more toxic than an equimolar dose of Direct Blue 6. This difference in toxicity is probably a reflection of the fact that the dye is not completely reduced to the parent amine and chromophore. Thus, dye treated rats did not receive the same exposure to benzidine as did the animals that were treated with benzidine *per se*. Neither treatment produced hepatocellular carcinomas; however, they both produced severe hepatic lesions (regenerative nodule formation) which were considered to be signs of initial hepatotoxicity and subsequent hepatic regeneration. (CONTACT PERSON: Dr. J. H. Mennear, NIEHS)

*FY 1983 Program Plans*

Chemical Disposition Studies—The chemical disposition portion of the benzidine dye initiative has been largely completed. The single remaining study will be an assessment of the absorption, distribution, metabolism and excretion of Direct Blue 218. This portion of the project will entail the synthesis of $^{14}C$-labeled Direct Blue 218 and conduct of the *in vivo* portions of the experiment. This work will be completed during FY 1983. (CONTACT PERSONS: Dr. C. W. Jameson and Dr. H. B. Matthews, NIEHS)

Genetic Toxicology—During FY 1983 protocols for the anaerobic preincubation of the benzidine congener dyes, followed by aerobic incubation and mutagenicity testing will be developed. This will be followed by the testing to the 13 benzidine congener dyes as well as the three parent amines. Also, urine samples collected during the completed metabolism studies will be tested for mutagenicity. (CONTACT PERSON: Dr. E. Zeiger, NIEHS)

*In vivo Toxicology and Carcinogenicity Testing*—The two-year bioassays of DMB, DMOB, Direct Blue 15 and Acid Red 114 will be initiated. These studies will be conducted only in rats and will include up to four dose levels of each chemical and interim sacrifices which might allow for an early termination of the studies, depending on the findings. (CONTACT PERSON: Dr. J. H. Mennear, NIEHS)

The 13-week study of the toxicity and carcinogenicity of Direct Blue 213 will be completed during FY 1983. The results of this study will be considered along with the results of the absorption, distribution, metabolism and excretion study on Direct Blue 218 in making a decision on the need for a two-year bioassay on this dye. (CONTACT PERSON: Dr. J. H. Mennear, NIEHS)

Studies will be conducted on the nature and mechanism of hepatic lesions produced by benzidine and Direct Blue 6 in rats. Rats will be treated with benzidine and Direct

Blue 6 for various periods (up to 13-weeks) and histopathological examinations will be made at regular intervals to assess the nature of the early hepatic lesions and to study their progession in order to determine if these lesions can be considered to be preneoplastic in nature. (CONTACT PERSON: Dr. J. H. Mennear, NIEHS)

**Chemical Disposition**

Knowledge of chemical disposition—the rates and degrees of absorption, tissue distribution, metabolism and excretion of chemicals by intact animals—is fundamental to determination of the mechaniams by which exposure to various chemicals induces toxicity.

The chemical dispositon program involves laboratories at NIEHS, NIOSH and NCTR. New and ongoing activities for the most part fall into one of three general categories: (1) Chemicals and classes of chemicals chosen for toxicology and/or carcinogenesis bioassays which provide an opportunity for a study of structure-activity relationships; (2) chemicals which are benzidine congeners and derived dyes, part of the NTP initiative; and (3) chemicals to which industrial workers are exposed.

**NIEHS**

The immediate objective of most studies of chemical disposition done in support of the NTP is to determine the effective disposition of candidate chemicals chosen for study in the NTP bioassay or to help explain anomalous results observed in the bioassay. That is, studies of chemical disposition done prior to initiation of the bioassay are designed to determine the rate and degree of absorption and metabolism, tissue distribution and rate and route of clearance of the chemical in question by intact animals. These studies also consider the effect of dose and route of administration on these parameters and are thereby designed to facilitate the choice of optimal doses to be used in the bioassay. Studies of chemical dispositon done after the completion of the bioassay to help explain anomalous results are designed to answer more specific questions. For example, if sex or species related differences were observed in response to the bioassay, studies would be designed to compare the metabolism and disposition of the chemical in question in each sex or species involved.

The long-range goals of chemical disposition studies done under the NTP are to develop and publish data which will permit a better appreciation of those factors which influence the disposition are designed to permit a better assessment of the chemical structure-activity relationships which determine rates of absorption, metabolism, distribution and persistence in tissues and influence rates of clearance from the body. Thus, the ultimate goal of this work is to provide basic information on chemical disposition which will facilitate the extrapolation of laboratory data to man.

Studies of chemical disposition for the NTP are conducted through an inhouse program and four contracts which are administered by in-house personnel. Nomination of chemicals for chemical disposition studies is open to every professional within the NTP and interested individuals outside the NTP. Nominations must be from the list of chemicals chosen for NTP bioassay or closely related chemicals which provide an opportunity for a study of structure-activity relationships. The standard approach to a study of chemical disposition is to use the available literature data, e.g. $LD_{50}$'s, chemical structure and properties, and anticipated route of human exposure, to design the protocol for the preliminary study, i.e., to set doses and choose the vehicle and route of exposure. In most instances these studies follow the disposition of carbon-14 labeled chemicals in the adult male rat; however, when it is desirable or necessary, studies are designed to use other analytical techniques, other species or ages or female animals.

*FY 1982 Accomplishments*

Work on the Benzidine Congener Initiative has continued; major findings through FY 1982 are as follows:

(1) The metabolism, distribution and excretion of 3,3'-dimethoxybenzidine-$^{14}$C (DMOB) have been studied in the rat. This compound was readily absorbed from the gastrointestinal (GI) tract, metabolized and excreted primarily in bile and subsequently in feces. DMOB was metabolized to more than 20 metabolites most of which are excreted in the form of glucuronide and sulphate conjugates. N-acetyl metabolites of DMOB are formed, but they are not as prevalent as was previously observed for benzidine. This work is complete and a manuscript describing it has been completed and submitted for publication.

(2) A disposition study of 3,3'-dimethylbenzidine-$^{14}$C (DMB) has been completed in the rat. This benzidine congener is also readily absorbed, rapidly metabolized, and excreted almost exclusively in the form of metabolites. Excretion in bile and feces is three times greater than in urine. The metabolites excreted include glucuronide, sulphate and N-acetyl conjugates. A manuscript describing the work has been prepared and submitted for publication.

(3) Direct Blue 6, a benzidine based dye, with a $^{14}$C label in the benzindine nucleus has been the subject of a metabolism and disposition study in rat. Results indicate the intact dye is not well adsorbed from the GI tract. The azo linkages binding the $^{14}$C-benzidine nucleus to the chromophores are reduced by intestinal microbes releasing significant amounts of free benzidine which is absorbed from the GI tract and metabolized as described previously. That portion of the dose not metabolized is excreted in feces.

(4) Acid Red 114, synthesized with as $^{14}$C label in the 3,3'-dimethylbenzidine (DMB) nucleus, was metabolized in the rat by azo reduction to release DMB which is further metabolized and excreted as described above. The relatively large Acid Red 114 molecule is not absorbed and most of an oral dose not reduced by intestinal microbes to DMB is excreted intact in the feces.

(5) 3,3'-Dichlorobenzidine-$^{14}$C was readily absorbed by the rat, extensively metabolized. Greater than 70% of the dose is excreted in bile and feces as mono- and diacetyl-3,3'-dichlorobenzidine, N-glucuronides and hydroxylated metabolites. The parent compound was mutagenic in *Salmonella* in the presence of S-9 fraction and some of the metabolites of this compound appear to be even more mutagenic in this system than the parent compound. The results of this study are being prepared for publication.

Most of the work done as part of the NTP program in Chemical Disposition is more diversified than the Benzidine Congener Initiative and has included studies of halogenated alkyls and aromatics, aromatic amines, and dyes and dye intermediates as well as studies of cyclic and inorganic compounds. Major findings in these studies in FY 1982 are as follows:

(1) Studies of the absorption metabolism and clearance of the sparingly soluble dye intermediate, 1-amino-2,4-dibromoanthraquinone-$^{14}$C (ADQ), revealed that GI absorption of this compound was highly dose dependent. Based on $^{14}CO_2$ exhaled following ADW administration, GI absorption decreased from approximately 90% at a dose of 2 mg/kg to 21% at 120 mg/kg to approximately 2% at 814 mg/kg. Therefore the total ADQ absorbed at the two higher doses was not significantly different and these results have direct relevance to studies involving chronic administration of ADQ. The absorbed fraction was readily metabolized and excreted in bile and feces. There was no evidence of ADQ accumulation in tissues.

(2) After intravenous (iv) administration of 0.76 mg/kg $^{14}$C-cyclohexane to adult male F344 rats, 54% of the dose was excreted in the breath in the first hour, 80% in 24 hours, and 83% in 72 hours. After oral administration at doses of 2000, 1000, 200 and 100 mg/kg, 78, 76, 62 and 63%, respectively, of the dose was expired over 72 hours with the maximum rate of excretion usually from 2–8 hours. Twelve, 15, 29 and 29%, respectively, was excretion in urine, compared to 14% excreted in urine after the iv dose. Greater excretion of polar metabolites in urine following the smaller oral doses is attributed to relatively greater metabolism in liver following absorption from the GI tract. No significant excretion of $^{14}$C in feces was observed. Cyclohexane accounted for 93–99% of the radiolabel excreted in breath, but less than 0.1% of that in the urine. A maximum of 0.04–0.4% of the dose was excreted in breath as the more toxic cyclohexa-none and 0.09–0.6% as cyclohexanol. Less than 0.1% of the dose was excreted in the urine as either of these compounds. Cyclohexane was concentrated primarily in adipose tissues, but this accumulation was very transient and total excretion was quite rapid.

(3) The disposition of a commonly used dye, CI Vat Blue 1 (Blue 1), was studied in the rat following oral, dermal and iv-administration. Results indicate Blue 1 was poorly absorbed following both oral and dermal administration, due primarily to extreme insolubility in biological media. The dosage form administered also plays an important role in absorption. For example dermal absorption of Blue 1 was approximately 1.7 $\mu g/cm^2$/week following dermal administration of 550 $\mu g/cm^2$ of dry

dye, and 5.2 μg/cm²/week when applied in a polyethylene glycol based ointment. Disposition studies following iv administration of a small dose, 0.22 mg/kg, indicated slow metabolism and elimination primarily in feces. Blue 1 may have some potential for bioaccumulation with chronic exposure.

(4) The disposition of hexachlorocyclopentadiene-$^{14}$C (HCP) was studied in the rat following administration or oral or iv doses or after inhalation of the vaporized chemical. Following oral administration of HCP to the rat most of the HCP reacted with stomach and gut contents and was never absorbed. Following iv administration, HCP reacted with blood components, primarily hemoglobin, to form unextractable complexes. Following inhalation, HCP reacted with lung tissue in addition to being absored and distributed to most of the major tissues. The reactivity of HCP in biological systems was confirmed *in vitro* by showing that it forms unextractable complexes when incubated with blood, liver or feces. The reactivity of HCP in the GI tract decreasing its absorption versus that observed following inhalation explains why this compound is much more toxic when inhaled than when ingested. The results of this study are being prepared for publication.

(5) The GI absorption of a series of highly insoluble compounds is being studied in the rat. Studies with three pigments, CI Pigment Red 3, CI Pigment Red 23, and CI Pigment Yellow 74, have shown that GI absorption of intact pigments is minimal. Even after large doses, 60–600 mg/kg, tissue levels of these pigments are below the limits of detection, 5 ppb. The effect of microbial action on these chemicals and the possibility of absorption of the resulting metabolites are also being investigated.

(6) Allyl isothiocyanate-$^{14}$ C (AITC), in male and female F344 rats, is readily absorbed, metabolized and excreted in the form of several metabolites. Approximately 60–70% of the dose is excreted in urine and 2–3% in feces within 24 hours in both sexes after either oral or iv administration of AITC. Whole body half-life was less than 24 hours in both sexes. high concentrations of AITC-derived radioactivity were present in blood and lung 15 minutes after, and in liver, muscle, skin and adipose tissue 45 minutes after oral administration. Very small amounts of AITC were present 24 hours after administration. This compound appears to have little or no potential for bioaccumulation in any tissue assayed. The metabolism and disposition of AITC will also be studied in male and female B6C3F$_1$ mice. The results of this study will be compared to those obtained from male and female F344 rats in an attempt to explain differences in AITC-induced urinary bladder tumor formation among sexes and species.

(7) Halogenated biphenyl transport by components of rat blood was studied under both *in vivo* and *in vitro* conditions. Fractionation of plasma components indicate halogenated biphenyls are associated with each major class of plasma proteins but are most concentrated in the lipoproteins. A significant portion of the total halogenated biphenyls in whole blood is also associated with the cellular components. Halogenated biphenyls are readily exchanged between plasma and the cellular components and between lipoproteins and other classes of plasma proteins. Partition experiments indicated that the relative affinity of a biphenyl for each fraction was directly proportional to the lipid solubility of the biphenyl. The major portion of the halogenated biphenyls in blood is not thought to be bound to specific sites on blood proteins but rather is believed to be associated non-specifically with hydrophobic sites on plasma proteins or the cellular components of blood. The rapid transfer of these compounds to tissues is thought to be by partition to similar sites on cellular proteins.

(8) 1,3-diphenylguanidine (DPG), a rubber acclerator, was readily absorbed from the GI tract of male Fischer rats and rapidly distributed throughout the body. Absorption and disposition of DPG were not significantly affected by the route of administration or by the dose over the 1.5 to 150 mol/kg dose range. Most of a dose of DPG was excreted in the urine and feces in approximately equal amounts within 24 hours after oral or iv administration, and greater than 99% was cleared into the urine and feces within 3 days. Approximately 50–60% of the DPG-derived radioactivity excreted in urine was the parent compound, while the remainder was present as one major and two minor metabolites. Close to 90% of the radioactivity excreted in bile was as a single major metabolite. Administration of multiple doses resulted in accumulation of DPG-derived radioactivity in the liver but not in other tissues.

(9) p-Nitroaniline (PNA) was readily absorbed from the GI tract, distributed to all tissues, and rapidly excreted. PNA was excreted in urine as a number of metabolites. Half-life for most tissues was less than 12 hours and little PAN-derived radioactivity remained in the body after 24 hours. Trace levels of PNA persisted in blood, possibly due to reaction with hemoglobin. Metabolites of PNA were excreted primarily as sulphate conjugates in urine and bile. Excretion of parent compound accounted for a small part of the dose.

(10) 4-Chloro-2-nitroaniline (CNA) was almost completely absorbed from the GI tract after oral doses of 0.136, 1.36, and 13.6 mg/kg body wt. The distribution pattern was the same by oral or iv administration. Adipose tissue was the major depot of CNA, with moderate amounts being redistributed to the skin. More than 65% was excreted in the urine in 7 hours. CNA-derived radioactivity excreted in the urine over 3 days was approximately 75%, and in the bile about 12%. CNA was readily metabolized to at least nine metabolites with the major metabolite identified as a sulfate conjugate of the parent compound. This metabolite accounts for 65% of the total dose and is excreted almost exclusively in urine.

(11) The disposition of 2,4-dinitroaniline (DNA) was independent of dose or route of administration when administered orally at doses of 1, 10 or 90 μ mol/kg or by iv injection of 10 μ mol/kg. Absorption from the GI tract was near vomplete throughout the range of oral doses. Excretion in urine accounted for 90% of the dose within 24 hours. Most of the DNA-derived material excreted was in the form of conjugates of various metabolites. There was no evidence to indicate that the parent compound or any of its metabolites were tetained in any of fifteen major tissue assyed.

(12) o-Nitroanisole-$^{14}$ C (ONA) was absorbed following either oral or dermal exposure with the half-life for dermal absorption being approximately 20 hours in rat. After iv administration, ONA was rapidly distributed to all tissues assayed, readily metabolized and eliminated in a biphasic manner with an initial half-life of 1 to 2 hours and a terminal half-life of approximately 4 days. The initial component of the biphasic elimination of ONA accounted for approximately 90% of the dose, and there was little evidence of ONA accumulation or persistance in tissues. ONA distribution and metabolism were independent of route of administration or does in the range of 5–50 mg/kg. However, at an oral dose of 500 mg/kg there was some evidence that the mechanisms responsible for ONA metabolism and/or elimination were saturated. ONA was excreted primarily in urine, 85% and almost exclusively, 99%, as a variety of metabolites. Major metabolites were o-nitrophenyl-sulfate, 63%, and o-nitrophenylglucuronide, 11%. These results are being prepared for publication.

(13) p-Chloroaniline-$^{14}$ C (PCA) was readily absorbed from the GI tract and very rapidly metabolized in the rat. Clearance from tissues was also rapid and virtually all of the PCA excreted was in the form of metabolites. The elimination half-life for PCA-derived radioactivity from most tissues was 1.5 to 3 hours and the major route of elimination was in urine (>80%). The major metabolite of PCA was p-chloroacetanilide. Disposition kinetics for PCA appear to be independent of route of administration and dose in the range studied (0.3 to 30 mg/kg).

(14) 1,2,3-Trichloropropane-$^{14}$C (TCP) was studied in the rat following oral doses of 0.32, 3.2 and 32 mg/kg and an iv dose of 3.6 mg/kg. No effect of dose on metabolism and disposition of TCP was observed. After iv administration, TCP was the component of the decay curve having the shorter half-life accounting for most of the dose. Highest tissue concentrations were in adipose tissue, but this and all other tissue concentrations were transient and 78% of the dose was excreted within 8 hours following iv administration. Except for 5% of the dose eliminated in the exhaled air as parent compound, TCP was cleared from the body as metabolites. The major route of excretion was urine which accounted for the elimination of 46% of the dose, primarily as glutathione conjugates; 25% of the dose was expired as COOG5**2**, and 23% was eliminated in feces.

(15) p-Nitrotoluene-$^{14}$C (PNT) was readily absorbed from the GI tract of rats, rapidly metabolized and excreted primarily in urine. There was no effect of dose on absorption, metabolism or excretion at the doses studied, 1, 10 and 100 mg/kg. After iv administration PNT was metabolized rapidly and no parent

compound could be detected in any tissue by 4 hours. PNT metabolities were rapidly cleared from the body and 70% of the dose was excreted in urine by 4 hours. Excretion in feces was minimal, but studies with bile cannulated animals indicate that a significant portion of the dose is eliminated in bile prior to enterohepatic circulation and subsequent elimination in urine. This observation may be relevant in view of the fact that enterohepatic circulation is thought to contribute to the carcinogenicity of dinitrotoluene. Major metabolites of PNT were 4-nitrobenzoic acid and 2-hydroxy-4-nitrotoluene, accounting for 50–60% of the PNT derived radioactivity in urine. Minor metabolites were primarily conjugates and included the glucuronide of p-nitrobenzyl alcohol.

(16) Studies of gallium arsenide (GA) disposition have concentrated on methods for the preparation of GA for animal dosing and analysis of these elements in biological media. The proper oxidation state can be maintained if GA is ground under nitrogen to a powder of 1–5 micron particle size. Most forms of GA are insoluble, but *in vitro* studies of GA in the powdered form indicate that it has rapid and substantial solubility in buffered media. A technique has been devised for the analysis of arsenic in tissues in ng quantities using atomic absorption with a sensitivity of 2–5 ppb. Atomic absorption is also used for analysis of gallium, but present limits of the assay are only 1–2 parts per million. Work to improve this assay for use in a study of the disposition of GA in rats is continuing.

(17) A continuing project to study the metabolism of three polychlorinated biphenyl (PCB) isomers in *in vitro* preparations from dog, monkey and human liver is yielding data which corroborates data obtained in previous *in vivo* studies. That is, the species as well as the degree and position of chlorination have profound effects on the rate at which PCBs are metabolized. Enzyme kinetic studies of the metabolism of 4,4'-dichlorobiphenyl (4, 4–DCB) and 2, 3, 6, 2', 3', 6'-hexachloro-biphenyl (2, 3, 6–HCB) by microsomal prepartions from human liver yielded the following values for 4,4–DCB and 2, 3,6-HCB, respectively:

Km = 10 μmolar
Vmax = 5.4 p mol/mg protein/min
Km = 10 μmolar
Vmax = 1.2 p mol/mg protein/min

The major metabolite formed from 4,4-DCB was 3-hydroxy-4,4'-dichlorobiphenyl. The major metabolites formed from 2,3,6-HCB were 4- and 5-hydroxy-2,3,6,2',3',6'-hexachlorobiphenyls. Similar metabolites and kinetic parameters were obtained with microsomal preparations from monkey liver, but neither human nor monkey liver was able to metabolize the third PCB studied, 2,4,5,2',4',5'-hexachlorobiphenyl (2,4,5-HCB). On the other hand, microsomal preparations from dog liver can metabolize 4,4-DCB and 2,3,6-HCB more rapidly than those from human or monkey liver, and dog liver microsomes can metabolize 2,4,5-HCB at an appreciable rate. The results of these studies indicate that the monkey is a better animal model for human metabolism of PCBs than the dog. Efforts to accurately predict rates of *in vivo* metabolism based on results obtained *in vitro* are continuing.

(18) 1,2,3,4,6,7-Hexabromonaphthalene (HBN), in the rat, was imcompletely absorbed from the gut and initially concentrated in the liver. Some of the compound was rapidly metabolized in the liver and excreted via the bile into the feces. The remainder was rapidly distributed to the fat and skin from where in slowly returned to the liver where it persisted. During the first few days after acute exposure, metabolities were excreted in the feces. Almost no radioactivity appeared in the urine. Following this initial excretion, little HBN-derived radioactivity was excreted from 3 to 35 days. The basis for the rapid initial metabolism and excretion of HBN followed by the persistence of the remainder in liver is being investigated.

(19) Studies of the chemical disposition of 2,3,7,8-tetrachlorodibenzofuran (TCDF) demonstrated how the disposition and toxicity of this compound varies with both species and strain of animal exposed. Little metabolism of TCDF can be detected in guinea pigs. When fat is mobilized as an energy source, TCDF is redistributed back to the liver. Upon repeated exposure to low levels of TCDF, no TCDF intoxication occurs until a critical body burden is reached. When this occurs, extensive weight loss and death ensue rapidly. The repeat dose studies indicate that the fat content affects the amount of TCDF needed to reach toxicity. Mature animals have larger fat deposits and have a higher $LD_{50}$ than observed for young animals. The time to death also seems to increase with age while a lower percentage of the body weight seems to be lost before death occurs.

The disposition of TCDF in two mouse strains was affected by their differential content of adipose tissue. C57BL/6J mice had about half as much fat as DBA/2J mice and half of the whole body half-life. The greater amount of adipose tissue in DBA mice served to retain the TCDF and thus decrease its availability for metabolism and excretion. The enhanced size of the fat depot in these animals may in part explain the lessened sensitivity of this strain to the toxicity of halogenated polyaromatics.

(20) The disposition of 1,2,4,6,8,9-hexachlorodibenzofuran (HCDF) has been examined in order to extend the structure/activity relationships for polyhalogenated aromatics. HCDF is incompletely absorbed from the gut, but that portion of the dose which is absorbed was quite persistent, tending to accumulate more in the liver than in the fat. Small amounts of metabolites are excreted in the feces, but overall metabolism is minimal.

(21) Altered pharmacological responses as a result of aging have also been investigated as part of the program in Chemical Disposition. Changes in the disposition of two polychlorinated biphenyls (PCBs) in aging rats have been examined. 2,3,6,2',3',6'-Hexachlorobiphenyl (236-HCB) and 2,4,5,2',4',5'-hexachlorobiphenyl (245-HCB) are symmetrical isomers whose distribution, metabolism, and excretion have been studied previously in young rats. In the present study, senescent rats (22–24 months old) were given a single iv dose of the HCB, sacrificed at times ranging from 1 hour to 21 days, and distribution of the $^{14}C$-labeled dose (0.6 mg/kg) was examined in tissues and excreta. The half-lives and pool sizes were increased for both compounds, suggesting a slower rate of metabolism. Increased metabolite/parent compound ratios in the tissues suggested a slower elimination of metabolites in the old rats. The effects of aging seem to be more pronounced for 245-HCB than for 236-HCB. Thus, senescence may more markedly affect the disposition of more persistent PCBs.

Lymphatic tissues and associated cells, including thymus, spleen, and macrophages, were examined for age-related changes in intermediary metabolism. Key enzymes from the hexose monophosphate shunt, the glycolytic pathway, and the Krebs cycle were compared in rats of 6, 12, 18, and 24 months of age. Pyruvate kinase and lactate dehydrogenase decreased in thymus, but increased in spleen. Glucose-6-phosphate dehydrogenase, isocitrate dehydrogenase, and malate dehydrogenase activities all decreased in pulmonary macrophages. These data suggest that the biochemical supports for phagocytosis and cell-mediated immunity are diminished during aging in macrophages and in the thymus, while the humoral immune response mediated by splenic B cells may not be compromised in senescent rats.
(CONTACT PERSON: Dr. H. B. Matthews)

*FY 1983 Program Plans*

The NIH/NTP program in Chemical Disposition will continue to provide metabolism and disposition data for as many chemicals as possible. The immediate goals of this work will be to assist chemical managers in the design and interpretation of NTP bioassays for chronic toxicity. Therefore, the Chemical Disposition Program always remains open to requests for such studies as they are needed. However, a number of studies are planned for the coming year. These plans include basic disposition studies for 1,2-dichloro-5,5'-dimethyl-hydantoin, 2-bromo-4,6-dinitroaniline, benzo(f)quinoline and toluene-2,6-diisocyanate. A comparative study of the metabolism and disposition of triortho-, trimeta- and triparacresylphosphate will be done in the rat and at least one species which is sensitive to the neurotoxicity of triorthocresyl phosphate.

A relatively large study on phthalic acid esters will be conducted to provide an evaluation of the effects of chemical structure on the dermal and gastrointestinal absorption, disposition and clearance of a series of representatives from this chemical class. The chemicals to be studied are phthalic acid, dimethyl-, diethyl-, di-n-butyl-, diisobutyl-, di-n-hexyl-, di-n-octyl-, di(2-ethylhexyl)-, diisodecyl- and butyl benzyl phthalates plus 3 or 4 monoalkyl phthalates. In addition to these studies a comparative metabolism and disposition study in rats and mice will be done for diallyl phthalate. Plans for FY 1983 also call for a comparative metabolism, disposition and covalent binding and how chlorination of the p-phenylenediamine molecule increases its binding to subcellular macromolecules.

The Chemical Disposition Program has lacked the capability to study volatile compounds. Plans for FY 1983 call for

initiation of a new contract or interagency agreement to study the fate of chemicals administered by inhalation or eliminated primarily by exhalation. This contract or interagency agreement will replace a contract which will terminate at the end of FY 1982 so the actual number of contracts will remain at four. However, the contract allowing inhalation studies should significantly increase the capacity of the Chemical Disposition Program to respond to the need for studies of a broader range of chemicals. (CONTACT PERSON: Dr. H. B. Matthews)

NIOSH

*FY 1982 Accomplishments*

*Chemicals Chosen as Part of The NTP Benzidine Congener Initiative*—Studies on the metabolism and structure-activity relationships of 9 benzidine congener dyes in the rat were completed by NCTR. All dyes tested (Direct Red 39, Direct Blue 14, Direct Blue 53, Direct Orange 6, Direct Blue 8, Direct Black 114, Direct Blue 10, Direct Violet 32, and Direct Red 46) were metabolized to their respective congeners. This program is associated with activities of the NTP Benzidine Dyes Metabolism Workgroup. (CONTACT PERSON: Dr. L. Lowry, NIOSH, and Mr. C. Nony, NCTR)

*Chemicals Chosen with Known or Potential Exposure of Industrial Workers*—The metabolism and tissue distribution study in rats of the benzidine congener dyes, Direct Blue 15 and Direct Red 2 (IA 80–34, Metabolism of Azo Dyes to Aromatic Amines, NIOSH-NCTR), was completed during FY 1982. There was extensive metabolism of the dyes with the free benzidine congeners being identified in the urine. A major publication/final report "Metabolism and Distribution of Two $^{14}C$-Benzidine-Congener-Based Dyes in Rats as Determined by Gas Chromatography, High-Pressure Liquid Chromatography, and Radioassays" will be published in the Journal of Analytical Toxicology (1982). (CONTACT PERSON: Dr. L. Lowry)

NCTR

*FY 1982 Accomplishments*

*Azo Dyes*—The primary thrust of this research was to develop sensitive and specific analytical chemical methodolgy so that valid studies of azo dye metabolism in experimental animals could be conducted. Another goal of this research was the development of an analytical capability to determine parts per billion levels of certain dye metabolites so urine analysis could be used to determine if industrial workers had been exposed to azo dyes.

Prior research was concentrated on the water soluble benzidine-based, tris azo dye, Direct Black 38, and the 3,3'-dichlorobenzidine-based water insoluble compound, Pigment Yellow 12. The development of analytical methodology, the stability and purification of the dye and pigment, and metabolism of these compounds in the hamster are complete and have been published in the literature (Nony 1979, 1980; Bowman 1981, and Lowry 1980).

The methodology for 3,3'-dimethylbenzidene (*o*-tolidine) and 3,3'-dimethoxybenzidene (o-dianisidine) and their mono- and diacetylated derivatives (synthesized at the NCTR) has been completed for assaying rat urine by high-pressure liquid chromatography (concentrations to 50 ppb) or rat, hamster or human urine by electron-capture gas chromatography (concentrations to 1 ppb). This has been reported by Nony (1981, 1982). Results of the metabolism of Direct Red 2 in the rat and hamster also has been reported (Nony 1981, 1982).

The regulatory agencies through the auspices of the National Toxicology Program arranged with the NCTR to participate in a joint initiative to determine whether metabolism of certain azo dyes occurs in Fischer 344 rats and to elucidate structure-activity relationships of the different dyes. The dyes selected for this experiment were Direct Red 39, Direct Blue 8, Direct Blue 14, Direct Blue 53, Direct Red 46, Direct Orange 6, Direct Black 114, Direct Blue 10, and Direct Violet 32. All of these dyes have been analyzed for purity and stability and given as single gavage doses to rats. The urine samples, collected under dry ice, were assayed for corresponding free amines, their mono- and diacetylated derivatives and alkaline hydrolyzable conjugates and reported to the Chairman for Metabolism Studies. As agreed upon by the Interagency Committee, the results were released by the Chairman when the study was completed; a summary of results is reported in Table 17. A technical report by Nony (1982) and papers by Bowman (1982) and Levine (1982) are in press.

An interagency agreement between NIOSH and NCTR that calls for metabolism, absorption and tissue distribution studies in rats using $^{14}C$-labelled Direct Red 2 and Direct Blue 15 is complete. A technical report by Oller (1982) and a paper by Bowman (1982) describing the results are in press. No azo dye related NTP work is anticipated in FY 1983. All planned aspects of this program were completed in FY 1982. (CONTACT PERSON: Mr. C. Nony)

*Gentian Violet*— The metabolism of this triphenylmethane dye, which is added to poultry feed as a preservative, is being elucidated in the chicken (target animal) and in the Fischer 344 rat and B6C3F$_1$ mouse (test animals). Metabolite profiles of extracts of some chicken and rodent tissues have been obtained. Excretion of gentian violet (hexamethyl-p-rosaniline chloride) in rat liver bile has been measured, and initial experiments on microbiological metabolism have been conducted.

The multidose metabolism study with $^{14}C$-gentian violet has been conducted with both sexes of Cornish-White Rock broilers. The chickens were dosed orally by gelatin capsule three times daily for seven days. The females and males were administered a total of 1.45 mg and 1.72 mg daily, respectively, based on the amount of gentian violet present in feed at a 15 ppm level. The dose was calculated on the basis of daily feed consumption of 97 g and 115 g for broilers at 6 weeks of age.

Group of five animals per sex were sacrificed starting at six hours after the last dose. Tissues were excised, frozen and stored at −70°C until analysis. The raising, dosing, sacrifice and necropsy of the chickens were performed under an interagency agreement with the Comparative Animal Research Laboratory at Oak Ridge National Laboratory (ORNL). Preparation of doses and analysis of biological samples were handled at the NCTR.

Duplicate samples were cut from partially thawed liver, kidney, breast muscle, thigh muscle, heart and gizzard for weighing and combustion in a tissue oxidizer. The entire skin with adhering fat was homogenized in water before duplicate aliquots were taken for combustion. The total residues were expressed as ppb of $^{14}C$-gentian violet equivalents. A notable feature of the preliminary date is the slow depletion of label from the tissues, especially from liver. Excreta were collected and frozen daily from each chicken in the 240-hour sacrifice group. Weighted samples were homogenized in water before aliquots were taken for combustion analysis. Over 90% of the label was recovered in the excreta.

A procedure consisting of extraction, solvent partitioning, alumina and reversed phase high performance liquid chromatography (hplc) has been applied to the preliminary analysis of pooled tissues from the 6-hour sacrifice group to reveal an average of 40% bound residues and extensive metabolism of the $^{14}C$-gentian violet. Gentian violet is a minor component of the extractable residue in liver. However, in gizzard gentian violet constitutes up to 70% of the extractable residues. The demethylated products pentamethylpararosaniline, N,N,N',N'-tetramethylpararosaniline, and N,N,N',N''-tetramethylpararosaniline comprise the major identified metabolites in liver, kidney, gizzard, breast, heart, and skin with adhering fat. In the skin extracts, however, there are as yet major unidentified metabolites which account for over 50% of the extractable residue. There seems to be no difference in metabolite profile between sexes in this early sacrifice group.

Although radioactivity from an iv injection of 1 uCi (85 μg) of $^{14}C$-gentian violet appears in the bile of anaesthetized Fischer 344 rats within 10 minutes after administration, only 18–26% of the dose is collected over 12 hours. The biliary excretion of a gentian violet dose given by gavage is only 8–9% over a 12-hour period. In each case, at least 10 metabolites were observed with unchanged gentian violet accounting for no more than 10% of the total radioactivity.

We have preliminary indications that several pure cultures of anaerobic bacteria and cultures of mixed microflora from rat intestine reduce gentian violet under conditions of anaerobic incubation. In the most active cultures, the blue color of gentian violet fades within 2 hours of incubation. Extracts of the culture medium when subjected to analysis by hplc are found to contain increasing amounts of the uncharged reduction product, leuco gentian violet. The kinetics of this reaction are under investigation. This product has not yet been identified in tissue extracts of test animals.

*Sulfamethazine*—Work in progress on the metabolism of sulfamethazine in swine, the

target animal of this study, is being condcuted through an interagency agreement at the Metabolism and Radiation Research Laboratory (MRRL) of the Regional Laboratory of the U.S. Department of Agriculture (USDA) at Fargo, North Dakota. Furthermore, tissue samples for the study of depletion kinetics in edible tissues of swine administered labeled sulfamethazine have been provided to MRRL under an interagency agreement with the Comparative Animal Research Laboratory (CARL) at ORNL. All analyses of swine tissues and excreta are being performed at MRRL.

Combustion analyses of tissues have been completed both for the "steady state" experiments at MRRL and for tissues from the depletion study supplied by CARL. The "steady-state" experiments involve analysis of tissues obtained 8 hours after the last dose from swine fed 115 ppm of $^{14}C$-sulfamethazine in two daily meals for 3, 5, or 7 days. Preliminary data on combustion analysis indicate that total radioactivity reaches a plateau in the tissues after five days of dosing.

For the depletion study, tissues from swine fed 115 ppm of $^{14}C$-sulfamethazine in two daily meals for 7 days were collected at 8, 24, 48, 120, and 240 hours after the last dose. Values for total radioactivity of tissues for common time points in the steady state and depletion experiments agree well. (CONTACT PERSON: Dr. J. McDonald)

*FY 1983 Program Plans*

*Gentian Violet*—It is anticipated that nearly all work on the metabolism of gentian violet will be completed in 1982.

*Sulfamethazine*—Metabolism studies on rodents are scheduled to begin at NCTR in July 1982. Purification and identification of major metabolites will be completed in FY 1983. Review of the swine metabolism work performed by MRRL will be performed at NCTR In FY 1983 upon receipt of the final report from MRRL supplying details on the identification and depletion of various metabolites of sulfamethazine from swine tissues.

In response to suggestions by Giera *et al*, that the glucopyranosyl derivative of sulfamethazine in swine tissue may be an artifact due to extraction or storage conditions, the proper control experiments will be initiated at MRRL. By spiking unmedicated swine tissues with $^{14}C$-sulfamethazine and comparing extracts of aliquots frozen at various time periods with the t=o sample, a quantitative determination can then be made of presumed artifactual formation of the glucopyranosyl derivative of sulfamethazine, earlier identified in swine at MRRL.

The present experimental protocol for the metabolism of sulfamethazine in rodents involves a 7-day dosing period with labeled compounds. To test the effect of possible enzyme induction and alteration by intestinal microflora of the sulfa drug on the metabolite profile in tissues, a preconditioning experiment is being proposed. The total radioactivity in tissues, and sulfamethazine metabolite profiles will be used to evaluate the effect of preconditioning or accumulation of metabolites in comparison to non-pretreated rats.

Because of the recent concern about the production of a transplacental mutagen from the interaction of nitrite with sulfanilamide it is proposed that *in vivo* and *in vitro* studies be undertaken involving the reactions of sulfamethazine with nitrite. Desaminosulfamethazine has been detected in swine tissues, and it now appears from work with the closely chemically-related sulfadiazine that nitrite is involved through formation of the intermediate diazonium ion followed by "reductive deamination."Treatment of sulfanilamide itself with nitrite under simulated acidic gastric conditions leads to the formation of a transplacentally mutagenic triazene resulting from condensation of the intermediate diazonium ion with sulfanilamide.

*In vivo* studies of the interaction of sulfamethazine with nitrite will comprise a variation of the preconditioning study in which nitrite will be administered to rats in drinking water. It is expected that the desamino-sulfamethazine accumulating in tissues will then be pulse labeled during the 7-day dosage with $^{14}C$-sulfamethazine. Nitrite will continually be provided in drinking water during this period. Tissues will then be analyzed for extractable desamino and triazene derivatives. Tissues will be analyzed for bound residues which may be expected to accumulate by interaction of cellular components with the chemically reactive deazonium ion intermediate. The importance of the desamino derives from the fact that the related desaminosulfadiazine is depleted very slowly from swine tissues.

Direct demonstration of the diazonium ion intermediate will be attempted *in vivo* through the use of a diazonium trapping agent such as 2-naphthol. Fischer 344 rats provided with nitrite in drinking water will be gavaged with a mixture of C-sulfamethazine and a trapping agent. Excreta will be collected and analyzed for the azo coupling product. A control will be run without trapping agent to check for any inhibition of labeling of tissues.

The contribution of intestinal microflora to the metabolism of sulfamethazine will be investigated by incubation of substrate in pure cultures and in cultures of mixed inocula from rat intestine. Pathways have recently been proposed for the conversion of 3,4-dichloroaniline to biphenyl, azo, and triazene derivatives through incubation with pure bacterail cultures in the presence of nitrate. The reaction requires reducing conditions. Sulfamethazine, a substituted aniline, will be incubated under anaerobic conditions with pure cultures and rat intestinal inocula in the presence of nitrite to test for similar reactions. Some attention will also be paid to the detection of these possible products in tissues of the test and target animals in the metabolism experiments. Investigations will continue into the possible N-ovidation of sulfamethazine to a reactive metabolite. (CONTACT PERSON: Mr. J. McDonald)

**Chemical Pathology**

**NIEHS**

The Chemical Pathology Branch is responsible for monitoring the quality of all aspects of anatomic and clinical pathology associated with studies conducted at NIEHS under the auspices of the National Toxicology Program (NTP). In addition the Branch provides histology, electron microscopy, and collaborative support to the Intramural Research Program (IRP) of the NIEHS. The Branch's research efforts are directed toward evaluating and developing short-term *in vivo* carcinogenesis assays and characterizing and defining specific lesions observed in bioassay studies. To accomplish its mission the Branch is composed of four integrated Sections: Tumor Pathology, Toxicologic Pathology, Experimental Pathology, and Histology and Electron Microscopy.

*Tumor Pathology*

The Tumor Pathology Section assures that pathology evaluation if NTP chronic bioassays is precise, accurate, and state-of-the-art. The major emphasis in FY 1982 has been on improving the quality of histological sections, standardizing tumor nomenclature and establishing uniform criteria for classification of neoplasms. In a workshop this past year, criteria for proliferative lesions of the pituitary, thyroid and adrenal glands were presented to Program pathologists. In FY 1983, workshops defining diagnostic criteria for lymphoreticular and pancreatic lesions will be held. In addition, there is more Program emphasis on non-neoplastic lesions than in past years.

*FY 1982 Accomplishments*

*Chronic Pathology Studies Reviewed*—During FY 1982, pathology reviews of 39 chronic bioassays were held (Table 18). Each chronic bioassays was given a quality assurance (QA) evaluation by an independent pathology laboratory; this included evaluation of the histotechnique, verification of computer tables with the original animal data records, verification of slide and tissue counts and the initial pathology evaluation of all target tissues and all tumors. The QA report with a list of differences of diagnostic opinion between the QA pathologist and the original (bioassay laboratory) pathologist(s) was sent to the Head of the Tumor Pathology Section who reviewed the report and selected members for a Pathology Working Group (PWG). A PWG consists of 4–6 pathologists, some of whom are selected because of research experience with lesions peculiar to the bioassay being evaluated. The PWG pathologists are affiliated with the NTP, industry and academia. The PWG members independently evaluate "blindly" those slides where diagnostic differences of opinion occur and attempt to arrive at a consensus diagnosis. If the consensus diagnosis is different from that of the original pathologist, the appropriate slides are returned to the original pathologist for re-evaluation. The original pathologist's re-evaluation becomes the final data of record. However, if it is significantly different from the PWG consensus, an additional set of pathology data may be included in the NTP Technical Report to reflect the PWG opinion. In most cases this is not necessary.

The PWG also has the responsibility of determining the overall quality of the

histotechnique and the initial pathologist's evaluation. If an undue number of deficiencies are noted, the study may be considered inadequate and a partial or complete pathology re-evaluation may be required before acceptance by the NTP.

The workings of the QA and PWG assure more accurate and uniform pathology arising out of chronic bioassays. PWG members are also helpful in assessing biological potential of chemically-induced lesions. The PWG chairperson submits a pathology narrative on each bioassay to the chemical manager incorporating PWG opinions on induced lesions plus a detailed pathological description of the pertinent lesions. This information is used in writing the NTP Technical Report. (CONTACT PERSON: Dr. G.A. Boorman)

*Tumor Nomenclature and Criteria*—In March 1981 a workshop on proliferative lesions of the pituitary, thyroid and adrenal glands was held for the Program contractor pathologists. The impetus for this workshop was that in most studies these lesions constitute a frequent source of diagnostic confusion. Speakers included NTP, contractor and academia pathologists. Following the workshop a slide study set of typical lesions with diagnoses and criteria were produced for each laboratory in the Program.

In three studies during FY 1982 pancreatic acinar cell lesions were found that appeared to be treatment related. Since it appears that some of these lesions may have been overlooked in the past because of their subtle nature, a complete review of the pancreases from control animals in six recently completed studies was undertaken with special emphasis on differences between untreated and vehicle control (corn oil) animals. Results of this study will be used for a future workshop for Program pathologists on rodent pancreactic lesions.

Proliferative pulmonary lesions of rats and mice are currently being reviewed for presentation and publication through the ISLAR series. Interest in this series of lesions was stimulated by the recently completed NIEHS inhalation study of asbestos in which a variety of lung tumors were found. (CONTACT PERSON: Dr. G. A. Boorman)

*Myelotoxicity/Immunotoxicology*—In collaboration with the scientific staff of the NIEHS/NTP Immunotoxicology section the Tumor Pathology section provided pathology support and myelotoxicity evaluation for several mouse studies (Table 19). Myelotoxicity evaluation included bone marrow cellularity, pleuripotent stem cell assay (CFU–S), macrophage granulocyte assays (CFU–GM) plus a measure of erythropoiesis ($Fe^{59}$ uptake). In addition to screening chemicals for myelo/immunotoxicity, efforts included methods development for evaluating and understanding mechanisms of myelotoxicity.

The results of a series of studies involving estrogenic substances (e.g., zearalenone and estradiol) were interpreted as indicating that these substances have a similar "A"-region to diethylstilbestrol (DES), and produce macrophage activation but not the DES myelotoxicity. In other studies estrogenic myelotoxic effects were reversed by progesterone and according to preliminary results an intact thymus may be required for expression of estradiol myelotoxicity.

Mice exposed to chrysotile asbestos had depressed bone marrow parameters at 2, 12 and 26 weeks following a three-day exposure. These mice also had enhanced IgA levels, analogous to humans with radiological evidence of asbestosis. While myelotoxicity has not been widely recognized in asbestos exposed patients, there is evidence that Canadian miners exposed to asbestos have depressed circulating leukocytes possibly due to myelotoxicity. *In vitro* exposure of pulmonary macrophages to asbestos results in prostaglandin E (PGE) release. PGE has a known negative feedback effect on the bone marrow. Based on these studies, the mouse model may prove useful in characterizing the nature of the immune dysfunction that has been reported to occur in asbestos exposed patients.

The subchronic (90-day) bioassay results for the NTP chemical, ochratoxin A, suggested a degree of bone marrow hypocellurarity consistent with myelotoxicity. To better characterize this chemical, it was included in the immunotoxicology program. In this study ochratoxin was shown to depress hematopoietic stem cell proliferation and antibody plaque forming cell response. (CONTACT PERSON: Dr. G. A. Boorman)

*Toxicologic Pathology*

The Toxocologic Pathology section assures the quality of pathology from acute and subchronic studies in mice and rats, established diagnostic nomenclature for toxicology pathology, and defines organ specific toxic lesions.

*FY 1982 Accomplishments*

*Prechronic Pathology Studies Reviewed*—During FY 1982, 63 bioassays were reviewed by the Toxicologic Pathology section (Table 20). Prechronic studies (usually 90-day duration) conducted under the prime contract are quality assessed by the prime contractor and reviewed by the Head of the Toxicologic Pathology section. Repeat dose (14-day) and prechronic studies on chemicals contracted and managed directly by NTP through a master agreement are quality assessed as described in the Tumor Pathology section. Attention is given to quality of histotechnique tissue counts, slide inventory, accuracy of diagnosis, and dosage recommendations for subsequent studies. These findings are then reviewed by the section head. Selected slides are put together for a Pathology Working Group (PWG), consisting of 3 to 4 pathologists and a chairperson, which reviews all discrepancies in diagnoses, major target organs, and selected spontaneously occurring lesions observed in the study. A report is then prepared by the section head describing the results of the PWG and interpretation of the study up to that point. Points addressed in the report include a narrative description of target organ lesions, differences in opinion between the initial pathologist and quality assessment (QA) pathologist, the quality of work performed by both the initial pathologist and the QA pathologist, and an assessment of the quality of histotechnique. Dosage recommendations are suggested based upon the results of the pathology portion of the study.

This extensive review of prechronic studies has resulted in better communication between the NTP and contract laboratory pathologists, more uniformity in the classification of toxic lesions, better clarification of NTP goals, more emphasis on descriptive pathology narratives, better monitoring of the quality of histotechnique at contracting laboratories, and revisions in the master agreement statement of work, where necessary. (CONTACT PERSON: Dr. C. A. Montgomery)

*Pathology Data Base for Prechronic Studies*—Historically, 90-day studies have not been entered into the computerized Carcinogenesis Bioassay Data System (CBDS) for retrieval purposes. Thirty-one prechronic bioassays have been identified that have been completed and have Individual Animal Data Reports (IADR's) in the repository. Summary tables of the incidence of neoplastic and non-neoplastic lesions from these studies will be generated under the CBDS contract. Pathology data from these 31 chemical studies were selected based on the following criteria:

(1) Positive (chemical effect) prechronic bioassay.

(2) Representation of several different laboratories.

(3) All bioassays were quality assessed.

(4) Very few changes made in the IADR's after review of the study.

Data generated from this project will be used for two specific purposes:

(1) Control animal data will be analyzed for the incidence of spontaneously occurring lesions in various organs, both neoplastic and non-neoplastic;

(2) Dosed animals will be analyzed for target organ specificity and evaluation of toxicologic pathology nomenclature used in prior studies. This latter information will be used to evaluate the Toxicology Data Management System (TDMS) micropathlogy glossary. (CONTACT PERSON: Dr. C. A. Montgomery)

*Cause of Death Project*—The National Toxicology Program has recently made a firm decision to determine th probable "cause of death" in chemical bioassays. One of the difficulties in this type of judgement is the problem of determining whether a neoplasm actually resulted in death or only contributed to the animal's demise. Pathologists in the Chemical Pathology Branch have recently taken the most common tumors of the Fischer 344 rat and B6C3F, hybrid mouse and categorized them based on high risk, low risk, or no risk of causing death. Using this data, members of the Biometry and Risk Assessment Program (NIEHS) will retrospectively examine studies and determine whether our knowledge of Tumor behavior in these rodent species is enough to prognosticate whether these tumors could kill an animal in a given time frame. (CONTACT PERSON: Dr. C. A. Montgomery)

*Toxicology Data Management System (TDMS)*—In 1981, a major decision was made to implement the Toxicology Data Management System (TDMS) in the NTP bioassay contract laboratories. At that time,

the pathology portion of this system was considered inadequate. The micropathology glossary, as it existed in July 1981, was primarily designed for the specific needs of the National Center for Toxicologic Research. To date, approximately 90% of the micropathology glossary has been rewritten and restructured. The system entails a build-a-block diagnosis concept, using base terms such as inflammation or degeneration with appropriate modifiers to describe these lesions. Lesions may be diagnosed by specific anatomic site down to subtopography. This should result in a more detailed data base of chemically-induced lesions for NTP studies.

The gross pathology portion of TDMS had not been developed prior to October 1981. An *ad hoc* committee composed of pathologists from academia, government, and industry met and developed the gross pathology glossary. Pathology forms and summary reports are nearing completion. TDMS has recently been implemented for the first time at one of the contractor laboratories. Tissues from the bioassay of C. I. Pigment Red 3 were evaluated microscopically using TDMS. It appears at this time that the micropathology glossary is adequate and the hardware, for the most part, is satisfactory.

The TDMS is presently being implemented in seven different laboratories. This will result in the establishment of a new data base for naturally occurring and chemically-induced lesions of the Fischer 344 rat and B6C3F$_1$ mouse. Retrieval of such data is not anticipated for at least one year. (CONTACT PERSON: Dr. C. A. Montgomery)

*Experimental Pathology*

The Experimental Pathology section develops and validates animal models for chemical toxicity and carcinogenicity, investigates the pathogenesis of lesions observed in toxicity and carcinogenicity studies, and develops and standardizes clinical pathology procedures for use in rodent studies.

*Fiscal Year 1982 Accomplishments*

*Strain A Mouse Pulmonary Tumor Validation Study*—During fiscal year 1982 data from strain A mouse bioassays for 60 chemicals were examined to determine if this short-term bioassay would identify carcinogenic chemicals. The initial conclusion is that the strain A mouse pulmonary adenoma model has limited utility for identifying chemicals which were carcinogenic in conventional rat and/or mouse two-year bioassays. Furthermore, there was poor agreement in strain A bioassay results on the same chemicals tested in two separate laboratories. The initial conclusions regarding this validation exercise were comprehensively reviewed when remaining test data were made available in September 1982. (CONTACT PERSON: Dr. R. R. Maronpot)

*Hepatocarcinogenesis Research*—A study is currently underway utilizing a short-term rat liver tumor model to investigate the 2-hit hypothesis of carcinogenesis. Following a single intraperitoneal dose of diethylnitrosamine (DEN), the population of initiated hepatocytes is expanded by promotion for two months with dietary phenobarbital. After a second dose of DEN, an expanded population of cells with prior initiation (1-hit) will be available for a second initiation (2nd-hit) ultimately resulting in a greater production of liver neoplasms, if the 2-hit hypothesis of carcinogenesis is operative. Stereologic measurements of phenotypically altered (γ-glutamyl transpeptidase positive) preneoplastic foci will be made in addition to documentation of hepatocellular neoplasms. In-life portions of this study were completed in October 1982. (CONTACT PERSON: Dr. R. R. Maronpot)

*Pathogenesis of Furfuryl Alcohol Toxicity*—As a result of unusual liver lesions observed in B6C3F$_1$ mice in the prechronic furfuryl alcohol study, a special study to investigate the pathogenesis of these lesions was carried out. Following a single intraperitoneal injection of furfuryl alcohol (3 dose levels), male and female B6C3F$_1$ mice were killed at several intervals. Liver, kidney, lung, heart and tissues were fixed for microscopic and ultrastructural study. Sera from these mice were submitted for clinical chemistry measurements and ultimate correlation with morphologic findings. Livers from mice in the furan study (3 dose levels) were also similarly tested for comparison with toxicity patterns and lesion progression elicited by furfuryl alcohol. Microscopic evaluation of tissues is underway. In addition to liver lesions, kidney lesions and unusual peribronchial lung lesions are being documented in treated rats. Completion of microscopic tissue evaluation and subsequent ultrastructural studies will be completed during the next year. (CONTACT PERSON: Dr. R. R. Maronpot)

*Ultrastructural Study of Lung Lesions Found in the Prechronic 2,3-Dibromo-1-propanol Study*—Enlarged bronchiolar lining cells were observed in several treated and control mice in the 2,3-dibromo-1-propanol prechronic study. Since this observation has been made in other mouse toxicity studies, it was important to identify these enlarged bronchiolar cells. Paraffin blocks of affected lungs from six mice were retrieved from the NTP tissue archives and processed for transmission electron microscopic examination. In most instances affected bronchioles were lined by contiguous Clara cells. (CONTACT PERSON: Dr. R. R. Maronpot)

*Fibrogenic and Carcinogenic Potential of Asbestos and Man-made Mineral Fibers*—A joint study on the fibrogenic and carcinogenic potential of chrysotile asbestos and man-made mineral fibers was conducted in conjunction with the Pneumoconiosis Research Unit, Medical Research Council (MRC), Penarth, Wales, United Kingdom. An additional objective of the study was to determine the comparability of results using the same protocol at two geographically different locations.

The basic protocol consisted of the exposure of male and female F344 rats to the fibers (inhalation chamber) for 6 hours/day, 5 days/week for 12 months. The rats were then held for lifetime observations. Interim kills were conducted after 3 and 12 months exposure and 12 months postexposure. Fibers studied at both facilities were UICC chrysotile B asbestos and microglass fiber (JM-100). In addition, short and long range (fiber length) chrysotile asbestos was studied at NIEHS while various types of rock wools were evaluated at MRC. The results of this joint study were similar at both facilities. Fibrosis and neoplasia occurred with the asbestos fibers but not with the microglass fibers. (CONTACT PERSON: Dr. E. E. McConnell)

*Clinical Pathology Studies*—Several clinical pathology base-line studies were carried out to provide data useful in the design and interpretation of clinical pathology portions of NTP toxicity studies. These base-line studies included: sequential bleeding, effect of decreased body weight gain on hematologic measurements in rats, effects of fasting and water deprivation on hematologic and clinical chemistry measurements in rats, effects of freezing and frozen storage of rat sera on clinical chemistry values, comparison of reticulocyte counts in young vs. old Fischer 344/N rats, and within-day and between-day precision studies for commonly measured analyses. (CONTACT PERSON: Dr. R. R. Maronpot)

*Histology and Electron Microscopy*

The Histology and Electron Microscopy Section is primarily a support facility providing services to both the Intramural Research Program (80%) and Toxicology Research and Testing Program (20%). The histology laboratory provides basic cutting and staining services and has limited capability for special stains and techniques. The electron microscopy laboratory also provides routine cutting and staining services. In addition it provides technical help in the use of electron microscopy and interpretation of these observations.

*FY 1982 Accomplishments*

During FY 1982 the histology laboratory supported 41 NIEHS scientists. In pursuing this effort the laboratory sectioned and stained a total of 28,464 tissues.

The electron microscopy laboratory supported 24 NIEHS scientists in their needs for ultrastructural examination of animal materials. (CONTACT PERSON: Mr. F. A. Talley)

**Chemical Pathology**

*Other FY 1982 Accomplishments*

The Chemical Pathology Branch developed a protocol which will significantly modify the amount of microscopic pathology required on future chronic bioassays. The current procedure requires that 42 sections from 32 tissues be examined microscopically from all animals that die during the bioassay and from those that survive the 104-week treatment period. Analyses of the results from previous NCI and NTP bioassays indicated that significant reductions in the number of tissues examined could be implemented without compromising the ability to detect chemically-induced tumors. Further, the quality of the toxicologic pathology could be markedly improved through examination of some animals at a time period earlier than 24 months, when normal aging lesions often interfere with the

detection and interpretation of chemical related lesions.

Based on discussions with the NTP Board of Scientific Counselors and expert consultants, NTP developed the following protocol:

1. *Interim evaluation*—Ten animals/dose/sex/species will be added to the design protocol. At 15 months into the chronic study, these animals will be sacrificed and evaluated as follows: (1) Organ Weights—liver, kidney, brain; (2) Chemical Pathology—including complete blood count and selected serum chemistry; (3) Complete necropsy of all animals; and (4) Complete histopathology (32 tissues) of the high dose and control groups, tracking to lower dose groups where indicated (same procedure used for the 90-day prechronic studies).

2. *Necropsy Evaluation*—All animals from all dose groups which die or are killed during and at the end of the experiment receive a complete necropsy examination. All tissues from animals from all dose groups will be preserved for possible histopathologic examination (same procedure as currently done).

3. *Histopathologic Examination*—Interim deaths (before 21 months of study) are subjected to a complete histopathologic examination (no change from current protocol). The remaining animals in the high dose and control groups receive an essential, yet limited, histopathologic examination (see below). Only selected tissues from animals in the lower dose groups will be examined histopathologically.

4. *Essential Histopathology*—Sixteen (female) or eighteen (male) organs or tissues (21–23 sections) from the remaining animals from the high dose and control groups are prepared and examined microscopically. Included are:

| | |
|---|---|
| Liver—left and right anterior lobe | Urinary bladder |
| Kidney—left and right | Spleen |
| Lung | Thyroid and Parathyroid glands |
| Brain—3 sections | Adrenal gland—left and right |
| Pituitary gland | Ovary/uterus |
| Pancreas | Testis/epidiymis |
| Heart | Prostrate/seminal vesicles |
| Stomach | Lymph node—submandibular |

Additional tissues examined microscopically include: Nasal cavity and turbinates (inhalation studies, 3 sections), skin (dermal study), all gross lesions detected at necropsy, and target organs identified in prechronic studies or in animals which died or where sacrificed during the two-year bioassay.

5. *Extended Histopathology*—Once the 16 or 18 organs are examined microscopically and pathologic effects are identified, tissues from all animals in lower dose groups are examined using the following convention: all gross lesions detected at necropsy; organs in which neoplasms were found significantly increased ($p < 0.10$) compared to controls; organs in which rare tumors were found even if the comparison with controls does not achieve the $p < 0.10$ level; and organs in which toxic lesions were observed.

6. *General Guidelines*—If the survival rate of the animals at the highest dose is decreased by 15% or more compared to survival of concurrent controls because of toxicity, then the next lower dose is used as the baseline for pursuing lesions examined microscopically in the high dose animals. If the decrease in survival is due to tumor related, deaths this caveat does not apply. Additional tissues will be examined at lower doses as deemed appropriate. Necropsy, trimming, and staining procedures are the same as those established in the current protocol.

When possible the pathologist should establish a *probable* cause of death. In animals with neoplasia, the pathologist should determine if the neoplasm could have been a *contributing factor* in the cause of death.

It is felt that the modified protocol will yield equivalent pertinent information to the previous protocol with regard to carcinogenic potential of a chemical. The inclusion of an interim kill at 15 months should permit a better delineation of chronic toxicity. The Quality Assurance review and the Pathology Working Group exercises will be conducted as currently practiced and should reveal deficiencies in pathologic interpretation. This new protocol is straight-forward and should be easily implemented in contractor pathology laboratories although a higher level of management on the part of the pathologist will be required. (CONTACT PERSON: Dr. E. E. McConnell)

*FY 1983 Program Plans*

*Pathology Review and Workshop Activites*—In FY 1983 Quality Assurance and Pathology Working Group functions will be continued for prechronic and chronic bioassays to maintain a uniform high quality of pathology for the Program. This workload will increase significantly over that of FY 1982 since a large number of bioassays are scheduled for completion during the next twelve months. A workshop dealing with rodent leukemias and lymphomas was held for contract laboratory pathologists in November 1982. The subject matter for a similar workshop in the spring of 1983 will be selected based upon Program needs.

*Tumor Combination and Interpretation Guidelines*—Uniform guidelines for combining and interpreting tumors which occur in chronic bioassays will be established in FY 1983 based upon imput from NTP pathologists and the NTP Board of Scientific Counselors. For specific organs where there is clear evidence of tumor progression, the benign and malignant tumors will be tabulated separately for statistical purposes and may be combined to more clearly delineate the carcinogenic potential of a given chemical. Guidelines for combining of tumors will also be established for biologically similar tumors that occur in the same organ such as fibromas and fibroadenomas of the rat mammary gland. Similarly, ground rules for documenting tumor multiplicity in a given organ and in paired organs will be established in FY 1983. Once these guidelines are established, recommendations will be made for how the various separate, combined and mutiple tumor frequencies should be interpreted for purposes of judging the evidence of carcinogenicity. (CONTACT PERSON: Dr. E. E. McConnell)

*Investigation of Use of Plastic Embedded Thin Sections*—During FY 1983 the feasibility and utility of using one-micron sections from plastic embedded tissues for better characterization of subtle renal and hepatic lesions will be determined.

*Investigation of Morphometric Analysis of Teased Nerve Preparations*—Since routine histologic procedures are relatively insensitive for assessing structural alterations in peripheral nerves, special procedures may be indicated for chemicals which are suspected of producing peripheral neuropathy. Morphometric analysis of tested nerve preparations and use of one-micron cross sections of nerves should permit detection of early structural alterations. Use of these special procedures will be investigated during FY 1983.

*Study of the Pathogenesis of Furan-Inducted Liver Lesions*—Using a sequential kill protocol, the development of furan-induced liver lesions in the rats will be investigated. This in-house study will include light microscopy, histochemistry, and clinical chemistry. Furan causes toxic liver changes with subsequent nodular regenerative hyperplasia. This regenerative hyperplasia has been interpreted by some pathologists to represent neoplasia. The proposed furan study will be designed to clarify the biological significance of the liver lesions. (CONTACT PERSON: Dr. R. R. Maronpot)

*Baseline Clinical Pathology Studies*—Clinical pathology studies to generate information useful in the design and interpretation of rodent toxicity bioassays will be continued during FY 1983. In addition, clinical pathology protocol guidelines and standard operating procedures will be developed for use in NTP contract laboratories.

*Investigation of Mechanisms of Carcinogenesis*—Through contactual mechanisms, an effort will be mounted to clarify the nature of the rodent liver tumor response frequently observed in two-year bioassays. Following refinement of short-term rat in vivo liver tumor models, selected chemicals will be tested for initiating and promoting activity. This is primarily a research rather than a testing effort.

During FY 1983 a collaborative in-house study using a short-term *in vivo* rat urinary bladder tumor model will be started to investigate the urinary bladder carcinogenic response associated with recently bioassayed chemicals. (CONTACT PERSON: Dr. R. R. Maronpot)

*Evaluation of the Reduced Pathology Protocol for Bioassays*—During FY 1983 results of the implementation of the modified pathology protocol for bioassays will undergo initial evaluation. Since final evaluation will require the completion of several chronic bioassays, the impact of this Program decision will not be realized for 3 to 5 years.

**Cutaneous Toxicology**

A common target for injury and disease, the skin serves as a route of entry for toxic chemicals present in drugs, cosmetics, the workplace and other environments. Within

NTP, research activities are focused on toxicologic assessments of the potential of chemicals for producing skin irritation, sensitization, and tumors, and on the ability of chemicals to enter the body through the skin. The latter aspect is of increasing concern where exposures may occur to chemicals which affect reproduction, growth and development, chemical carcinogenesis and neurotoxicity. Also being evaluated are the effects of repeated mechanical trauma to the skin. Chronic trauma is associated with disfigurement and breakdown in the barrier function of the skin.

*FY 1982 Accomplishments*

A working group was formed to identify and coordinate research activities within NTP and to determine future research needs. Interaction was initiated with the DHHS Ad Hoc Interagency Dermatology Working Group as a means of obtaining input from Government agencies outside of NTP and incorporating this information into future NTP planning and research activities. These activities will also serve to identify experts within and outside of NTP to participate in peer review of projects and manuscripts.

NIOSH

Research within NIOSH is focused on studying the extent and rate of dermal absorption of chemicals, and on evaluating the effects on the skin of chemicals found in the workplace. During the past year, design, construction and testing began on two methods for studying *in vivo* percutaneous absorption using small laboratory animals (hairless mouse). The methods involve a body-only exposure system to study the dermal absorption of gases and vapors and a second system for quantitatively assessing the rate and extent of absorption of volatile liquids which contact the skin. Initial experiments are being accomplished using benzene and carbon disulfide.

As part of NIOSH's Health Hazard Evaluation Program, Azamine T810, a tertiary amine used during solvent extraction of vanadium oxides, was evaluated for its ability to produce skin irritation and sensitization. When applied under a patch for 24 hours, the substance was found to be irritating to rabbit skin at concentrations as low as 0.1% (in 95% ethanol). When applied daily for twenty days to nonoccluded sites on the backs of guinea pigs the test substance was shown to be irritating at concentrations as low as 0.5% but not at 0.1%. Skin sensitization was not observed even at concentrations which were irritating to the skin.

To identify job categories and workers affected by chronic repeated mechanical insults to the skin, a report is being developed, under contract, which will provide an estimate of the extent of the problem. Potentially, the report will be used to focus on worker populations where a combination of skin trauma and chemical exposures may lead to increased disease or illness. (CONTACT PERSON: Dr. A. Susten)

NIEHS

NIEHS is investigating the carcinogenic and toxicologic properties of a number of chemicals following chronic applications to the skin of the Fischer 344 rat and $B6C3F_1$ mouse (Table 21). The ability of the flame retardant 2,2-bis(bromomethyl)-1, 3-propandiol (BMP) to be absorbed through the skin is being evaluated as part of that toxicologic protocol. Results will be compared with levels obtained during feeding studies.

The toxicologic properties of the psoralens with and without ultraviolet light are being studies in the Fischer 344 rat and HRA/skin hairless mouse. The FDA has recommended the study of psoralens because psoralen plus ultraviolet light (320–360 nm), commonly referred to as PUVA therapy, is a widely used treatment for psoriasis in clinical studies conducted by FDA, and systemic animal toxicology has not been performed. It is estimated that 1–3% of the world's population suffers from psoriasis, and in 1978 an estimated 35,000 Americans received this treatment.

The NTP program is investigating a variety of psoralens with different chemical formulas including the most widely used psoralen, 8-methoxypsoralen. These studies include mutagenicity, pharmacokinetics and metabolism, long-term bioassays, and effects of treatment on skin enzyme levels. During the past year the NTP has determined the dark and light DNA binding parameters of 8-methoxypsoralen and other related psoralens. This information will be correlated with the toxic response of animals to the psoralens, in order to determine the relationship between DNA interaction and mutagenicity and/or carcinogenicity.

As part of the psoralen program, the NTP sponsored a conference on the "Photobiologic, Toxicologic and Pharmacologic Aspects of Psoralens" on March 1–3, 1982 at NIEHS, Research Triangle Park, NC. The conference discussed various aspects of psoralens including: photobiologic properties; pharmacokinetics and pharmacodynamics; mutagenicity; carcinogenic and immunologic aspects of psoralen (PUVA) therapy; safety and therapeutic effectiveness; and the analytic aspects of psoralen activity. The proceedings of this conference will be published as a monograph by the *Journal of the National Cancer Institute*. (CONTACT PERSON: Dr. J. K. Dunnick)

*FY 1983 Program Plans*

NIOSH

Testing and validation of the two percutaneous absorption systems will continue. Due to the interest in the adverse reproductive effects of certain glycol ethers, the rates of dermal absorption of two glycol ethers, (ethylene glycol monoethyl ether and ethylene glycol monomethly ether), will be evaluated. Data from these studies will be correlated with the toxicologic and tissue distribution profiles currently being conducted by NIOSH. (CONTACT PERSON: Dr. A. Susten)

As a part of the chronic trauma initiative, a small workshop is planned for the spring of 1983. The workshop will bring together a number of international experts to discuss problems related to chronic mechanical trauma to the skin and provide insight into controlling or reducting these work-related hazards.

NIEHS

Research activities under the psoralen program will continue. Additional compounds to be tested by the skin route will be selected and tested. (CONTACT PERSON: Dr. J. K. Dunnick)

**Immunological Toxicology**

The immune system imparts host defenses, maintenance of homeostasis and surveillance, most notably against infectious agents or tumor development. Three classes of undesirable effects may potentially occur when the immune system is perturbed by advertent (e.g., drugs) or inadvertent (e.g., environmental pollutants) exposure to chemicals and include: (1) Those which result in immunodeficiency or suppression; (2) those which result in alteration of host defense mechanisms; and (3) those which result in induction of hypersensitivity or allergy either nonspecifically or directly against the chemical antagonist.

NIEHS

The primary objectives of the NIEHS immunotoxicology program are to select, refine and validate a panel of immunology and host resistance procedures to define immunotoxicity of chemicals and to correlate changes in immune function with changes in host resistance. The comprehensive assay panel which has been developed evaluates: (1) Host resistance to bacterial, parasitic and tumor cell challenges; (2) cell mediated immune functions; (3) humoral mediated immune functions; (4) macrophage functions; (5) natural killer cell activity; and (6) myelotoxicity.

In addition selected chemicals of environmental concern are being examined using this panel. Most of these chemicals are known or suspected human carcinogens and are examined to determine: (1) The carcinogenic-immunotoxic relationship; (2) structure-activity relationship; and (3) mechanism(s) of immunotoxicity. These studies are ultimately designed to better define immunotoxicity, determine no effect levels and obtain a data base for accurate assessment of human health risk.

*FY 1982 Accomplishments*

During FY 1982 several chemicals were examined for immunotoxicity in NTP intramural laboratories using our comprehensive panel. $B6C3F_1$ mice were exposed to mercuric chloride for 7 weeks in drinking water. Specific immunotoxic and biochemical alterations occurred in lymphoid organs of mice at dosages of mercury which did not induce other signs of toxicity such as altered liver enzymes, body weight or histopathology. The immunological defects were consistent with altered T-cell function as evidenced by deceases in both T-cell mitogen, mixed leukocyte responses, and T-cell mediated host resistance parameters. There was a particular association between the T-cell defects and inhibition of thymic pyruvate kinase, the rate limiting enzyme for glycolysis. The differences in the pattern of enzyme responses among lymphoid organs

implied that two mechanisms of mercury toxicity were operative—one at high concentrations that caused physiochemical enzyme inhibition and another at low concentrations that caused indirect enzyme inhibition. *In vitro* studies have established that mercury-induced immunotoxicity is due to binding of intracellular sulfhydryl groups since addition of cell-penetrating but not cell-impermeable sulfhydryl-containing compounds are capable of protecting the lymphocytes from mercury-induced suppression.

Several inhalation studies were also conducted in FY 1982 to determine the potential of inhaled pollutants to affect systemic immunity. The effects of chrysotile asbestos exposure on immune and bone marrow parameters were examined in mice at 2, 12, and 26 weeks following a 3-day exposure. Proliferation of bone marrow hematopoietic stem cells was decreased at all time periods. In general, immune alterations were not present in mice at one and three months following exposure but selected effects were found at five months. This correlated with histopathological findings where evidence of asbestos-related centriacinar pulmonary fibrosis and histiocytosis was first found at five months. Immune alterations included elevated numbers and enhanced activity of pulmonary alveolar macrophages and, as reported to occur in humans who develop asbestosis, increased antibody response and serum immunoglobulin (IgA) levels. These studies indicated that inhalation of asbestos fibers can produce delayed systemic immune alterations in mice. This mouse model should prove useful in characterizing the nature of immune dysfunction that has been reported to occur in asbestos exposed humans.

In other studies mice were exposed by inhalation to 1000 ppm of vinyl chloride for 30 days. Liver pathology (accentuation of the hepatic lobular patterns) was observed in treated mice which was consistent with known effects of high dose vinylchloride exposure. However, vinyl chloride exposure failed to alter immune function or host resistance.

In earlier studies, we reported that female mice treated with diethylstilbestrol (DES) developed severe thymic atrophy, profound suppression of lymphocyte function and activation of resident macrophages. A similar degree of effect can be obtained by treating mice with 17-$\beta$-estradiol at concentrations 10-fold higher than with DES. Administration of estrogenic mycotoxins (e.g., zearalenone) which possess "A"-region similarities to DES and estradiol induce a similar degree of macrophage activation as DES or estradiol, on a molar basis, without the concommitant suppression of lymphocyte responses or myelotoxicity. This functional disassociation can also be evident when examining response kinetics and functional inhibition by progesterone and various anti-estrogens. Furthermore, macrophage activation but not lymphocyte suppression can be reversed by thymectomy in adult animals prior to chemical treatment. These studies indicated a direct relationship exists between estrogenicity and suppression of lymphocyte activation. Thymic factors, however, appear related to macrophage activation which probably occurs through indirect mechanisms.

Several chemicals examined in FY 1982 were of interest because they appeared to have selective effects on the immune system. Systemic exposure to polyvinylpyrrolidone, like many maleic anhydride-vinyl ether copolymers, activated peritoneal macrophages, induced interferon, and enhanced antitumor activity in the B16F10 transplantable tumor model, but only at high doses. In preliminary studies, ochratoxin (from *Aspergillus ochraceus*) selectively affected hematopoietic stem cell proliferation and antibody plaque forming cell responses. Ochratoxin-producing fungi are widespread in nature and are termed the "storage fungi." (CONTACT PERSON: Dr. M. Luster)

Several of the procedures selected by the immunotoxicology program are being employed by contract laboratories to examine suspect immunotoxic chemicals. The abbreviated assay panel has been implemented in the prechronic testing phase of NTP's chemical bioassay program. These procedure are only performed in those bioassay contract laboratories which have demonstrated competence by the performance criteria specified in the immune assessment protocol and which have prior approval of the immunotoxicology program. (CONTACT PERSON: Dr. M. Luster)

In FY 1982, NTP held a conference/wordshop at NIEHS entitled "Immunologic Hypersensitivity Resulting from Exposure to Environmenal Agents." A multi-disciplinary group of over 85 scientists and clinicians were brought together for this conference. The objectives of this program were as follows:

(1) To evaluate the present state of knowledge regarding the role of environmental pollutants in allergic and sensitivity reactions;

(2) To discuss animal models and clinical methods for detecting hypersensitivity to environmental chemicals;

(3) To discuss epidemiological and clinical data regarding the extent of environmental and occupationally-induced allergy and hypersensitivity reactions; and

(4) To identify research needs in this important area of immunotoxicology. (CONTACT PERSON: Dr. M. Luster)

A collaborative agreement for immunotoxicology methods development and validation is in progress between NTP participating agencies. During the past year the Microbiology Division of the FDA has been involved in the quantitation of lymphokines, particularly interferon, as well as evaluating *in vitro* antibody assays for examining immunotoxic chemicals. These assays are being correlated with host resistance challenge models being used at NIEHS. (CONTACT PERSON: Dr. M. Luster)

In February 1981 two research and development contracts were awarded to the Medical College of Virginia and the Illinois Institute of Technology Research Institute. In FY 1982 the contract laboratories validated and further refined the immunological procedures used to examine suspect immunotoxic chemicals. Furthermore, substantial progress has been made in developing sensitive and reproducible host resistance assays using prototype immunotoxicants, including diethylstibestrol, cyclophosphamide and dexamethasone.

*FY 1983 Program Plan*

Emphasis in the NTP immunotoxicology program will continue on methods development and validation, correlations between changes in immune function parameters and altered host resistance, development of virus challenge models, and examination of the mechanisms of immunotoxicity for the projects described. NTP contract laboratories will continue the interlaboratory immunology methods validation. (CONTACT PERSON: Dr. M. Luster)

**NIOSH**

*FY 1982 Accomplishments*

A study was initiated in FY 1982 to determine if inhaled isobutylnitrite will induce suppression of the immune system in a widely used inbred mouse model. Male and female BALB/c mice were exposed to the maximum tolerated concentration of isobutylnitrite vapor (6 hr/day, 5 days/wk for 12 weeks) to evaluate effects of this chemical on the immune system. Mice will be sacrificed after 3, 6, and 12 weeks of exposure. The immunosuppressive effects of isobutylnitrite will be evaluated at each sacrifice using both *in vivo* and *in vitro* tests. Data generated in this study will have a significant impact on recently reported occurrences of immunosuppression expressed as opportunistic infections and Kaposi's sarcoma in persons who have used alkylnitrites, including isobutylnitrite, as chemicals of abuse. (CONTACT PERSON: Mr. D. Lynch)

**Neurobehavioral Toxicology**

The central nervous system has evolved as a highly specialized organ designed to accept signals from the internal and external environments and to initiate metabolic and behavioral responses of the total organism appropriate to its survival. The complex structure and function of the brain and the need for it to be simultaneously protected from and responsive to the environment make this organ uniquely susceptible to environmental insults. Behavioral and neurologic alterations in response to environmental pullutants often represent the earliest manifestations of toxicity in animals. Thus, neurobehavioral test systems must be developed further and chemicals must be tested for neurobehavioral effects.

The NTP neurobehavioral program involves the formation of a strategy for the development, standardization, and validation of neuobehavioral screening tests. Such a test battery would provide a general indication of the presence of neurotoxicity and would possibly indicate the type of nature of neurotoxicity in terms of neurobehavioral function that may be affected. Known representative neurotoxicants are studied using the test battery to determine the level of sensitivity and selectivity of each component test. This battery with continuing refinements is used as part of the general

toxicology screen and in the prechronic phase of the two-year toxicology and carcinogenesis bioassay. Additionally, there will be continued development and evaluation of human neurotoxicity tests to be used at the worksite or in the laboratory.

An additional objective is the development of a test capability for more extensive in-depth toxicological characterization of selected chemicals either identified in preliminary neurobehavioral screening or which are of public health concern, and including behavioral teratologic evaluation.

**NIEHS**

*FY 1982 Accomplishments*

*Neurobehavioral test battery*—The NIEHS laboratory completed the standardization and validation phase for a neurobehavioral test battery to be used in subchronic studies with rats. The results of this work have been submitted for publication. The battery was designed to detect the presence of sensorimotor deficits, to provide information concerning the neurobehavorial function that is affected, and to yield an estimation of relative overall toxicity for several chemical agents. The test battery was validated using known neurotoxicants (acrylamide, arsenic trioxide, chlordecone, monosodium salicylate, methyl mercury, lead acetate, tetraethyl tin, and triethyl lead). (CONTACT PERSON: Dr. H. Tilson)

*Neurobehavioral Effects—Mature Animals*—In research on the neurological effects of 2,4-dichlorophenoxyacetic acid (2,4,-D), rats exposed repeatedly to various doses of 2,4-D were found to display a progressive alteration in neuromuscular function. The effect was dose- and time-related and followed either subcutaneous or oral administration. The neurological effects of 2,4-D were reversible. Other signs of neurotoxicity (i.e., tremor, convulsions, hyperexcitability, etc.) were not observed.

Research on chlordecone (Kepone®) continued during FY 1982. Chlordecone is a polycyclic chlorinated hydrocarbon insecticide known to produce hyperexcitability, tremor, and cognitive deficits. One of the most prominent effects of chlordecone toxicity is tremor. An animal model was developed to study the mechnanism of this neurological effect. Chlordecone-induced tremor in rats was quantified and found to be dose- and time-related. Subsequent experiments with pharmacological challenges have suggested that chlordecone-induced tremor has spinal and supraspinal origins. More importantly, chlordecone-induced tremor appears to be mediated, at least in part, by gabaminergic mechanisms. Additional studies are underway to determine more precisely the site of action of chlordecone.

Other studies done with chlordecone in mature animals have indicated that it has marked neurohumoral effects. Exposure to chlordecone was found to disturb the balance of the hypothalamic-pituitary-adrenal axis, possibly by producing a massive release of steroids which elicits associated feedback mechanisms. (CONTACT PERSON: Dr. H. Tilson)

*Neurobehavioral Effects-Developmental Period*—Research in FY 1982 continued to emphasize the effects of chlordecone on developing animals. Perinatal or neonatal exposure to chlordecone was found to produce a decrease in serum and adrenal steriods when measured in exposed animals during adulthood. These changes in neurohumoral status appear to be associated with alterations in behavioral reactivity as measured by several neurobehavioral procedures. (CONTACT PERSON: Dr. H. Tilson)

*FY 1983 Program Plans*

Research planned or proposed in FY 1983 will continue to emphasize chlordecone. Experiments to localize the site of tremor induced by chlordecone are currently underway. In addition, more studies on the nature and extent of neurobehavioral dysfunctions following developmental exposure are planned.

Work has been initiated to develop automated procedures to assess toxicity in animals using naturally occuring domiciliary behaviors, such as spontaneous motor activity and ingestive related behaviors. One of the first signs of chemical toxicity is loss of body weight and alterations in locomotor movements, and it is predicted that alterations in the diurnal cycle or pattern of home cage behaviors may precede overt signs of toxicity. Over the next three years, plans are to develop a monitoring system and evaluate six chemicals (acrylamide, arsenic, chlordecone, methyl mercury, tetraethyl tin, and triethyl lead) in a chronic repeated dosing paradigm. (CONTACT PERSON: Dr. H. Tilson)

**NIOSH**

*FY 1982 Accomplishments*

*Human Studies*—During FY 1982, NIOSH conducted on-site testing of persons employed as structural fumigators who were using methyl bromide as a fumigant. A total of 156 fumigators and unexposed control persons from 36 companies and two California state agencies participated in a two-hour test battery at 11 sites in California. Symptoms of acute and subchronic methyl bromide poisoning that were assessed included neuromotor (coordination, weakness, tremor), sensory (vertigo, paresthesia, vision) and cognitive effects.

In addition, a review of test methods used to characterize neurotoxicity in human worker populations and a critical review of previous worksite studies were completed and will be published as chapter in upcoming books on neurotoxicology.

*Animal Studies*—Behavioral studies were completed which compared animals exposed to triorthocresyl phosphate and acrylamide. New methods of neurobehaviorial evaluation were evaluated in these studies. Classical teratological studies of four glycol ethers were completed in preparation for behavioral teratological studies intended to characterize the structure activity relationships within this class of chemicals. (CONTACT PERSON: Dr. W. K. Anger)

*FY 1983 Program Plans*

NIOSH proposes to continue evaluation and development of human neurotoxicity tests to be used at the worksite as well as validation of tests of reflex activity in animal and human laboratory studies. A new 4-person human test laboratory for experimental inhalation exposures will be brought on line to test for acute effects of methyl ethyl ketone, methyl isobutyl ketone, and acetone. The data obtained will be used to develop more accurate Short Term Exposure Limits (STELS).

Workers using carbon tetrachloride/carbon disulfide mixtures for commodity fumigation will be evaluated with neurobehaviorial tests at the worksite (pending the results of a contract effort characterizing the extent of exposures and work patters in such jobs).

Work in behaviorial teratology will complete characterization of structure activity relationships of cellosolves with a behaviorial/neurochemical analysis of ethylene glycol monomethyl ether. Animal experiments will also be directed toward developing structure/activity relationships of straight-chain carbon compounds using tests of reflex response following acute and subchronic exposures to select compounds. (CONTACT PERSON: Dr. W. K. Anger)

In 1983, NIOSH will co-sponsor, with the World Health Organization (WHO), an international workshop on the subject of neurotoxicology. The meeting will be held in Cincinnati, Ohio, and will emphasize the needs of developing countries. The product of the workshop will be a WHO monograph that describes the current state of knowledge in neurotoxicology, with recommended actions that will prevent working populations from experiencing illness due to neurotoxic chemicals.

**ORTHO Phthalic Acid Esters—Safety Evaluation**

The results of two-year bioassays recently reported by the National Toxicology Program (NTP) have identified di(2-ethylhexyl)phthalate (DEHP) and di(2-ethylhexyl)adipate (DEHA) as hepatocarcinogens in rodents. A third compound tested by the NTP, butyl benzyl phthalate (BBP), increased the incidence of myelogenous leukemia in female rats, an effect judged to be of equivocal biological significance. BBP was not demonstrated to be carcinogenic in mice, while the test in male rats was inadequate because of early BBP-induced deaths. The detection of carcinogenic effects of DEHP and DEHA in rodents has stimulated interest in the chronic toxic potentials of phthalate esters and related chemicals, many of which are used in plastics or for other purposes that results in extensive human exposures. Recognizing the technical and economic importance of phthalates and the limited scientific basis for extrapolating rodent bioassay data to human health effects, the NTP continues to study the deleterious effects of DEHP and to probe the mechanisms of action of phthalates. In addition, the NTP continues to evaluate the toxic potentials of several other phthalate esters, both individually and in a comparative manner.

The NTP is aware of the testing of phthalate esters currently being conducted by several independent, governmental and private organizations, including a

comprehensive class study by the Chemical Manufacturers Association.[1] Some of these programs were discussed publicly at the recent Conference on Phthalates.[2] The sets of studies described herein are intended to be complementary both to previous NTP studies and to the endeavors of other groups. Of primary interest to the NTP at the present time is an assessment of the mechanisms, dose response relationships and species-dependencies of toxic responses to DEHP, parameters relevant to predicting human response to various levels of DEHP exposure. Of secondary interest are structure-activity correlates that would indicate the relative propensities of similar chemicals to produce "DEHP-like" toxic effects.

The major areas of planned study—DEHP genotoxicity, mechanisms of DEHP carcinogenicity, reporductive toxicity, characteristics of dermal absorption and the carcinogenic potentials of diallyl-, diethyl- and butyl benzyl phthalates—are described below.

*Genotoxic Potential*—The lack of mutagenic response of DEHP in several systems indicates little value for such tests in predicting the carcinogenic potentials of other phthalates in rodent bioassays. One plausible theory of DEHP carcinogenicity is that DEHP-induced proliferation of hepatic peroxisomes (a subcellular organelle) results in the increased presence of hydrogen peroxide or hydroxy radicals. Such reactive molecules could injure both genetic and non-genetic cellular materials. Peroxisomes are not present in 9,000xg liver supernatant fractions (S9) or other mammalian activating systems commonly used in mutagenicity assays. Moreover, the DEHP-induced peroxisomes may differ functionally from normal peroxisomes. The following experiments, therefore, have been designed to incorporate peroxisomal influences into an assessment of the genotoxic potential of DEHP:

(1) Measurement *in vitro* of unscheduled DNA synthesis after single and repeated *in vivo* exposures of female rats to DEHP using the *in vivo/in vitro* hepatocyte primary culture [HPC] unscheduled DNA synthesis [UDS] assay;

(2) Cytogenetic analysis (chromosomal aberrations and sister chromatid exchanges in bone marrow) in B6C3F, mice after repeated (approximately two weeks) treatment with DEHP;

(3) *In vitro* cytogenetic analysis (Chinese hamster ovary cells) in the presence of a DEHP-induced peroxisome-enriched liver fraction.

*Mechanisms of Carcinogenicity*—In the absence of a probable mechanism of carcinogenic action it is prudent to assume a linear relationship between chemical dose and the occurrence of tumors. Development of neoplasia, however, can also be influenced by chemical effects other than direct malignant transformation, and such effects may occur at exposure levels that greatly alter normal anatomical, biochemical or physiological interrelationships. Recognized biological effects of DEHP, in addition to hepatocarcinogenicity, include hypolipidemia, enzyme inhibition, peroxisome proliferation and pituitary hypertrophy (male rats only). The relationships of these effects to the toxic manifestations are unknown. To study the dependencies of toxic response on biochemical or physiological abnormalities, the NTP will conduct a subchronic feeding study in rats and mice at various doses of DEHP, including those which have produced liver tumors. Among the parameters measured will be circulating concentratjons of several pituitary hormones, serum lipids, peroxisomes (visual enumeration and enzyme activities), and oxidative injury to the liver. Dose-dependent damage to DNA *in vivo* will be assessed if studies in the HPC/UDS system (see Genotoxic Potential) indicate the DEHP can produce this type of lesion.

The NTP will also attempt to reproduce the hepatic effects of DEHP, *in vitro* with cultured hepatocytes, and to use this system for interspecies comparisons.

*Reproductive Toxicity*—The teratogenic actions of dietary DEHP in rats and mice will be defined, as well as the potential for neonatally-administered DEHP to produce morphological or behavioral abnormalities. Further studies in a single species will define structure-activity relationships and evaluate possible mechanisms of action.

The chemosterilizing effects of DEHP and the potential for dominant lethal mutations in germ cells will be studied in male rats and mice administered multiple doses in the diet. The relationships of zinc and possible endocrinological abnormalities to the development of the gonadal lesions will be evaluated.

*Dermal Absorption*—A paucity of information on the rate and extent of dermal absorption of phthalate esters complicates the extrapolation of toxic response data from feeding or gavage studies to dermal exposures. Therefore, the NTP will conduct a cursory study of dermal absorption by monitoring urinary and fecal excretion of radioactivity following dermal application of radiolabelled phthalate esters. The excretion of intravenously-administered compounds will be measured for comparative purposes. Structure-absorption characteristics will be evaluated by the use of the following phthalates:

| | |
|---|---|
| phthalic acid | di-n-hexyl phthalate |
| dimethyl phthalate | di-n-octyl phthalate |
| diethyl phthalate | di(2-ethylhexyl)phthalate |
| di-n-butyl phthalate | diisodecyl phthalate |
| diisobutyl phthalate | butyl benzyl phthalate |

In addition, the dermal absorption of mono(2-ethylhexyl)phthalate, mono-n-butylphthalate and benzyl phthalate will be studied to determine the effects of ester hydrolysis on skin absorption.

*Carcinogenicity Bioassays*

1. Butyl benzyl phthalate (BBP)—The subchronic feeding study in male Fischer 344 rats will be repeated with emphasis on determining the cause of early deaths in the previous study, and on an assessment of reproductive function. The dose-dependent disposition and metabolism of BBP in rats will be studied to more appropriately correlate toxicity with pharmacokinetics and to ascertain amounts of the metabolites, n-butanol and benzyl alcohol, released (the latter chemical is currently in a chronic bioassay).

A chronic carcinogenicity bioassay of BBP in male rats will be initiated subsequent to an adequate subchronic study.

2. Diallylphthalate—A chronic bioassay in mice is currently being interpreted, while that in rats is nearing completion. Pharmacokinetic studies in mice and rats will be conducted to assess the possible implications of metabolism of diallylphthalate to known carcinogens or mutagens (allyl alcohol, acrolein, various epoxides) and to provide a reasonable basis for species differences in toxic responses.

3. Diethylphthalate—A chronic carcinogenicity bioassay by dermal exposure will be initiated. Tests for initiation and promotion of skin tumorigenesis may be included in this assessment.

**Pulmonary Toxicology**

It is widely recognized that inhalation is the most important means of toxic exposure both occupationally and environmentally. This importance is evident when consideration is given to the uniquely extensive surface area ($80m^2$ in man) of the pulmonary system that is brought into intimate contact with any agent having a positive vapor pressure or in an aerosolized state. As a result, the lung is frequently the target or organ of entry for a wide variety of air-borne toxicants. Currently, epidemiologists are finding that pulmonary dysfunction is a principal predictor of mortality resulting from pulmonary and non-pulmonary disease. It is reasoned that pulmonary dysfunction leads to increased accumlation of toxicants and thereby acts as initiator, promotor, or cofactor in the pathogenesis of numerous diseases. Hence, the evaluation of toxicants by the inhalation route of exposue and the toxicologic evaluation of the structure and function of the lung are of critical importance.

One of the objectives of the NTP program in Pulmonary Toxicology is to compare pulmonary function and pathologic indices as predictors of pulmonary function in animal species—tests of mechanical properties, gaseous distribution, static and dynamic lung volumes, distribution of inspired air, and more recently, ventilatory performance. A key issue in the decision to perform pulmonary fuction testing for detection of toxicity to the lung from inhaled substances is whether such tests provide any additional toxicologic information beyond the pathologic evaluation of lung injury. Pulmonary function tests must be reproducible, sensitive, specific, and capable of large-scale utilization if they are to be used effectively in the diagnosis of early and subtle pulmonary lesions in experimental animal models for chemically-induced pulmonary disease in humans.

[1] Phthalate Esters. Voluntary Test Program under Section 4 of the Toxic Substances Control Act. Chemical Manufacturers Association, Washington, DC, 1981.

[2] Conference on Phthalates. Washington, DC, June 11-13, 1981.

**NIOSH**

*FY 1982 Accomplishments*

*Effects of Chemical on the Pulmonary System*—In FY 1982 studies continued at the Brookhaven National Laboratory (BNL) assessing the potential role of pulmonary fuction tests in the evaluation of airborne agent toxicity and relating fuctional changes to observed pathologic and lung compositional changes. Two further products from the study of the effect of subchronic multidose ozone exposure in rats were delivered. A "Statistical Addendum to: Sixty-two Exposure Day Study in Fischer 344 Rats Exposed to Three Concentrations of Ozone (BNL Informal Report No. 29084)" was completed. Secondly, results of the study were presented at an International Oxidants Conference (Pinehurst, NC, March 14–18, 1982). The data presented centered on the pulmonary functional, structural, and compositional findings of the BNL-NTP study.

A final report was received from BNL describing biologic responses in Fischer 344 rats exposed at 0.0, 04, 1.2 or 4.0 ppm acrolein for 6 hours/day, 5 days/week for 62 days. Responses were dramatic at 4.0 ppm—32 of 57 exposed males died, weight gain was depressed, bronchiolar epithelial sloughing and necrotic lesions were observed, focal pulmonary edema was present, increased lung dry weights, and substantial decrements in pulmonary function occurred. While the pulmonary function of the 4.0 ppm group suggested an obstructive lesion, the data from the 0.4 group indicated a restrictive lung lesion; pulmonary function of the 1.2 ppm grup was between that of the low and high-dose groups and was nearly identical to that of control animals.These data suggested the development of two functional lesions exhibiting distinctly different effects on the pulmonary function measurements. The physiologic impairment in animals exposed to 0.4 ppm was not morphologically evident upon histopathologic examination. Increases in lung weight were due to increased cellularity, lung connective tissue, elastin and hydroxyproline content. No reproductive or clastogenic responses occurred under these acrolein exposure conditions. These data were presented in three poster sessions at the 1982 society of Toxicology meeting in Boston, Mass. (Feb. 22–26, 1982).

Data analyses are underway on rats exposed intermittently at 0.0, 0.5, 1.5 and 5.0 ppm chlorine. Pathologic examinations show that these subchronic exposures did not result in significant exposure-related respiratory lesions in Fischer 344 rats. subtle tracheal changes including loss of cilia and focal erosion of the epithelium were observed in the 5.0 ppm group. Such changes will be examined further to determine if they are related to chlorine exposure in a dose dependent manner.

Exposure of rats to silica dust (MIN-U-SIL 5) was initated on Feb. 1, 1982. The dust atmospheres were generated by fluidizing bed generators. Groups of Fischer 344 rats were exposed to either filtered air, 2, 10, or 20 mg $SiO_2 m^3$ for 6 hours daily, 5 days per week. Exposures were for 127 workdays with interim and final pulmonary function testing; a portion of the rats are being held for six months following exposure and then will be assessed (CONTACT PERSON: Dr. T. Lewis)

Chronic effects of ethylene oxide and propylene oxide on pulmonary fuction parameters of monkeys were evaluated. Some individual subjects showed mechanical and ventilatory dysfunction. The data are currently being analyzed statistically. (CONTACT PERSON: Mr. W. Moorman)

Comprehensive pulmonary function testing is being conducted in both monkeys and rats chronically exposed to diesel exhaust, coal dust and an equal mixture of the two. Preliminary findings denote several physiologic responses characteristic of chronic obstructive airway disease (coal dust exposures) and restrictive lung disease (diesel particulate exposures). These data are being analyzed statistically to validate these observations. Two species are being studied to assess the potential differences which may relate to the anatomical and physiological features unique to each specie. (CONTACT PERSON: Dr. T. Lewis)

The two most common methods of producing forced vital capacity maneuvers in anesthetized subjects will be compared for sensitivity in detecting obstructive impairment in rats. Initially, flow and volume differences will be evaluated in control rats to characterize specific differences relatable to the test methods. Then, rats serially impaired with elastase (at IT 6 units and 12 units) will be tested by each test method. Evaluation of method defferences and sensitivity will lead to better animal model systems for obstructive lung disease in man. (CONTACT PERSON: Mr. W. Moorman)

*Animal Model of Occupational Asthma*—During FY 1982, a monkey model of human occupational asthma, first developed in 1980, was further characterized. Efforts included the evaluation of dose-response relationships of exposure and the significance of co-asthmagenic irritant/oxidant exposures on the severity and incidence of the disease. The significance of pre-exposure airway status was evaluated by methacholine dose-response investigations. The primate model was used for passive cutaneous anaphylactic evaluations identifying a heretofore unidentified sensitivity to palladium in platinum refinery workers. Current research is directed towards assessing the fact that pharmacologic (versus immunologic) hypersensitivity may play an important role in the development of clinical symptoms in the occupational setting. During FY 1982, a paper was presented before the Federation of American Societies for Experimental Biology entitled "Passive Transfer in the Monkey of Human Immediate Hypersensitivity to Complex Salts of Platinum and Palladium". (CONTACT PERSON: Mr. W. Moorman)

*Other Studies*—A draft final report has been prepared which characterized toxicological effects of fibrous glass in rats and monkeys during long-term inhalation exposure. Four fiber geometries were evaluated with varying diameters and fiber lengths. Findings indicate minimal physiologic changes and no fibrogenic or carcinogenic pulmonary responses. The most severe pulmonary lesions were observed in the group exposed to short length microfibers. A significantly increased incidence of Fischer rat leukemia was also observed among all fiber exposed rats. (CONTACT PERSON: Mr. W. Moorman)

*FY Program Plans*

*Effects of Chemicals on the Pulmonary System*—Experiments to assess the relative sensitivities and specificities of pulmonary pathology and pulmonary physiology will be continued in FY 1983. Data collection and analysis will continue on the crystalline quartz study. Other compounds for study include (1) Cadmium chloride and (2) tungsten carbide, with and without concomitant inhaled cobalt exposures.

Evaluation of pulmonary function in rats and monkeys exposed to diesel exhaust, coal dust and combined diesel exhaust/coal dust at airborne concentrations of 2 $mg/m^3$ respirable dust will continue. These studies, coupled with epidemiological and industrial hygiene surveys of coal mines utilizing diesel equipment, will provide a compreshensive and integrated assessment of respiratory and other health hazards posed by diesel exhaust emissions. (CONTACT PERSON: Dr. T. Lewis

*Animal Model of Occupational Asthma*—There will be further assessment of the allergic and pharmacologic aspects of occupational lung disease. Exposures to vanadium pentoxide in combination with ozone will be performed to investigate the potential of $V_2O_5$ to induce asthma. Screening of organic allergens, e.g., those of agricultural origin, for activity in the model will be initiated. (CONTACT PERSON: Mr. W. Moorman)

**NIEHS**

The research program of the inhalation toxicology group of the NIEHS/NTP is divided into three areas: (1) Studies in cardiac toxicology using isolated perfused hearts and other cardiac tissues, (2) studies of the carcinogenic potential of simultaneous exposure to nitrogen dioxide and nitrosatable amines, and (3) a project identified as the inhalation toxicology of environmental chemicals, which currently includes a study of the effects of exposure profiles with time-varying concentrations on expressions of inhalation toxicology as well as a study of the vascular toxicology of carbon disulfide. (CONTACT PERSON: Dr. E. Van Stee)

**Reproductive and Developmental Toxicology**

The number of chemicals being evaluated for effects on reproductive function and development has increased significantly during FY 1982. This increase is due to the development of several new shorter-term test procedures that are being evaluated as potential screening tests. In one case, this has involved incorporation of reproductive endpoints into the prechronic bioassay to obtain additional information on animals already being studied for spectrum of toxic effects. This approach allows the testing of a much larger number of chemicals and priority-setting for more in-depth study of those chemicals which present a significant risk for human exposure. Thus, resources within the program are being used most efficiently, and eventually will provide for the ability to address questions about the magnitude of problems in reproductive and

developmental toxicology and about mechanisms of action.

*FY 1982 Accomplishments*

The Coordinating Group, made up of representatives from NCTR, NIEHS and NIOSH, met quarterly to review activities within the individual groups regarding reproductive and developmental toxicology, to select appropriate chemicals for evaluation of new test procedures, and to plan further efforts for addressing the needs in this program area. Information on studies which are completed or underway is currently being entered into the NTP computer tracking system.

The shorter-term testing approaches developed in FY 1981 for both reproductive and developmenal toxicology are now being evaluated. These include Fertility Assessment by Continuous Breeding, the Sperm Morphology and Vaginal Cytology Assay, the Short-Term *In Vivo* Reproductive Toxicity Assay, and *In Vitro* Teratology Test Development.

*NCTR Accomplishments*

*Conventional Teratology Testing*—The routine teratologic evaluation of chemicals has continued on contract in FY 1982 and a number of studies were completed or are still in progress. Testing is in progress on 9 chemicals, and evaluations were completed on 8 chemicals (Table 22). Data on the sulfamethazine study which showed teratogenic effects at doses below those producing maternal toxicity were presented at the Teratology Society meeting in June, 1982. A few of the conventional teratology studies are being followed up with postnatal functional studies, including a behavioral teratology study on diphenhydramine hydrochloride and behavioral and reproductive function studies in mice and rats on di(2-ethylhexyl) phthalate. Chemical selection for FY 1983 is in progress. (CONTACT PERSON: Dr. C. Kimmel)

*Collaborative Behavioral Teratology Study*—Methods are being evaluated for the behavioral assessment of postnatal animals following prenatal chemical exposure. A standardized protocol is being tested in the collaborative behavioral teratology study. The six behavioral tests in the protocol are being evaluated for reliability within and between five separate laboratories (two academic, two private, one government). The sensitivity of the tests is also being evaluated following exposure to two known positive behavioral teratogens (d-amphetamine sulfate and methylmercuric chloride). The laboratories began the study on d-amphetamine in October, 1981, and completed this study in July, 1982. The methylmercury study began in July, 1982. The intramural pilot study on d-amphetamine is completed and results were presented at the Teratology Society meeting, June, 1982. (CONTACT PERSON: Dr. C. Kimmel)

*In Vitro Teratology Test Development*—The proceedings of the consensus Workshop in *In Vitro* Teratogenesis Testing will be published as a separate issue of *Teratogenesis, Carcinogenesis, and Mutagenesis* (982). The proceedings include an overview of the workgroup discussions as well as a description of individual assay systems. The specific questions that were addressed and discussed at the workshop focused on validation criteria, and the overview focuses on the current state of our knowledge relative to the development of *in vitro* tests as indicators of teratogenic potential. The definition and discussion of many points including acceptable endpoints, developmental relevance, metabolism and test design are now more clearly defined and will serve as as guide to the future validation process of all *in vitro* assays. One outcome of the workshop was to establish a panel to develop a list of agents that could be used in validation studies. This panel met during the summer of 1982. When the list of agents is agreed upon, attempts to create a central repository for these agents will be initiated. (CONTACT PERSON: Dr. C. Kimmel)

*NIOSH Accomplishments*

*Inhalation Teratology Testing*—Inhalation teratology studies in rats and rabbits were completed with n-Butyl acetate, ethylene oxide and propylene oxide (Table 23). Ethylene oxide exposures had no toxic effects on maternal rabbits, and there were no adverse effects on the growth and development of fetal rabbits. Ethylene oxide at 150 ppm was maternally toxic and fetotoxic in rats. There was no evidence of a teratogenic effect. Propylene oxide at 500 ppm was maternally toxic for rabbits, but embryotoxicity was not seen. Maternal rats were severely affected by 500 ppm propylene oxide and embryotoxic effects were noted in exposed litters. Also observed was a reduction in the number of corpora lutea in rats exposed to 500 ppm propylene oxide for 3 weeks before breeding. n-Butyl acetate at 1,500 ppm was toxic for maternal rats, but maternal rabbits were essentially unaffected. Fetotoxicity was observed in both species. (CONTACT PERSON: Mr. B. Hardin)

*Short term In Vivo Reproductive Toxicity Assay*—This mouse reproductive test is being evaluated under four contracts awarded in FY 1981. A total of 30 chemicals (Table 24) were screened in this test system Contracts were developed to continue application of this system with the evaluation approximately 25 chemicals to be selected from NIOSH and NTP priority lists. (CONTACT PERSON: Mr. R. Schuler)

*Reproductive and Developmental Toxicity of Glycol Ethers*—Investigations of the reproductive and developmental toxicity of the glycol ethers were continued in FY 1982. In addition to the short-term *in vitro* reproductive toxicity assay (see above and Table 24), the teratogenicity in rats of ethylene glycol (EG) monoethly ether was investigated by cutaneous exposure (Table 25). Undiluted EG monoethyl ether, in volumes of 0.25 or 0.50 ml, was applied 4-times daily on days 7–16 of gestation to the shaved interscapular region of rats. In the control, 0.25 ml and 0.50 ml groups 0%, 48% and 100%, respectively, of the litters were totally resorbed. Among live fetuses in the 0.25 ml group, there was a statistically significant increase in the incidence of cardiovascular defects, enlarged lateral ventricles, and of various skeletal variations, including incomplete ossification and 14th ribs.

Contracts were developed to evaluate the 15 glycol ethers listed in Table 24 for male reproductive/mutagenic potential in three test systems: mouse dominant lethal, mouse sperm head morphology, and *Drosophila* sex-linked recessive lethal tests. A contract was also developed for inhalation teratology tests in mice and rats using three glycol ethers selected as probable reproductive toxicants on the basis of results in the short-term *in vivo* reproductive toxicity assay (see above). (CONTACT PERSON: Mr. B. Hardin)

Since previous in-house research at NIOSH demonstrated behavioral and neurochemical alterations in offspring of rats exposed to 100 ppm of EG monoethyl ether, three structurally related glycol ethers were screened for teratogenic effects (Table 25). It was found that EG monomethyl ether was teratogenic at 50 and 100 ppm. EG monoethyl ether acetate was equivalent in teratogenicity to EG monoethyl ether with congenital malformations at 390 ppm; 130 ppm appeared to be near the teratogenic threshold, producing a single defect. EG monobutyl ether was not teratogenic at 200 ppm but was maternally toxic at higher concentrations. (CONTACT PERSON: Mr. B. K. Nelson)

*Short-Term Test Methods Development in Drosophila*—Development of a standard test protocol and scoring methodology was completed for use of the fruit fly (*Drosophila melanogaster*) as an "*in vitro*" teratogenesis test system. Validation studies are in progress involving tests with known mammalian teratogens. Test chemicals are incorporated into the medium on which untreated flies deposit eggs. Emerging adults are scored, according to the standard methodology, for morphologic defects resulting from larval exposure to the test chemicals. (CONTACT PERSON: Mr. R. Schuler)

*Reproductive Effects-Testing*—Testing was completed and results compiled on 20 priority chemicals (Table 26) being screened for potential reproductive effects using *in vivo* and *in vitro* test systems: *Drosophila* sex-linked recessive lethal (SLR), rat dominant lethal (DL), mouse sperm head morphology (SHM), rat bone marrow cytogenetics (BMC), and unscheduled DNA synthesis (UDS) in cultured human fibroblasts. (CONTACT PERSON: Dr. R. Niemeier)

*NIEHS Accomplishments*

*Fertility Assessment by Continuous Breeding*—Two contracts were awarded in fiscal year 1982 to evaluate this testing system. Eight tests were scheduled at each of the two testing laboratories. These first 16 tests started in fiscal year 1982 and will be completed in fiscal year 1983 (Table 27). Sixteen new tests will begin in fiscal year 1983. Chemicals for fiscal year 1983 testing will be selected in late fiscal year 1982.

Like the multigeneration assays, the continuous breeding protocol uses a prolonged chemical exposure. However, while the multigeneration study tests mating at a specified and limited time, in this new test system male and female mice are housed in breeding pairs continuously for 100 days. This allows the generation of an index of cumulative fertility for each breeding pair. In

the first 100 days the offspring are counted and then discarded, to allow continuous mating of the pairs. Between 100 and 120 days, offspring are saved for fertility evaluation, but they are studied only when the parents are unaffected. When the chemical is toxic to reproductive function, the affected animals (parents or offspring) are necropsied and the reproductive organs are examined carefully to identify target organs. (CONTACT PERSON: Dr. J. Lamb)

*Sperm Morphology and Vaginal Cytology Evaluation*—A contract was awarded in fiscal year 1982 to centralize slide evaluation and data collection of the reproductive toxicology special studies for the bioassay program. In the bioassay program, approximately 25 new chemicals per year are being tested for prechronic toxicity in both rats and mice (Table 28). Many of the animals already selected for prechronic tests are being used and the effect of 90-day chemical exposure on sperm number and morphology and vaginal cyclicity is being studied.

For male rats and mice, a protocol has been designed which calls for special collection of reproductive organs at the scheduled 90-day necropsy. The bioassay laboratories have been instructed in how to collect and measure epididymal sperm concentrations and sperm motility. The bioassay laboratories prepare slides for sperm morphology and send them to an NTP-designated laboratory. Since one laboratory is reading all of the sperm morphology slides, findings can be compared from different bioassay laboratories. This NTP-designated laboratory also gives technical direction to the bioassay laboratories.

In the females, vaginal cyclicity is being evaluated in addition to the routine histopathological studies. This was chosen because a large number of chemicals, representing a wide range of chemical structures, have been shown to possess hormonal activity. Vaginal cyclicity would most likely be affected by estrogens or antiestrogens acting on the female genital tract and by chemicals acting on the ovaries, pituitary or hypothalamus. The vaginal cytology slides are prepared by the bioassay laboratories and sent to the same NTP-designated laboratory which reads the slides and assembles the data. While these prescreens do not necessarily identify the target organ, they do indicate which compounds deserve closer scrutiny. (CONTACT PERSON: D. J. Lamb)

*Effects of Chemicals on Male and Female Fertility*—In-house research studies have continued on the influence of 1,2-dibromo-3-chloropropane (DBCP) on male fertility. These studies are assessing the etiology of testicular lesions in rats exposed to DBCP and the reversibility of the lesions. Studies have also progressed using chlordecone (Kepone) as a model compound causing reproductive toxicity in females. These studies have focused on the response of the female Fischer-344 rat endocrine system to chlordecone. The reproductive toxicity of chlordecone has been attributed to its estrogenic potential. Studies comparing chlordecone to the estrogen diethylstilbestrol (DES) have shown that the compounds do share some chemical activities in the rat uterus and pituitary but chlordecone does not mimic all *in vivo* estrogenic properties of DES, especially in the pituitary. (CONTACT PERSON: Dr. J. Lamb)

*FY 1983 Program Plans*

The Coordinating Group will continue to meet quarterly to integrate activities among the three participating agencies. Results from the shorter-term tests will be studied to determine which chemicals should be tested further. The NTP tracking system will be used to generate individual chemical reports on the status and results of reproductive and developmental toxicology studies. Efforts will be made to interact more closely with chemical managers in order to assure thorough evaluation of chemicals that are selected for testing by NTP.

*NCTR Plans*

*Conventional Teratology Testing*—Current studies will be completed in FY 1983 and a number of new studies will be undertaken. Bisphenol A has been selected for testing, and other chemicals tested will be based on the outcome of any of the shorter-term test procedures or on the basis of NTP priorities. Additional postnatal studies may also be undertaken, depending on the outcome of the conventional teratology studies or on other considerations. (CONTACT PERSON: Dr. C. Kimmel)

*Collaborative Behavioral Teratology Study*—The second year of the study which involves methylmercury exposure will be completed in FY 1983. Summarization and analysis of the data will continue into FY 1984. (CONTACT PERSON: Dr. C. Kimmel)

*In Vitro Teratology Test Development*—For *in vitro* teratology testing, three areas of activity will be pursued: (1) Development of a repository for agents that make up the list of compounds to be used for validation; (2) initial validation studies of various systems depending on availability of research support; and (3) investigation of a literature review system for maintaining an update of advances in *in vitro* teratology testing. (CONTACT PERSON: Dr. G. Kimmel)

*NIOSH Plans*

*Short-Term In Vivo Reproductive Toxicity Assay*—Testing will continue under contracts developed and awarded in FY 1982. Approximately 25 chemicals selected from NIOSH and NTP lists will be evaluated in this test to determine which, if any, should be more thoroughly investigated in more conventional test systems. (CONTACT PERSON: Mr. R. Schuler)

*Reproductive Toxicity of Glycol Ethers*—Contracts developed in FY 1982 to test the male reproductive/mutagenic effects of 15 glycol ethers will be monitored. The FY 1982 contract for inhalation teratologic evaluations of three glycol ethers will also be monitored. Follow-up investigations will be initiated as appropriate. (CONTACT PERSON: Mr. B. Hardin)

*Effects of Glycol Ethers on Postnatal Development*—Based upon the results of the screening studies on glycol ethers in FY 1982, the solvent, EG monomethyl ether, will be evaluated following gestational exposure at sub-teratogenic exposure levels for behavioral and neurochemical effects in offspring which, also, will be evaluated following paternal exposure to EG monomethyl ether. (CONTACT PERSON: Mr. B. K. Nelson)

*Short-Term Methods Development in Drosophila*—Feasibility and validation studies will continue to establish the potential of *Drosophila* as an *in vitro* teratogenesis screening system. In addition to the continuation of in-house efforts, a contract will be developed to investigate the reproducibility of test results in other laboratories and to increase the number of known teratogenic and non-teratogenic chemicals tested. (CONTACT PERSON: Dr. R. Schuler)

*NIEHS Plans*

*Fertility Assessment Using Continuous Breeding*—When compared to the three generation study, the continuous breeding protocol takes less than half as long to complete and is less than half as expensive to perform, but may prove to yield comparable information on fertility and give even more information about the affected sex or target organs. The two test validation contracts are using several chemicals which have been tested in multigeneration test systems (Table 27), and each laboratory can test eight chemicals per year. In the first four of the same chemicals are being tested in the two laboratories. Thus, the test system is being evaluated versus another test system as well as being evaluated in an interlaboratory comparison study. The protocol will be modified, if needed, at the end of the first year. In the second year, evaluation will continue and testing will begin on two chemical classes which have been identified by the NTP for major testing initiatives, the phthalate esters and the glycol ethers. (CONTACT PERSON: Dr. J. Lamb)

*Sperm Morphology and Vaginal Cytology Evaluation*—The specimen collection and data evaluation began on the first 24 selected chemicals in FY 1982 and will continue into FY 1983. Approximately 15 of the new bioassay chemicals will be added to the list in FY 1983. The protocol will be modified as necessary to improve the data quality or cost effectiveness. (CONTACT PERSON: Dr. J. Lamb)

*Effects of Chemicals on Male and Female Fertility*—Studies are continuing on the toxicity of DBCP in male rats. Further investigations are planned in FY 1983 on the effects of DBCP and several other testicular toxicants. These investigations will evaluate the morphological response of the testis to selected toxicants acting on different cellular compartments in the testis. We intend to follow up the morphological findings with specialized biochemical assays of Sertoli cell function and of Androgen Binding Protein (ABP) secretion by Sertoli cells.

*In vivo* studies have demonstrated that chlordecone does not always parallel the estrogen action of DES in female rat pituitaries. A pituitary cell culture system has been established to compare pituitary cell function after *in vivo* exposure to DES and chlordecone. The effects of direct *in vitro* incubation of pituitary cells with DES and chlordecone and other chemicals will also be

evaluated. This cell culture system may prove valuable as a screen for certain toxicants of the endocrine system. (CONTACT PERSON: Dr. J. Lamb)

**Coordinative Management Activities**

*Chemical Nomination and Chemical Selection*

The chemical nomination and selection process remains integral to the effective long-term operation of the NTP with respect to both the testing of chemicals using current methodologies and the validation of new methodologies.

The following discussion briefly summarizes the current NTP chemical nomination and selection process. The process is shown schematically in Figure 4. (CONTACT PERSON: Dr. D. Canter)

*NTP Chemical Nomination*—Member agencies of the National Toxicology Program and other sources (other Federal agencies, state agencies, the public, labor, industry) submit to the NTP nominations of chemicals for various types of toxicologic testing. The nominating source should submit the name of the chemical and the particular toxicologic tests desired; the rationale for the nomination; and the available background data on production, use, exposure, environmental occurrence, and extent of toxicologic characterization in a supporting summary document (Table 29). However, all nominations are considered regardless of the depth of the information submitted. Nominations should be addressed to: Chemical Nominations, National Toxicology Program, Room 2B-55, Building 31, National Institutes of Health, Bethesda, Maryland 20205.

All nominated chemicals are first referred to the NTP chemical selection coordinator for review to determine which chemicals have been tested, are already on test or scheduled for test, or have been previously considered and rejected for testing by the NTP or its predecessors. This involves preliminary examination of the nominations with minimal searches of existing on-line data bases and reference books. The nominations and background information are then forwarded to the Chemical Review staff at the National Center for Toxicological Research (NCTR) who examine the available literature, assess the relevant data, and prepare draft Executive Summaries of this information. (Executive Summaries are not prepared for chemicals nominated solely for mutagenicity testing.) Included in each draft Executive Summary are these sections: Chemical Identification, Surveillance Index (production, use, occurrence, analysis), Toxicological Effects, and Source of and Reason for Nomination. (CONTACT PERSON: Dr. L. Fishbein)

*Evaluation of Nominated Chemicals*—The Chemical Review staff sends the draft Executive Summaries to the Chemical Evaluation Committee (CEC), composed of representatives from the Consumer Product Safety Commission (CPSC), Environmental Protection Agency (EPA), Food and Drug Administration (FDA), Occupational Safety and Health Administration (OSHA), National Cancer Institute (NCI), National Institute of Environmental Health Sciences (NIEHS), National Institute for Occupational Safety and Health (NIOSH), National Center for Toxicological Research (NCTR), and National Toxicology Program (NTP). The CEC evaluates the draft Executive Summaries and recommends the types of testing to be performed. Primary and secondary reviewers are assigned to each chemical after consideration of the nature of exposure so that, to the extent possible, appropriate regulatory concerns will be addressed. Members are requested to search data bases unique to their agencies for further information on the nominated chemicals (and structurally related compounds) to improve the evaluation process.

At the CEC meeting the primary reviewer for each chemical summarizes the data on that chemical and makes recommendations for testing. The secondary reviewer presents additional information, where available, and also discusses the merits of testing the compound. Following a general discussion, the Committee votes on the recommended types of testing and assigns priorities for types of testing. The recommendations are based upon whether the chemical satisfies one or more of the eight NTP chemical selection principles (Table 30). Following the meeting, the Chemical Review Staff revises the Executive Summaries as needed and adds a section on the CEC testing recommendations.

*Public Comment*—A **Federal Register** notice is published which lists the chemicals reviewed by the CEC and the recommended types of testing. Also, the notice solicits comments from interested parties as well as information on completed, ongoing, and planned testing in the private sector. Responses are requested within 30 days of the date of publication. The list of chemicals is also published in the *NTP Technical Bulletin* along with a request for comments. These steps are taken to enable other individuals and groups to provide data useful to the NTP chemical evaluation process.

*Peer Review*—The revised Executive Summaries and public comments on the nominated chemicals are then forwarded to the NTP Board of Scientific Counselors for review. The Board subsequently meets to evaluate these data and to make testing recommendations based on the available information.

*Chemical Selection*—The Chemical Review Staff then incorporates both the Board's ratings and comments and pertinent public input into final Executive Summaries which are submitted to the NTP Executive Committee. The Committee decides whether to test, defer, or delete each of the nominated chemicals for the various types of testing. Executive Committee decisions are published in the *NTP Technical Bulletin*. The Committee also recommends priorities for testing and test development/validation to the NTP.

Following Executive Committee action, the NTP Steering Committee (see Organization section) meets to refer the chemicals to one or more of the three organizational units participating in the NTP: NIEHS, NIOSH, and NCTR. Following referral of the chemical to a participating unit, a chemical manager is assigned who evaluates both the data developed during the NTP chemical evaluation process and other information retrieved from detailed searches of the published literature. The manager also consults with industrial sources on such issues as planned or ongoing testing and availability of the chemical for testing. The manager then presents a proposal to the Toxicology Design Committee (TDC) either to perform appropriate toxicologic testing or to delete the chemical from consideration for testing. The TDC, which consists of research scientists from NIEHS and NTP, assesses the proposal and either develops a final protocol for testing or returns the chemical to the Executive Committee with a recommendation not to pursue testing. The recommendation may be based upon technical difficulties in testing, budgetary reasons, or the existence of adequate outside testing.

All chemicals selected as a result of this process are then tested as time and resources permit.

Results of toxicological testing of selected chemicals are routinely reviewed to determine whether further types of testing are appropriate. Candidates for additional testing are then submitted to the NTP chemical nomination and selection process for evaluation and decision making.

*FY 1982 Accomplishments*

*NTP Chemical Nomination*—During FY 1982, 31 chemicals and black newsprint inks were nominated for toxicologic testing by the NTP. Table 31 lists the nominated chemicals, their CAS numbers, the source of the nominations and the recommended tests. In addition, 151 chemicals representing 10 chemical classes (acetyl amides, amides, aniline derivaties, aminophenols, aminimides, nitriles, chlorohydrins, bromohydrins, alkyltins, and peroxides and hydroperoxides) and one use class (corrosion inhibitors) were nominated solely for mutagenicity testing in the *Salmonella* assay.

As of June 1, 1982, draft Executive Summaries for 36 nominated chemicals were prepared and submitted to the Chemical Evaluation Committee for its use in recommending chemicals which should be tested and for which types of toxic effects. The total number of Executive Summaries submitted to NTP to date is 410.

*Evaluation of Nominated Chemicals*—During FY 1982, the Chemical Evaluation Committee reviewed 47 chemicals previously nominated to the Program. On December 9, 1981, the CEC evaluated 15 chemicals; on March 3, 1982, 16 chemicals; and on July 15, 1982, 16 chemicals. Of these, seven chemicals were recommended for chronic carcinogenicity testing, two for subchronic studies, two for reproductive effects testing, one for nurotoxicity studies, and 17 for one or more tests for mutagenicity. Table 32 lists the 47 chemicals and the testing recommendations.

Ninety two chemicals nominated in FY 1981 for mutagenicity testing in the *Salmonella* assay by NIOSH, on the basis of occupational exposure, were approved for such testing. In addition, the 151 chemicals nominated for testing in the *Salmonella* assay as representatives of particular classes of

chemicals were selected for testing, as well as two additional alkyl nitrile compounds referred to the Program by the Interagency Testing Committee.

*Public Comment*—To solicit public input into the chemical nomination and selection process, **Federal Register** notices were published on the chemicals evaluated for in-depth toxicologic testing at the December, 1981, and March, 1982, CEC meetings. These notices requested both comments and the submission of relevant data.

As a result of these notices, information on production and/or toxicology data were submitted by interested parties on the following chemicals: carminic acid, 2-ethylhexanol, fumaric acid, linoleic acid, linolenic acid, potassium iodide, and vitamin E. Addenda to the Executive Summaries of these compounds were prepared for use by the Board of Scientific Counselors at its review of nominated chemicals in September, 1982.

*Peer Review*—In October 1981, the NTP Board of Scientific Counselors reviewed the 26 chemicals evaluated by the CEC at their April 8 and May 19, 1981 meetings. Approved recommendations, priority for testing, and additional remarks and/or caveats are summarized in Table 33. The Board reviewed the 31 chemicals evaluated by the CEC at the December, 1981 and March, 1982 meetings and made testing recommendations of its own at its September, 1982 meeting (Table 34).

*Chemical Selection*—In October, 1981, the NTP Executive Committee selected 26 chemicals as the NTP FY 1982 priority chemicals for in-depth toxicologic evaluation. The research and regulatory agencies participated in the selection of the chemicals which are listed in Table 35.

In July 1982, the Executive Committee selected 24 compounds as the FY 1983 priority chemicals for in-depth toxicologic evaluation (Table 36).

*FY 1983 Program Plans*

*Evaluation of Nominated Chemicals*—The Chemical Evaluation Committee expects to review approximately 30 compounds nominated for toxicology testing during FY 1983 and to select up to 300 compounds for mutagenicity testing in the *Salmonella* assay.

*Public Comment*—A **Federal Register** notice will be published in October, 1982 to solicit input on the 16 chemicals evaluated by the CEC in July, 1982. Notices will be published on chemicals evaluated during FY 1983.

*Peer Review*—At its first meeting in FY 1983, the Board of Scientific Counselors will review the 16 chemicals evaluated at the July 15, 1982 CEC meeting. Additional chemicals evaluated by the CEC in FY 1983 will be reviewed by the Board later in the year.

*Chemical Selection*—The Executive Committee will select up to 20 compounds as the FY 1984 priority chemicals for in-depth toxicologic evaluation.

*Identification of Toxic and Potentially Toxic Chemicals for Consideration by the National Toxicology Program—"Testing Needs Study"*—The National Academy of Sciences (NAS) was awarded a three-year contract to address two major issues: (1) The percentage of those chemicals to which man may be exposed, either directly or through the environment, that might have public health considerations; and (2) the development and testing of an approach for consideration by NTP that will integrate the intensity of selected toxicity data elements, including absense of any data that might be used by NTP to set priorities among chemicals that would be candidates for toxicity testing.

The NAS-NRC initial report, "Strategies to determine Needs and Priorities for Toxicity Testing, Volume 1, Design," may be obtained from the National Academy Press, Publications Office, 2101 Constitution Ave., N.W., Washington, D.C. 20418 for the sum of $11.39 per copy. This report outlines the procedures and then uses them to obtain a random sample of 100 chemicals selected from a larger population of pesticides, cosmetics, drugs, food additives and other chemicals in commerce. Of these 100 chemicals, 85 of them are listed in the NAS-NRC report, 15 were subsequently added. For each of these 100 randomly-selected chemicals there is some toxicity information available. An in-depth assessment of the quality of these individual data bases will be conducted and the results reported in the second report from the NAS-NRC. This second report will discuss further development of the priority-setting scheme for consideration by NTP for possible use in the ranking of chemicals submitted for NTP consideration for testing. (CONTACT PERSON: Dr. R. E. Shapiro, NIEHS)

*Chemical and Laboratory Test Management*

Once a chemical has been selected for extensive testing and referred to the particular program area, a Chemical Manager is assigned to ensure that the chemical receives a complete scientific evaluation. The Chemical Manager follows the progress of the chemical through each of the various testing phases and has the responsibility to: (1) Know and understand the relevant scientific literature; (2) present draft protocol designs to the Toxicology Design Committee to ensure that testing is designed to measure relevant endpoints; (3) keep up-to-date on the experiment's progress and maintain current awareness; (4) provide liaison with groups doing special studies on the chemical; (5) assist in data evaluation; (6) draft the technical bioassay report; (7) be available to present test results at the Technical Reports Review Subcommittee meetings; (8) prepare the final technical report and journal manuscripts; and (9) respond to requests for information on that chemical after obtaining clearance from the agency which regulates the chemical. The Chemical Manager also maintains liaison with the party (Government, public, industry) who nominated the chemical and with the industry that manufactures or uses the chemical.

As an adjunct, the Pathology Working Group, the Data Analysis Group, and the Quality Assurance-Good Laboratory Practices Section perform quality control functions. These groups ensure that an independent pathology laboratory examines all target organ slides and 10 percent of all others, that studies are designed properly with regard to statistical requirements, and that the bioassay reports accurately reflect the data found.

Project Officers are responsible for monitoring the overall operations of the commercial laboratories performing prechronic and long-term studies for the Program and for ensuring that good laboratory practices are being followed. To ensure that the tests are well conducted in an efficacious manner (scientifically, cost-wise, and timely), these scientists inititate: (1) Annual program reviews by peer groups of scientists, (2) quarterly site visits, (3) *ad hoc* visits by experts in various scientific disciplines as needed, (4) communication with the laboratory and principal investigator through periodic reports and telephone calls, and (5) interaction with NTP contract specialists. (CONTACT PERSON: Dr. J. Douglas)

*Quality Maintenance Procedures in the NTP*—Because attainment and maintenance of quality in NTP scientific programs is essential to the validity, credibility and reproducibility of the results obtained, the following detailed description of quality procedures in the NTP is provided.

"Quality " is a virtue greatly desired but not attained without considerable thought, effort and constant vigilance of all concerned. It is define by Webster as "a distinguishing attribute". There are three procedures for providing quality which are often referred to interchangeably; however, these three aspects are different in their approach to ensuring quality. Since NTP uses all three of these parameters as active parts in providing a quality program, it is important to understand each and how they work together. These three aspects are as follows:

1. Quality Control (QC) is defined by Webster as "an aggregrate of activities designed to ensure quality of a manufactured product." For NTP the ultimate product is the final report on the laboratory study.

2. Quality Assessment (QAS) can be defined as determining the importance, size or *value* of quality. Assessment is defined by Webster as "appriaisal", therefore, QAS is the appraisal of quality. In NTP, we assess the quality of the laboratory by the quality of the facilities, equipment, personnel and ultimately the quality of the work it produces.

3. Quality Assurance (QA) is the culmination of QC and QAS. Webster defined assurance as "freedom from doubt, confidence of mind or matter * * *." Today, Quality Assurance generally refers to those aspects related to Good Laboratory Practices (GLP) Regulations as defined by the Flood and Drug Administration (part 58—Good Laboratory Practices for Nonclinical Laboratory Studies).

Since quality cannot be added on at the end, it must be built into each aspect of the program. This means the first parameter of quality is the NTP personnel. This includes the management, the chemical managers, the scientific discipline leaders, and the project officers.

The second parameter of NTP quality is the contract laboratory engaged to carry out toxicological studies. Through contractual

procedures, a group of qualified laboratories is established under a master agreement for the Bioassay Program. Only these qualified laboratories are allowed to bid on most of the bioassay packages of studies to be assigned to contract laboratories. Qualification (QAS) is established through a peer review of proposals by outside experts from academia and industry and site visits by NTP discipline leaders.

Various NTP internal controls (QC) are in place to ensure the best possible experimental design for the study. The Chemical Manager is responsible for identifying the parameters to be included in the toxicology experimental design. This is done by literature survey and conferring with various discipline leaders within the NTP program, with scientists expert in regulatory needs regarding the toxicity data required for a specific chemical, and with experts in academia and industry. All this information is peer reviewed (QC) by the Toxicology Design Committee made up of NTP colleagues with diverse backgrounds and interests. Each aspect of the study is scrutinized for logic, need and value added before approval by the Committee. This final experimental design is used to prepare a protocol for review by NTP management prior to assembly of material for competition among the approved laboratories. QC is performed to assure that the protocol package is consistent with the current statement of work and procedures for specific toxicologic parameters to be determined. The bid packages are assembled based on special requirements of each protocol and sent to laboratories qualified for specific dose administration routes (dosed feed, dosed water, gavage, skin painting, inhalation) and specific toxicological effects (immunotoxicology, enzymology, etc). Each of these QC steps is important in ensuring a successful study.

Prior to initiation of a study at any laboratory a series of QC events occur to assure the quality of the study. These result in providing high quality resources for the NTP program, that is, animals and chemicals. To provide high quality rodents of uniform genetic background, NTP provides the contract breeding facility with known NIH breeding stock to be used in rederiving their breeder stock in isolators. All rederived rats and mice are inoculated with "bacterial cocktail" to obtain uniformity between animal sources. Each production colony is monitored for parasites and serum titers for a variety of rodent viruses. The genetic quality of these animals is monitored on a routine basis to ensure genetic uniformity. Retired breeders are also examined grossly and selected tissues reviewed microscopically to determine the overall state of health.

Also prior to initiation of a bioassay, the chemical is procured by our contract analytical laboratory. As a part of QC, the analytical laboratory determines the identity, purity, stability under various storage conditions, solubility, procedures for homogenous mixing for dosed feed studies, vehicle and mixing procedures for drinking water, gavage and skin painting studies and the best procedure for analysis based on the equipment available at the bioassay laboratories and the dose levels anticipated for testing. For inhalation the bioassay laboratory, in conjunction with the analytical contractor, undertakes an extensive study to determine the best way of producing an atmosphere containing the chemical which depends upon the nature of the chemical (particulate, gas or aerosol mist). The chamber concentration is monitored throughout the exposure period on a daily basis.

QC and QAS activities for analytical chemistry continue throughout the study. The bioassay laboratory determines the purity of the bulk chemical on receipt and every four months while on study. Each bioassay laboratory analyzes dose preparation regularly and in addition, referee analysis is carried out by an independent analytical contractor twice yearly on paired samples to assure the dose preparations are properly prepared and analyzed. This is done for each chemical at regular intervals starting with the first preparation for the subchronic study.

NTP monitoring of contract research can be considered QAS. This monitoring takes several forms on the bioassay. The first line of monitoring is the project officer who makes an initial visit to the laboratory to determine readiness to start the study and quarterly site visits thereafter. These visits include very technical, as well as financial, aspect of the contract. If problem areas develop, specific discipline leaders—chemistry, pathology, health and safety, animal care, specific toxic effects and quality assurance—are consulted and, if required, they will make a special site visit to the laboratory. In addition to the quarterly site visits, an annual program review is held in which all discipline leaders visit the contract laboratories. These have proved very useful in detecting and solving problems (QAS and QC).

Monitoring also occurs through review of the monthly status reports from the laboratories. These reports have been structured to allow review by the project officer, the discipline leaders, chemical managers and management. This allows early detection of problem areas and a resolution of these problems and serves as both QAS and QC.

QAS and QA activities are a major part of the pathology program for NTP. All contract pathologist must be approved (QAS) before they can participate in the bioassay program. As a bioassay progresses, random slides are reviewed for QAS of the histological preparation of tissues. Workshops are held to standardize pathological diagnostic terms so that specific terms are used to describe the same toxic effect (QC).

When a subchronic or chronic study is completed, all slides and diagnoses are sent to a contract laboratory for QAS. They determine if all slides are present and contain all the required tissues and assess the quality of the slides. In addition, all masses and all target tissues are examined as well as all tissues from 10% of the animals selected at random. As a further QA and QAS step, slides showing differences in diagnostic opinion between original pathologist and QA pathologist are examined for specific organ or toxic effects by a Pathology Working Group (PEG) consisting of both NTP pathologists and outside expert pathologists from industry or academia. This review leads to a consensus diagnosis of toxic effects.

Hematology, urinalysis and clinical chemistry studies also have a QAS procedure. Prior to performing these procedures for a study, a new laboratory must demonstrate they can carry out the studies and obtain reproducible results. Many of our bioassay laboratories participate in a proficiency testing program.

The animal health is monitored (QAS) at regular intervals throughout the bioassay by collecting sera from sentinel animals housed under the same conditions as the test animal. This sera is tested for antibody titers to a variety of rodent viruses. If tests indicate an infection, cultures are made and histopathological examinations carried out to determine the cause. Monitoring of the condition will continue as long as needed.

The bioassay laboratory personnel are responsible for an active QC program to assure all data is collected correctly, calculations are correct, and the environmental conditions meet program requirements. All facilities are equipped with emergency power to ensure adequate temperature control even during power outage. All data entered into the Chemical Bioassay Data System (CBDS) or the Toxicology Data Management System (TDMS) are totally validated for correctness of input.

Quality Assurance (QA) is primarily the responsibility of the Quality Assurance Unit (QAU) established at each facility to meet the requirements of GLP compliance. The QUA personnel must have no conflicting interest with the programs to be reviewed. They must be qualified in a diversity of disciplines to meet the needs of the laboratory. It is their responsibility to inspect and audit the various critical phases of each study carried out under GLP compliance. Critical phases have been defined as those which have the potential for invalidating the study if done incorrectly or not in a timely fashion. The working protocol is the initial critical phase as it represents the principal investigator's interpretation of what is to be done by the contract laboratory. It is the responsibility of the project officer to check each working protocol prepared by the laboratory against the protocol prepared by the chemical manager and to approve the laboratory working protocol prior to the start of the study. Any changes or deviations from this protocol must be documented. Other critical phases of a bioassay consist of animal identity, chemical analysis, dosing, special toxicology studies, necropsy, data collection and report preparation. The less critical phases are considered to be randomization, clinical signs, animal weights, tissue weights, cage and rack changing, and environmental conditions. Although these are critical to obtaining a good study, errors generally do not invalidate a study.

During 1981, the NTP-QA program leader and QA manager for the bioassay prime contractor, Tracor Jitco, made a concerted effort to bring all bioassay laboratories into compliance with FDA-GLPs. Currently, the

machinery is in place for compliance by all bioassay laboratories and extensive audits of data are being carried out on selected studies. The contracts have been modified to require GLP compliance. A final report is prepared by the principal investigator and audited by QAU at the laboratories are being made by the NTP–QA laboratory prior to submission to NTP. Annual visits to all bioassay program leader. These visits include an inspection of the QAU organization, capabilities and activities. Generally, at least one inspection is made of some technical procedure and data are audited. The Standard Operating Procedures for various technical activities are reviewed. A facility inspection is made. The personnel training files and safety procedure are reviewed. When problems are found, followup visits or responses to action items are required. The discipline leaders, project officers and chemical managers are informed of the findings of the QA site visits.

In September, 1981, a QA workshop was held for the bioassay laboratory prinicpal investigators and QAU managers. All NTP and Tracor Jitco discipline leaders and project officers attended. The theme of this workshop was to define the duties of each members of the team—NTP, Tracor Jitco, and the contract laboratory.

The next problem in the area of QA is the implementation of GLP compliance and monitoring of the bioassay data collected on the Toxicology Data Management System (TDMS). The NTP QA program leader is investigating the design of procedures to assure the quality of this computer collected data in collaboration with other members of the team responsible for implementation of TDMS and will work with the bioassay laboratories in their QAU efforts.

One final step remains to be discussed in the GLP compliance program for bioassays—that is—the archiving of the raw data. NTP provides an archives for secured storage of the raw data and a repository for the slides, wet tissues and tissue blocks. The laboratories will be required to inventory all raw data sent to the archives and arrange them according to a format designed for easy access. Consideration is being given to microfilming this material for long-term storage. All data and slides are available for examination at the repository and archives but these data cannot be removed from the archives. Fire protection is provided for raw data and laboratory reports.

During 1982 a program was initiated to bring other aspects of NTP testing and validation studies under GLP compliance. This has required the site visiting of a variety of studies including teratology and cellular and genetic toxicology screening and validation testing. The immunotoxicology and pharmacokinetics programs will also be site visited. Collaboration has been established with the NIOSH Quality Assurance manager and four NIOSH/NTP teratogenesis validation studies have been site visited. In collaboration with the project officer at NCTR, five contracts for the validation of behavioral toxicology testing procedures have been site visited in preparation for GLP compliance during the next contract year.

Through establishment of GLP compliance NTP is making every effort to establish a level of quality which will provide "freedom from doubt" as Webster defines "assurance". (CONTACT PERSON: Dr. C. Whitmire)

*Chemistry Resources*

The chemistry program serves as a central resource for all testings and research activities of the NTP. Maintained to assure chemical quality and to minimize testing results variability due to external sources, the chemistry needs are facilitated via integrated contract mechanisms and cooperation and interaction with other NTP operations. The chemistry capabilities provide for procurement, chemical analysis, analytical methods development, purification and synthesis of test chemicals. In addition, a chemical repository resource has been established for the receipt, handling, long-term storage, shipment and preparation of chemical safety data handling sheets for approximately 3,000 chemicals. (See section on Chemical Repositories).

Capabilities are provided for analysis of bulk chemicals, chemicals in test vehicles, methods development for quality assurance, including purity, stability (both bulk chemical and chemical/vehicle mixtures) and concentration determinations, chemical residue analysis for body tissues and fluids and special handling for residual and reprocured chemicals. In addition, capabilities exist for purification, derivatization and synthesis of test chemicals. Trace level analysis of test chemicals for potential contaminants are available, when required, as well as provisions for percent level purity, stability and recovery analyses. Trace level chemical analysis may be necessary when known toxic impurities are suspected to be present in the test material. There may also be a requirement for trace analysis when toxicity tests of chemical mixtures or impure chemicals are positive and it is necessary to identify specific components that may be associated with the observed toxic effect.

NIEHS

*FY 1882 Accomplishment*

The analytical services support contract established in FY 1980 continued to support a large number of NTP programs. As in the past, the majority of the work was in support of the carcinogenesis bioassay program. Nineteen chemicals which started carcinogenesis bioassays in FY 1982 were procured, analyzed and shipped to the respective bioassay laboratories for testing. In addition, 14 of the 15 chemicals recently approved to start prechronic studies in FY 1983 have either been procured and analyzed or are currently in the procurement process.

The chemistry performed at the bioassay laboratories is constantly monitored by review of the monthly reports received from the laboratories and by annual chemistry discipline site visits to all bioassay laboratories. In some instances, it has been necessary to visit a laboratory more often than the regular annual visit to address chemistry related problems associated with the bioassay studies. During FY 1982, with the exception of procurement delays on several chemicals, There were no major chemistry related problems at any of the bioassay laboratories.

The analytical chemistry resources continued to support the NTP teratology program. During FY 1982, five new chemicals were obtained for teratology studies (Table 37). These chemicals were procured and analyzed in a similar manner to that of the chemicals for the carcinogenesis program, including complete purity and identity assays and methods development for bulk chemical stability and chemical/vehicle mixing, stability and concentration assay methods. In addition, interim bulk chemical reanalysis for purity was provided for all chemicals and tissue residue analysis for one chemical was provided for the teratology studies. All information generated during the analyses of these chemicals was provided to the teratology program leader and the contract laboratory. Also, technical input in the area of chemistry was given to the teratology program by means of the site visits to the teratology contract laboratory.

The chemistry resources initiated support of a reproductive toxicology program contract initiative started in FY 1982. Twelve chemicals were obtained (Table 38) for study in the program and distributed to the contract laboratories. These chemicals were procured and analyzed in a similar manner to those obtained for the teratology program. In addition, the chemistry resource provides routine dose analysis for all chemicals on test in the program as well as interim bulk chemical reanalysis for purity. All information generated during the analysis of these chemicals is provided to the project officer and contract laboratories. Technical input in the area of chemistry is provided by constant communication with both the project officer and contract laboratories.

The chemistry resources have also initiated support of the NTP's immunology program contract research by providing analytical chemistry services for the four chemicals currently on study under this initiative (Table 39). These services include bulk chemical analysis for purity and identity; methods development for bulk chemical stability and chemical/vehicle mixing, stability and concentration assay methods. Support in the area of routine dose analysis, interim bulk chemical reanalysis for purity and tissue residue analysis is also provided.

The chemistry resources continue to support the NTP psoralen initiative. Four chemicals (Table 40) were obtained from various sources and analyzed for identity and purity. In addition, routine dosed feed analysis on samples received from the contract laboratories is provided.

Another major initiative accomplished in FY 1982 was the completion of the routine chemical services performed in support of NTP studies at the NCTR. This activity was undertaken in order to allow NCTR chemists the opportunity to participate in the NTP's Benzidine Congener Dye Initiative. The services provided for the NCTR included surveillance of incoming supplies for experimental animals such as: feed, potable water, bedding and cardboard feeder boxes and certification that the dosed feed for the NTP studies of sulfamethazine and hexamethyl-p-rosaniline (gentian violet) contained the correct concentration of the

chemical. The chemical support provided by the chemistry resources was for an 18-month period and NCTR took back responsibility for these analyses in February 1982.

Continued support was provided to several NTP investigators in the area of chemical synthesis, tissue residue, bulk chemical and dose mixture analyses (Table 41). During FY 1982, tissue or body fluid residue analysis was performed on samples from a reproductive toxicology study of chlordecone (kepone) and diethylstilbestrol, teratology studies of di(2-ethylhexyl)phthalate, immunology studies of cadmium chloride and bioassays studies of chloramphenicol and titanocene dichloride.

The chemistry program also provides primary repository assistance to the genetic toxicology and carcinogenesis testing programs. The two repositories, which operate under similar standard operating procedures, have undertaken numerous joint projects that demonstrate the functional integration of the two programs. (CONTACT PERSON: Dr. C. W. Jameson)

*FY 1983 Program Plans*

During FY 1983, the chemistry resource will continue to support the carcinogenesis testing program by procuring and analyzing all new bioassay chemicals. The chemistry resource will also continue to support the teratology, reproductive toxicology, immunology and psoralen contract efforts and begin support of the short-term *in vivo* rat liver tumor model program which will initiate contract efforts in FY 1983. Continued collaboration with in-house investigators will be maintained, especially in the areas of reproductive toxicology and immunology. Continued effort for developing analytical chemistry services support for in-house NTP studies will be pursued. (CONTACT PERSON: Dr. C. W. Jameson)

*Chemical Repositories*

The NTP Chemical Repository program provides repository assistance to the carcinogenesis bioassay, cellular and genetic toxicology, chemical pathology and systemic toxicology programs. This includes not only storage but location and acquisition of approximately 1,000 chemicals with a final capacity of 5,000 chemicals, cataloging of Wisweisser Line Notations (WLNS), Chemical Abstract Service (CAS) numbers and numerous other pertinent information on chemical, physical and toxicological properties. This information is put into a custom designed computer program which also generates randomized codes for various aliquots that are to be tested blind. Tracking and monitoring of repository functions are accomplished by this computerized data base management system which allows multi-tier access into a hierarchical system of data retrieval and file security. The repository, upon searching through on-line computer data bases, edits and produces chemical specific handling documents both for day to day safe handling as well as for emergency situations, performs quality assurance (QA) tests for numerous NTP contract laboratories and ships these chemicals to national as well as international laboratories. Finally, upon completion of the bioassay studies, the repository receives and aliquots an archive sample of the chemical, then arranges for the environmentally safe disposal of surplus test chemicals. The NTP Chemical Repository is thus involved in the entire toxicity testing cycle from beginning to end. Two repositories have been established which operate under similar standard operating procedures; both divide the chemicals into three groups, when quantities permit: a testing lot, an archive sample and a public allotment. Present contractual requirements prohibit combination of the repositories at this time.

NIEHS

*FY 1982 Accomplishments*

More than 1,000 aliquots (Table 42) were sent to investigators in FY 1982 either as coded blind samples or as uncoded shipments for toxicity testing. This is a 50% increase in repository shipments and is primarily due to expansion of NTP cellular and genetic toxicology efforts. Redesignated chemical specific safe handling documents and emergency procedure documents have provided clearer and more explicit handling procedures for these potentially toxic test compounds.

Flash point determinations of liquid test chemicals were initiated to meet Department of Transportation shipping requirements when this information was unavailable from the literature. A total of 50 compounds have been tested by the closed cup method.

A method of direct probe insertion mass spectrometry was developed to enable impurities separated by high performance thin layer chromatography to be identified.

An apparatus for determining the permeation of glove materials by NTP test chemicals has been constructed and validation of the method by ASTM standards was completed. The purpose of this work was to provide valuable information to help enable NTP laboratory researchers to conduct studies on test chemicals in a safe manner. Glove permeability tests on 20 compounds with 4 different glove materials have been studied.

A method for gas transfer from large cylinders to smaller lecture bottles was accomplished and monitored using sulfur hexafluoride as a market compound. The design of this sampling procedure has allowed effective guidelines to be formulated for the safe handling of gaseous samples.

More effective and explicit packaging and shipping requirements were written to permit transfer of approximately 60 shipments of bulk chemicals to the repository for removal of archive samples and final disposal of surplus bioassay chemicals.

Completion of an addition to the Hazardous Materials Laboratory will now enable storage of approximately 5000, 500-gram samples at 4 different temperature levels (25°C, 5°C, −20°C and −70°C). A safe is also available for storage of narcotics. (A full Drug Enforcement Administration (DEA) license has been approved). (CONTACT PERSON: Dr. D. B. Walters)

*FY 1983 Program Plans*

During FY 1983 the Chemical Repository program will continue to provide assistance to all branches of NTP. Increased shipments are anticipated due to the expanded high priority testing battery of the Cellular and Genetic Toxicology program.

A more refined computer software and hardware package for tracking and monitoring is being investigated to meet the expanding needs of the NTP. It is anticipated that approximately 50 compounds will be tested for glove permeability to assist in development of possible structure-activity relationships.

Combination of the repositories has been delayed due to contract restraints but plans are proceeding to accomplish this at the end of FY 1984. (CONTACT PERSON: Dr. D. B. Walters)

*Pathology Repository and Archives*

The NTP maintains a centralized repository of histopathology materials collected during the bioassay studies. This is done in accordance with Good Laboratory Practice procedures and to provide a complete history of the pathology findings. Storage facilities are provided for wet tissues, paraffin blocks, microscopic slides, and printouts of the data that appear in the technical reports. User facilities complete with microscopes are provided for investigators to view the materials. For more information or scheduling of user facilities, contact Dr. E. E. McConnell, Chief, Chemical Pathology Program, National Toxicology Program, P.O. Box 12233, Research Triangle Park, NC 27709; or 919-541-3440 (commercial), 629-3440 (FTS).

*Data Management and Analysis*

NTP programs generate a large volume of complex data that must be acquired, validated, and stored so that these are easily and quickly retrievable, eventually at multiple locations. Thus, a continuing priority commitment is to develop efficient automatic data processing systems to capture various types of management and experimental data, and to make this information available for periodic examination, updating, summarization and statistical analyses. Furthermore, the complexity of the system requirements demands that systems for NTP not be developed as isolated units but rather that there be centralized coordination and management of the systems so that services are distributed according to established priorities and resources are used most efficiently and without duplication of effort.

Statistical research efforts include continued investigation of possible modification of the basis experimental design of the two-year carcinogenesis bioassay. The purpose of these modifications will be to provide the low-dose information needed for extrapolation without adversely affecting the power of the bioassay for detecting carcinogenic effects. The problem of incorporating historical control information into statistical analysis of bioassay data is being studied. Stastistical methodology is being developed that will take into account extrabinomial variability due to differences in test laboratory, animal sources, and other factors.

NIEHS

*FY 1982 Accomplishments*

*Data Processing Systems*—The Toxicology Data Management System (TDMS) being developed to support the animal bioassay program continued toward implementation. Specially designed microprocessors were delivered and are in use for live support of bioassay experiments at five contract laboratories. These early studies have shown the animal room data (animal weights, clinical observations, dosages, deaths, etc.) collection modules to be effective. Another component of the system being tested is for collection of micropathology information. A system to collect gross pathology observations is under development. Development of modules for statistical and summary reports is ongoing. More detailed information on TDMS may be found in the NCTR entry in this section. CONTACT PERSONS: For Systems—Mr. A. Konvicka, NCTR: for toxicology—Dr. M. Dieter, NIEHS)

In support of the Cellular and Genetic Toxicology program, a laboratory data collection and management system was developed. Data are entered into the system via intelligent data entry terminals at the laboratories which allows easy validation of data for each laboratory. Periodically the data base is updated into a host computer where the data are used for data analyses, quality control, and report generation. Efficient data structures and an automatic archiving system allow the data to be stored at a fraction of the usual cost. The system was installed and is operating in *Salmonella* testing laboratories at SRI International, Case Western Reserve University, and EG&G/ Mason Research Institute. A fourth terminal, located at NIEHS was installed to collect *Drosophila*, cellular transformation and cytogenetics data. CONTACT PERSON: Dr. E. Zeiger and Mr. M. Rowley.

An NTP chemical management and tracking system (CHEMTRACK) has been developed on the Model 204 Data Base System at the Parklawn Computer Center. CHEMTRACTK provides the NTP with the capability to interactively query information on chemical status, nomination, test results, milestones and publications. Procedures have been developed which will allow NTP scientists and administrators with little computer experience to generate queries and batch reports on NTP chemicals. User and system documentation have been developed and training of NTP personnel begun. (CONTACT PERSONS: Mr. M. Rowley and Ms. F. Jordan)

The system that has been supporting the animal bioassay program, the carcinogenesis bioassay data system (CBDS), continued to collect animal weight and pathology information for chronic studies. The system routinely produced the reports and basic statistics required for the program. In addition, systems were maintained to collect and report data for *in vitro* studies and for the Strain A mouse pulmonary adenoma studies. To aid in program management, several systems which collect and report fiscal and experimental statuses were utilized. Plans are being made for the orderly transition of CBDS activities, procedures and data to the TDMS. (CONTACT PERSON: Mr. M. Rowley)

*Statistical Studies*—Possible statistical modifications of the basic experimental design of the NTP's two-year carcinogenesis bioassay continued to be evaluated during FY 1982. Changes under consideration include additional dose levels, reallocation of animals among experimental and control groups, and the selection dose levels other than the traditional MTD (maximum tolerated dose) and one-half MTD. Monte Carlo simulation was used to compare several hundred two- and three-dose designs with respect to the precision of low-dose risk estimation, assuming a multistage model for carcinogenesis. A general class of designs was located which yields adequate power for testing and the high precision needed for extrapolation. The traditional NTP design was in this class of optimal designs. In addition, the number of animals utilized in the bioassay was investigated with respect to the power for testing and the precision of low-dose estimation. The results show that additional animals (beyond the standard 150 per sex species group) would only slightly improve the extrapolation but could greatly improve power. A bioassay using between 150 and 300 animals would yield sufficient power in an optimal design. (CONTACT PERSON: Dr. C. Portier)

Patterns of tumor incidence in the two-year cancer bioassay feeding studies in Fischer rats were investigated. It was found that the overall frequencies of statistically significant ($P<0.01$) increases and decreases in tumor incidence in treated groups relative to controls were approximately the same. The decreases were due primarily to mammary gland fibroadenomas in females (which were clearly associated with decreased weight gain in the treated groups) and leukemia/ lymphoma in both sexes (which were frequently associated with increased liver tumor incidences in the treated groups). A clear explanation for this latter association is not apparent. The increased tumor incidences in the treated groups relative to controls were due primarily to liver neoplastic nodules. (CONTACT PERSON: Dr. J. Haseman)

During FY 1982, a standardized statistical report format was developed for summarizing the results of statistical analyses of data from NTP prechronic and "special" studies. The analyses are currently provided under contract by Program Resources, Incorporated. Prechronic data are being maintained in a standard format for eventual transfer to the toxicology data management system (TDMS). Efforts are also underway to ensure that the statistical capabilities currently available through CBDS will be maintained when TDMS becomes fully operational. (CONTACT PERSON: Dr. J. Haseman)

Microbial mutagenicity experiments, especially large-scale collaborative studies, continued to receive substantial statistical research attention in FY 1982. Primary focus has been on sources of variability, such as within- and between-day, and especially the possibility of genetic draft. Research also was performed to determine the adequacy of statistical methods used to analyze recessive lethal test data, such as for *Drosophila*. Preliminary results indicate that there is room for substantial improvement. (CONTACT PERSON: Dr. B. Margolin)

*FY 1983 Program Plans*

*Data Processing Systems*—The CBDS will continue to collect pathology data and produce reports until it is completely replaced by the TDMS. (CONTACT PERSONS: Mr. M. Rowley and Mr. J. Washington)

Additional components of TDMS will be tested in FY 1983. The most important of these are the gross pathology system and the query language processor. As these major components are completed, more attention will be directed toward implementing the system in as many as ten additional NTP contract laboratories. Particular attention will be given to identifying the special needs of NTP users and to expanding the system to accommodate additional types of data collection within the bioassay program. (CONTACT PERSON: For systems—Mr. A. Konvicka, NCTR: for toxicology—Dr. M. Dieter, NIEHS)

Plans are being developed to move the laboratory data management system supporting cellular and genetic toxicology programs to an NTP in-house computer, a DEC VAX 11/780. A data base management system obtained from DEC and a graphics and query system currently under development will be utilized to provide the NTP with extensive data review, statistical analyses and graphics capabilities. (CONTACT PERSON: Mr. M. Rowley)

Additional report generation and query software will be developed for CHEMTRACK. Special reports will include those for teratology, immunotoxicology and pharmacokinetics programs. In FY 1983, CHEMTRACK will continue to provide the NTP with interactive query and report generation capabilities. Data will be loaded into CHEMTRACK from all NTP program areas. CHEMTRACK will function as the primary source of nomination/selection information and will provide a data base of information on NTP committee actions. (CONTACT PERSONS: Mr. M. Rowley and Ms. F. Jordan)

*Statistical Studies*—During FY 1983, further research will be carried out with regard to the utilization of historical control data in NTP carcinogenesis bioassays. Computer simulation techniques will be employed to compare the operating characteristics of three procedures that have recently been proposed to incorporate historical control data into a formal statistical analysis. (CONTACT PERSON: Dr. D. Hoel)

A related effort is underway to identify factors responsible for the extrabinomial variation present throughout the historical control data base. Potential sources of variation include time, laboratory, pathologist, animal supplier, and length of study. (CONTACT PERSON: Dr. J. Hasemen)

Statistical research will continue concerning possible modifications of the chronic bioassay design. Goodness-of-fit and the exact size of the trend tests will be considered. (CONTACT PERSON: Dr. C. Portier)

The current NTP historical control data bases maintained on CBDS will be re-defined during FY 1983. Early NCI studies not subject to the rigorous pathology quality assurance procedures currently employed by the NTP will be eliminated: Nomenclature inconsistencies will be resolved. Additional computer programs will be generated and/or existing programs revised to increase the usefulness of the data base to chemical managers and other interested scientists. (CONTACT PERSON: Dr. K. Chu)

Analyses of three separate *Salmonella* test databases will be pursued further, and assay reproducibility will be studied quantitatively. Research focus has broadened and now included *in vitro* and *in vivo* cytogeneticity assays. (CONTACT PERSON: Dr. B. Margolin)

NCTR

*Toxicology Data Management Systems*

The Division of Toxicology Data Management Systems (TDMS) actively supports the NTP in several areas. Currently, this includes:

- Site Support (Contract Laboratories)
- Software Maintenance and Enhancement
- Software Development
- Central Computer Facilities
- Other projects as defined by NTP

*FY 1982 Accomplishments*

*Site Support*—Involved was shipping, installing, and maintaining terminals, printers, modems and balances at the following NTP contract laboratories:

- Battelle-Columbus
- International Research and Development Corporation
- Hazelton Laboratories
- E.G. & G. Mason Research
- Microbiological Associates
- Southern Research Institute

There was development and implementation of training programs for the support of the TDMS Protocol Analysis System, Experiment Information System (EIS), and the Administrative System.

Initial visits were made to all the sites listed above. These visits were to introduce TDMS to the personnel at each facility and, when possible, to complete PAS manual forms for use in the Protocol Analysis System (PAS) on the laboratories first study using TDMS. Two of the laboratories each had two studies that began on manual forms rather than direct entry via computer terminals; therefore, these facilities were also trained on the use of EIS manual forms in the animal rooms during the initial visits. The data collected on these manual forms was sent to NCTR for entry into the system by TDMS personnel. Training sessions were held or have been scheduled at all sites.

TDMS prepared "first draft" user guides for all the systems. This documentation will be available to the user soon and will prove to be an invaluable aid during system use.

*Software Maintenance and Enhancement Support*—The Protocol Analysis System (PAS) was modified to accomodate multiple users. This allowed the concurrent entry of the PAS data of multiple experiments by two or more users. A copy function was also added which allows the user to copy a segment from one experiment to another. This tool is very valuable in that it saves hours of data entry time for segments that do not vary from test to test. The manual forms went through several revisions to accommodate NTP requirements, and a new segment—Responsible Parties—was added to the forms and the data base.

The Experiment Information System (EIS) was revised to include several enhancements and modifications which make this EIS version much more user oriented. A number of reports are now available at each laboratory site which provide information on experiments, e.g., dosing, food consumption.

Reports available only via the mainframe were modified in accordance with NTP's request. Provisions were made for batch submission and for running reports to accommodate users with or without memorex type terminals. Also, additional selection criteria options enable the user to specify a range of dates and/or a range of cages to run the report against.

The Administrative System (Diskette Control Subsystem) was modified to include the following functions: (1) Creation and verification of new floppy diskettes that can be introduced into the system; (2) backup of all floppy diskettes, along with the means of disk recovery for a backup in case of disk loss or failure; (3) an automated method of transmitting data from the remote microcomputer to the host system. Additionally, reports and software may be sent from the host system to the proper floppy diskette on the remote microcomputer; and (4) managment of transaction files including retransmissions in case of transmission error and deletion after the data had been received and verified by the host computer.

*Software Development Support*—The Micropathology System portion of the Post Experiment Information System (PEIS) will collect, store, and report microscopic pathology data. This system is currently being modified to include the NTP requirements for version 2, which includes site accountability, expanded target and other organ requirements. A version 2 design document was produced and reviewed by NTP and TDMS personnel. After receiving the revised pathology protocol for chronic studies, it was necessary to review the original design for handling target organ processing.

After defining an NTP tentative standard pathology protocol for prechronic experiments, the micropathology system was implemented at Southern Research Institute (SORI).

During the final review of the Pathology Code Table (PCT), several changes were made. To implement the NTP requirement of forced qualification to a specific qualifier group and to allow sorting of the observations, it was necessary to regroup the qualifiers into a more logical grouping sequence. New PCT micropathology reports were generated to reflect the changes. The gross pathology glossary received an intensive review by NTP pathologists and the resulting changes were implemented in PCT. All of the PCT reports have been designed and programmed with the exception of the gross lesion report. In addition to a series of mainframe reports on neoplastic and non-neoplastic pathology, a number of local (microcomputer) reports have been developed.

The pathology manual forms were sent to SORI to begin data collection during the necropsy process. At the request of the NTP, these forms were revised to more closely reflect the type of animal data to be collected for NTP studies.

The internal review process was begun on the pathology terminal operators guide. After the necessary revisions are made the manual will be ready for an external review.

The Gross Pathology System of the PEIS will collect, store and report gross (necropsy, trimming and receiving) pathology data. The external design document has been prepared and includes descriptions for data collection, pathology code table, protocol entry and validation, download, mainframe receipt and storage, and transmission. Report formats and descriptions for all aspects were also included. It is important to note that, after review by NTP, there are some possible changes in the design philosophy regarding data entry.

An analysis is being conducted which will determine the definition of a system to provide mechanisms and reports to fulfill the following primary functions: (1) Assure experimental protocol has been established before a study is initiated; (2) monitor experimental activity during the study; (3) verify and validate data for consistency and accuracy; and (4) provide summarization and analysis of data for evaluation of the study upon completion.

*Central Computer Support*—Procedures were developed and implemented for updating the animal room system data base separate from the other bases. Procedures for updating the pathology system data base have been developed and implemented. Currently in planning is a process which will make validation a separate job step from update. A feasibility study is also being conducted of commercially available data base management system products with regard to TDMS needs.

The Software Control System is currently in the requirements phase, with the objectives having been developed. This system will control all software elements, developmental or productional, with the main objective being that no software, either newly developed or just enhanced, will become productional without having passed through the Software Control System.

*Fiscal Year 1983 Program Plans*

Plans for the TDMS for FY 1983 include an expansion in both the number of laboratory sites and the number of studies being supported by TDMS. All new chronic study starts on existing contracts will be fully supported by TDMS as well as all chronic studies from newly awarded bioassay contracts. In accordance with NTP direction, TDMS will be implemented for support of selected 90-day prechronic studies. In addition, for certain ongoing chronic studies selected by NTP, support will be implemented for collection and management

of the pathology data generated by those studies. Among new initiatives requested by NTP will be the development of TDMS modules for support of hematology and clinical chemistry data. (CONTACT PERSON: Mr. A. Konvicka)

*Laboratory Animal and Quality Control*

The laboratory animal production program provides genetically defined rodents for the NTP bioassay and other testing studies. This resource is designed to assure the use of high quality, disease free rodents for chemical testing. The production of animals is facilitated via interaction between animal production facilities, contract bioassay laboratories, and the NTP.

Three breeding laboratories are currently under contract to provide F-344 rats and B6C3F$_1$ hybrid mice for the NTP bioassay programs. Rodents are also supplied by the Division of Cancer Treatment, NCI, at Frederick Cancer Research Facility (FCRF). Disease monitoring continues to be a major priority of this program. Two diagnostic laboratories are responsible for monitoring the production facilities. The sentinel animal program, initiated in FY 1980, continues to serve as the monitoring source for viral diseases in each animal room at testing laboratories under contract to the NTP.

**NIEHS**

*FY 1982 Accomplishments*

Genetic integrity of the production and test rodents is monitored by histocompatability (tail graft) or biochemical (isozyme electrophoresis) means under two contracts to FCRF. At the beginning of this year, it was discovered that the C3H production mice at one breeding facility were not homozygous at all loci. The heterogeneous production stock were killed and replaced with genetically homogeneous C3H breeder stock. Importantly, the rate at which chemicals were placed on test was not altered due to unavailability of test animals.

The use of detergents containing essential oils has been eliminated in chemical test animal rooms at contract laboratories, thereby removing a potential source of toxic reactions in the experimental animals. A new and innovative approach to diagnosing mycoplasma and mouse hepatitis virus infections was instituted in conjunction with the sentinel animal program. Using the ELISA method, we can now diagnose these infections with a much greater degree of precision and accuracy. Information from these and other assays over the past two to three years are currently being entered into a data file for future analyses.

*FY 1983 Program Plans*

The animal care and production resource will continue to produce quality rodents for the NTP testing programs. Additionally, achievement of three major objectives is planned:

1. Reduce animal production to approximately 60% of FY 1982 levels, while maintaining, and improving, the quality of animals.

2. Correlate information from the sentinel animal data file with result of the bioassay. For example, Sendai virus-pulmonary tumor associations can be ascertained.

3. A biochemical and immunochemical genetic monitoring program at both production and testing facilities will be continued and upgraded through institution of a support contract to the Program Resources Branch, TRTP/NIEHS.

Each of these objectives extends the overall goal of the animal resources program to produce sufficient numbers of healthy rodents to serve as NTP bioassay test systems. (CONTACT PERSON: Dr. C. K. Grieshaber)

*Chemical Health and Safety*

The scope of activities in the NTP is necessarily broad and involves research and testing of diverse types of potentially hazardous materials. The safety program serves to guard against excessive exposure of laboratory personnel and the surrounding environment to test materials, metabolites, and degradation products. In addition, every effort is made to integrate and coordinate the NTP health and safety requirements and guidelines with the operational work practices used in toxicity testing procedures to minimize any impact on the timeliness, efficiency and effectiveness of performing NTP research and testing.

Each contract laboratory develops and implements their own health and safety and environmental protection programs. The NTP chemical health and safety program sets standards, establishes guidelines and recommendations and ensures that pertinent local, State, and Federal regulations are followed. In addition, the chemical health and safety program has responsibility for monitoring and evaluating the effectiveness of individual laboratories' compliance to established standards, and renders advice in the event of emergency situations. The evaluation of chemical specific health and safety guidelines, safe handling documents and emergency procedures documents for all NTP test chemicals also constitutes a significant part of the program's functions.

The NTP chemical health and safety concerns differ considerably from those of academic or production facilities and require basic understanding and experience in chemistry, industrial hygiene, engineering control, non-routine specialized analytical chemistry, biological monitoring and medical surveillance, human factors and ergonomics, personal protective equipment evaluation and development, sampling strategies and biological testing procedures.

**NIEHS**

*FY 1982 Accomplishments*

Annual health and safety program reviews and site visits were conducted at all carcinogenesis bioassay contract laboratories. An evaluation as well as a description of action items were submitted to each laboratory with recommendations for corrections.

Two laboratories were monitored for specific test chemicals during industrial hygiene surveys. Five laboratories were monitored for formaldehyde levels involved in necropsy and tissue trimming operations observed during baseline health and safety surveys. A study was initiated using fluorescein to compare weighing procedures commonly used in *in vitro* research utilizing balances placed in hoods versus placement on open laboratory benches. The results were used as a basis for formulation of NTP minimum health and safety requirements for cellular and genetic toxicology laboratories. Gaseous marker chemicals representing chemicals scheduled for cellular and genetic toxicology testing were monitored at the repository and the test laboratory prior to testing of the more hazardous compounds (e.g., hydrogen cyanide). As a result a revised protocol was suggested.

Waste disposal procedures at all carcinogenesis bioassay laboratories were surveyed and reviewed for consistency and compliance with RCRA regulations. The high temperature system used for incineration of NTP surplus carcinogenesis bioassay chemicals was evaluated for efficacy in addition to evaluation of procedures used for disposal of chemicals not amenable to incineration. An on-site bioassay contract incinerator was evaluated for possible use in combustion of polybrominated biphenyls and determined to be inadequate for this use; alternate disposal recommendations were provided. NTP requirements were instituted for shipment to the repository of surplus bioassay chemicals scheduled for disposal.

Preliminary development studies have been completed for chemical-specific biological monitoring using 15 test chemicals as markers to assist medical surveillance of carcinogenesis bioassay laboratory personnel. Additional work is under consideration pending review of the results and recommendations of the study.

Approximately 40 cellular and genetic toxicology, carcinogenesis bioassay, pathology and program resources contract laboratories have been visited and baseline health and safety surveys were conducted with recommendations provided. Mechanisms are continuing for the health and safety evaluation, onsite inspection and monitoring, where necessary, of NTP laboratories which handle potentially hazardous materials. Plans have been instituted for evaluation and inspection of new laboratories as they join the program as well as periodic reinspection of current contractors. Guidelines and minimum requirements have been approved for all NTP programs except systemic toxicology, which is planned for FY 1983. These minimum requirements will be used in support of NIH Guidelines for Laboratory Use of Chemical Carcinogens, OSHA requirements, and other pertinent Federal, State and local regulations.

Approximately 25 chemical-specific health and safety guidelines have been prepared, reviewed and evaluated for new test chemicals and have been distributed to the respective chemical managers and other pertinent personnel.

A project was initiated to improve the fundamental design of tissue trimming stations in order to provide better capture of formaldehyde, fixatives and trace quantities of potentially hazardous test chemicals. The resultant design incorporated ventilation and ergonomics and can be applied to related work stations such as histopathology and necropsy.

An extensive study of the complex local exhaust ventilation system employed at one bioassay laboratory was undertaken as a result of potentially hazardous conditions. Modifications necessary to improve and rectify existing problems were suggested. Rapid response to an emergency situation was initiated to alleviate potentially hazardous conditions at a cellular and genetic toxicology contract laboratory.

*FY 1983 Program Plans*

The evaluation, program reviews, site visits, inspections, monitoring and other programs described as FY 1982 accomplishments will be continued. Health and safety evaluations and on-site inspections of all NTP contract laboratories are planned. Chemical-specific health and safety guidelines for new NTP test chemicals will be prepared and reviewed as necessary in addition to evaluation and inspection of new NTP contract laboratories. Efforts to improve and finalize guidelines and minimum requirements for all NTP contract laboratories will be completed for existing programs. A program for in-house NIEHS/NTP research laboratories to be visited, evaluated and, where necessary, monitored, will be instituted with close coordination with NIEHS safety personnel. Plans for the formulation of health and safety guidelines and requirements for in-house research will be considered. In addition, plans call for inspection of all systemic toxicology contract laboratories and formulation of health and safety guidelines and minimum standards for these laboratories. Waste management procedures for surplus NTP chemicals will be closely monitored to ensure that all potentially hazardous waste products are disposed of properly and in accordance with RCRA regulations. Studies will continue on program specific human factors and ergonomic evaluations at particular laboratories in seeking ways to improve worker safety coupled with worker effectiveness. A survey of NTP training efforts will be conducted and plans to assist and fulfill training needs will be initiated. (CONTACT PERSON: Dr. D. Walters)

*Information Generation and Dissemination*

Scientific information and communication about toxic and potentially toxic chemicals remains a critical aspect for program success. The National Toxicology Program must ascertain the toxicology of selected chemicals and assure that results will have scientific and regulatory significance. The end product is information—scientific information necessary in deciding social issues relative to public health and the environment. To provide that information, the NTP identified two important aspects; first, information must be disseminated to other scientists so that peer review and feedback assure scientific quality; second, since the scientific product helps society evaluate identified toxicological risks, information must be disseminated to not only the regulators responsible for protecting against potentially hazardous risks, but also to those exposed to the risks. Thus, the NTP has established and uses a coordinated communications network to disseminate toxicological information.

The value of information produced by NTP depends in part upon the quality and timeliness of information the Program receives. The NTP therefore actively seeks information from many sources: Federal, state and local governments; trade assoications; industry; labor; academia; professional societies; public interest groups; the press; individuals; other countries; and other interested parties. This includes nominations of chemicals to be tested; critiques and questions about scientific procedures, policies, priorities, and resource allocations; suggestions for program improvement; and most importantly, information about planned, ongoing, and recently completed studies on chemicals being considered or being tested by the NTP.

*Scientific Coordination and Information Dissemination*—To encourage public participation in the Program, the NTP holds public meetings to introduce the current year's program plans and to solicit comments and advice. The fourth NTP Open Meeting is in the planning stage and further information will be published in the *NTP Technical Bulletin*. Additionally, the NTP Board of Scientific Counselors convenes three times a year in open forum, as does the Board's Technical Reports Review Subcommittee and its *ad hoc* Panel of Experts to conduct peer review of technical reports on toxicology and carcinogenesis bioassays.

NTP must be aware of scientific procedures and results produced by other laboratories. Part II of the *Annual Plan*, the *Review of Current DHHS, DOE and EPA Research Related to Toxicology*, a major contribution towards this goal, provides overviews of research programs as well as extensive tabular information on chemical testing and test methods development and validation activities in the various agencies. Active efforts to learn about work in progress and to establish better communication links among investigators worldwide are integrated with many national and international organizations and are being pursued with others.

Fundamental to current awareness is the provision to NTP staff scientists and administrators of comprehensive searches and reviews of the world's scientific and technical literature on a given compound, in advance of decisions about priorities and experimental test designs. This is of special importance for the carcinogenesis bioassay program, where the testing process for each chemical represents a major commitment of time, labor, materials and funds for up to a five-year period.

Toxicologic research and testing require comprehensive scientific coordination for information generation and dissemination. To better utilize the concepts and the latest retrieval systems of information science, the on-line services available to the NTP from the National Library of Medicine (NLM) are particularly valuable: CHEMLINE, TOXLINE, RPROJ (Research Projects), MEDLINE, CANCERLINE, TOXICOLOGY DATA BANK, RTECS (Registry of Toxic Effects of Chemical Substances), and others. These and other sources are used by the Toxicology Information Response Center (TIRC) at the Oak Ridge National Laboratory (ORNL) to prepare dossiers on chemicals nominated for test and to provide information for the design of test protocols. Also, new information services will need to be located or developed for toxicology specialties not yet covered adequately in existing systems, for example, neurotoxicology, chemical immunotoxicology, ecotoxicology and chemical-chemical interactions. (CONTACT PERSONS: Dr. P. Craig, NLM, and Ms. J. Chase, NIEHS)

The Environmental Mutagen Information Center (EMIC), supported by the NTP, collects, organizes, and disseminates, primarily, published information on chemicals tested for mutagenicity. Located since its inception in 1969 at the ORNL, the EMIC computerized data file contained (as of May 1982) 40,841 records on 13,325 unique chemicals, 34,798 of which are available on-line from TOXLINE (at the NLM) and 40,115 from RECON (at the ORNL). Each record contains bibliographic information, assay systems, and keywords defining agents tested and organisms studied. (CONTACT PERSONS: Dr. J. Huff, NIEHS; Dr. P. Craig, NLM; and Mr. J. S. Wassom, ORNL)

The Environmental Teratology Information Center (ETIC), established in 1975 at ORNL and also supported by the NTP, maintains a computerized collection of published information on 5,407 chemicals tested for or known to induce teratogenic effects. The ETIC file contains references to 25,799 literature citations; 24,899 records are available from TOXLINE and from RECON. (CONTACT PERSONS: Ms. F. Jordan, NIEHS; Dr. P. Craig, NLM; and Ms. E. von Halle, ORNL)

The NTP, and in particular technical information specialists in cooperation with the various agencies' libraries, supplies information to Congress, scientists, the public, regulatory agencies, consumer advocates, labor, legal organizations, industry, and others.

*Application of Structure-Activity Toxicity Estimation Programs*—In FY 1982, on an experimental basis for NIP, the NLM/NIP group has prepared estimates of the probability of carcinogenesis, mutagenesis, teratogenesis, and of rat oral $LD_{50}$ values for almost 200 chemicals which were nominated to NTP for consideration in various testing programs. The estimation programs used are those developed by Craig and Enslein for NIOSH and NCI. Where no published reports of experimental test values have been located, or when conflicting results have been reported, these estimates were included by the Chemical Evaluation Committee in its evaluation of about fifty chemicals in FY 1982. (CONTACT PERSON: Dr. P. Craig)

*Technical Report Preparation and Dissemination*—The NTP Toxicology Information and Scientific Evaluation Group has the major responsibility of providing the Program's chemical managers (toxicologists) with the most relevant information necessary to design experiments and to oversee the progress of a compound from selection through toxicology and carcinogenesis testing to final report preparation and distribution. Preparation of the technical report begins with selection of a chemical for testing and the appointment of a chemical manager. Each

manager is responsible for recommending and designing the appropriate experiment, for records management throughout the test/research period, for preparation of the draft toxicology and carcinogenesis bioassay reports, and for presenting/defending these reports before the Peer Review Panel. While experiments are in progress, the chemical manager interacts with other Government agencies and serves as resource person for scientific inquiries concerning the chemical and its possible adverse effects. Lists of chemicals nominated and scheduled for testing, those on test, and those completed are published routinely in the **Federal Register**, the NTP *Annual Plan*, an the *NTP Technical Bulletin* as well as being distributed to a variety of newsletters and scientific magazines.

An important activity within the Program centers on preparation, interpretation, and evaluation of the toxicology and carcinogenesis technical reports. Data from the toxicologic characterization studies and the chronic exposure experiments are collected into comprehensive and evaluative technical reports. These compilations receive considerable staff attention during generation, initial data analyses, and draft report preparation; further intense focus is devoted to the draft report by the NTP staff as an iterative review process. After the draft receives internal approval, copies are sent for external peer review to the NTP Board of Scientific Counselors' Technical Reports Review Subcommittee (Peer Review Panel). At this stage draft reports are made available by the Toxicology Information and Scientific Evaluation Group to any individual or organization seeking or requesting copies as long as supplies last. The *ad hoc* panel, comprised of non-government scientists, then reviews critically these draft reports and voices their opinions and findings in sessions open to the public. [Routinely, comments and questions are requested from the individuals or groups attending these open meetings.] When the draft reports are considered by staff and the peer review panel to be scientifically acceptable and soundly based, the technical reports undergo a final technical and style edit prior to printing and distribution.

Meetings to perform peer review of NTP draft bioassay technical reports are held three times yearly either in Bethesda, MD or Research Triangle Park, NC. A list of the reports to be reviewed, reviewer assignments, review forms, and other information about a particular meeting are sent to Peer Review Panel members at least one month prior to the meeting date. At the same time notices about the meeting are published in the **Federal Register** and in the *NTP Technical Bulletin*. [Draft reports are also made available to anyone upon request.] (CONTACT PERSON: Ms. J. Chase, NIEHS)

Members of the Peer Review Panel receive copies of *all* reports to be reviewed during the designated meeting. Two and sometimes three principal reviewers are assigned for each report and each gives an oral critique at the meeting accompanied by written comments. Panel members are asked to provide the NTP with a critical review of each report in advance of the meeting. Deficiencies in design, conduct, or interpretation of the study should be identified, and errors or omissions in the draft report should be stated. Further, panel members are requested to read all reports scheduled for a particular meeting and to contribute their opinions and other criticisms during the discussion period on each report. The recommendations of the reviewers and summary comments recorded at the meeting are incorporated where appropriate and relevant in the final revision of the report.

Following the meeting, draft summary minutes for each report review are prepared and are sent to the reviewers for any necessary corrections and alterations. The edited minutes are then made available for distribution to any interested party. Likewise, soon after the peer review, reports are readied for publication. Subsequently reports are printed, and made available for distribution and sale by the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161. (Telephone: 703–487–4650). Also, the Public Information Office maintains a mailing list of those who wish to receive all technical reports as published. A limited number of technical reports are available without charge by writing the NTP Public Information Office, MD–B2–04, P.O. Box 12233, Research Triangle Park, NC 27709. (CONTACT PERSON: Mr. S. d'Arazien, NIEHS)

Further, NTP uses various toxicological information resources for extensive literature searching and acquistion of scientific papers. Included are a number of information organizations in the private sector which extend the capability of the NTP, and these organizations are available on short notice through interagency or basic ordering agreements. Comprehensive literature searches and quarterly updates to those searches were performed for the chemical manager by the Toxicology Information Response Center (TIRC). From these, the most important references are selected for inclusion in an experimental design package sent to reviewers for generating the protocols for carcinogenesis bioassay testing. (CONTACT PERSONS: Ms. J. Chase and Ms. F. Jordan, NIEHS)

*Tracking of Chemical and Test Status*—The Program Resources Branch updates the computerized status file for chemicals in various stages of carcinogenicity testing, producing a computerized listing of all chemicals. These lists are distributed quarterly on an individual basis to those who want to know about progression of chemicals through the Program.

Records from the carcinogenesis bioassay data system may be obtained from the Toxicology Information and Scientific Evaluation Group. These include protocols for the various bioassays and individual animal pathology tables as these are verified and entered into the system, often before the final report has been released. (CONTACT PERSONS: Ms. J. Chase and Ms. L. Juodeika, NIEHS)

A chemical management and tracking system (CHEMTRACK) has been developed that will provide information on NTP chemical nomination, selection, test status, and summary results. This is described further in the Data Management and Analysis section.

Among the activities of the NLM/NTP information group related to chemical tracking were the following:

Assignment of NTP numbers reached 1,300 in FY 1982, an increase of some 200 from the number assigned in FY 1981. The data concerning test assignments were computerized and merged with the NTP numbers and Chemical Abstracts Service (CAS) Registry Numbers to generate the tables contained in the FY 1981 and FY 1982 NTP *Annual Plans*. The first edition of the *NTP Chemical Registry Handbook* was completed and distributed to senior NTP personnel in FY 1981. The *Handbook* contains for each NTP chemical the CAS registry number, structure, molecular formula, tests being conducted, and synonyms. Copies are available from the National Technical Information Service (NTIS) for sale and distribution (NTIS, U.S. Department of Commerce, 5285 Port Royal Road, Springfield, Va 22161, 703/487–4150; Order No. PB. 82–142977).

The toxicology testing tables and indexes for the FY 1982 *Review of Current DHHS, DOE and EPA Research Related to Toxicology* were prepared by the NLM/NTP group. A "Master List of Chemicals of Concern as Possible Carcinogens" which will list chemicals regulated by U.S. agencies as carcinogens or which are under consideration for possible regulation is being constructed for NTP at ORNL under NLM direction. Printed listings will become available early in FY 1983. (CONTACT PERSON: Dr. P. Craig)

*International Coordination*—In partnership with the international community, the NTP strives to formulate a universally-based communication network of toxicologic information, and in particular, in the area of chemical carcinogenesis. Concomitantly, the NTP is seeking active participation from toxicologists throughout the world. The NTP will continue to expore and develop liaison with foreign agency counterparts. For instance, contacts have been established with the World Health Organization (WHO), with the International Program on Chemical Safety (IPCS), with the International Agency for Research on Cancer (IARC), with the International Registry of Potentially Toxic Chemicals (IRPTC), with the United Nations Environment Program (UNEP), with the European Chemical Industry Ecology and Toxicology Center (ECETOX), and with governments and individual scientists throughout the world. As an example, in July 1981, an agreement was entered into with the IARC to establish and maintain an international registry of persons exposed to phenoxy herbicides and contaminants, particularly the chlorinated dibenzodioxins and dibenzofurans. This registry will complement the national effort under the guidance of NIOSH.

An NTP/EPA interagency effort has been initiated to establish a worldwide clearinghouse on phthalate research activities. Information is being collected, catalogued, and stored, primarily about ongoing research and testing efforts; an international registry of scientists engaged in

phthalates research is being assembled, and in certain voluntary instances preliminary or recently completed research and testing results will be received and made available. In FY 1982, a data form was sent to persons involved in phthalate testing or research. In addition, a form was inserted in the April 1982 issue of the Technical Bulletin to encourage all parties not reached by the separate mailing to report work recently completed, in progress, or contemplated. (CONTACT PERSONS: Ms. J. Chase, NIEHS, and Dr. D. Canter, NIEHS)

*Public Awareness and Inquiry Responses*—Public awareness of the NTP increased during FY 1982. NTP meetings, Program results, and other activities were reported widely in the trade press and occasionally in the general media. The mailing list for the NTP *Annual Plan, Annual Report on Carcinogens, Technical Bulletin* and Technical Reports includes 6,300 names and addresses. Results from surveys of those receiving the *NTP Annual Plan* and the *Annual Report on Carcinogens* indicate that users are concentrated among: industry (28 percent), research or consulting (17 percent), academic or educational (17 percent), Federal Government (15 percent), health care (6 percent), labor and public interest (6 percent), state government (5 percent), trade or professional associations (3 percent) law firms (2 percent), and local governments (1 percent). This mailing list contains names of about 200 media representatives and over 500 foreign addressees.

A readership survey was sent to those receiving Volume II of *The 1981 NTP Annual Plan, (Review of Current DHHS, DOE, and EPA Research Related to Toxicology),* and the responses are being considered in preparation of current and future volumes. The Public Information Office (PIO) will periodically survey NTP readership to update mailing lists and to determine how information is used to make the Program more responsive to the needs of environmental health researchers and public health professionals.

The PIO, working with the Toxicology Information and Scientific Evaluation Group, answers public inquiries and conducts an outreach program to assure that the results of NTP testing and test methods development programs reach those involved in toxicology and public health policy. The PIO prepares press releases and **Federal Register** notices detailing NTP activities and program results.

The PIO has produced a 20-page pamphlet explaining the NTP's mission to the general public. This pamphlet was distributed with the *Second Annual Report on Carcinogens.* As resources become available, it is hoped that other general interest publications can be made available and outreach activities can be broadened. The PIO is also responsible for the Program's contact with the press. (CONTACT PERSON: Mr. S. d'Arazien, NIEHS)

The PIO maintains the NTP mailing list and distributes the following documents:

- The *NTP Annual Plan* (including Volume II, *Review of Current DHHS, DOE, and EPA Research Related to Toxicology);*
- The *NTP Technical Bulletin* (a quarterly publication which presents the latest program plans and results);
- A summary of the *Annual Report on Carcinogens;*
- NTP Technical Reports

Requests should be sent to: NTP Public Information Office, MD B2-04, P.O. Box 12233, Research Triangle Park, NC 27709.

**Annual Report on Carcinogens**

The *Third Annual Report on Carcinogens* will be published in the first half of FY 1983. The report was prepared by the NTP staff and its member agencies pursuant to a 1978 amendment (Section 301(b)(4)) to the Public Health Service Act which requires that the Secretary of the Department of Health and Human Services publish annually a list of "all substances which are either known to be carcinogens or which may reasonably be anticipated to be carcinogens and to which a significant number of persons residing in the United States are exposed * * *." Each annual report also contains available information on the nature and degree of exposure to such carcinogens and on the extent to which Federal regulations are effective in reducing the risk to public health.

The *Third Annual Report on Carcinogens* includes 116 entries on substances, chemicals, or manufacturing processes (Table 43). Included is information on 88 entries in last year's second annual report. These entries are included because the International Agency for Research on Cancer (IARC) has determined that there is "sufficient evidence of carcinogenicity in experimental animals" to classify them as animal carcinogens, because they are regulated by the Federal government as carcinogens, because they have been found to cause cancer in bioassays conducted by the National Cancer Institute or the NTP, or because their inclusion was suggested by the agencies involved in preparing the *Annual Report.*

Among the entries are naturally-occurring substances, additives to food or cosmetics, pesticides, pharmaceuticals, and many which are either associated with industrial production or are by-products of manufacture.

The fact that a substance is not included in the report does not mean that the agent is not a confirmed or suspected carcinogen. There are additional substances which represent potential health hazards to the population. The available data are being examined and these agents will be added to future reports.

Each of the entries includes information on the human and animal evidence for carcinogenicity, on production and occurrence and use, and on what is known about the route and amount of human exposure. The specific regulations promulgated by various Federal agencies are included as well.

The *Annual Report* also contains an extensive list of the common synonyms for the chemicals included, a glossary of terms and acronyms and, as required by law, a list of requests to the Department of Health and Human Services for information about carcinogens.

The information provided in the *Third Annual Report on Carcinogens* was developed by the following Federal regulatory and research agencies: The Centers for Disease Control/National Institute for Occupational Safety and Health; the Consumer Product Safety Commission; the Environmental Protection Agency; the Food and Drug Administration; the National Cancer Institute; the National Institute of Environmental Health Sciences; the National Library of Medicine; and the Department of Labor/Occupational Safety and Health Administration. (CONTACT PERSON: Dr. R. Shapiro, NIEHS)

Copies of the summary of the *Third Annual Report on Carcinogens* may be obtained without charge by contacting: NTP Public Information Office, MD B2-04, P.O. Box 12233, Research Triangle Park, NC 27709. Telephone: (919) 541-3991; FTS 629-3991.

Copies of the complete *Third Annual Report on Carcinogens* will be made available for a fee from the National Technical Information Service (NTIS) (NTIS, U.S. Department of Commerce, 5285 Port Royal Road, Springfield, VA 22161, 703/407-4150).

*Tables*

To conserve space and minimize cost, results are not given in the tables. Results are available in the bound version of the NTP Fiscal Year 1983 Annual Plan which may be ordered from: NTP Public Information Office, P. O. Box 12233, Research Triangle Park, NC 27709, (919) 541-3991 or (FTS) 629-3991.

*Questions or Additional Information*

Questions or requests for information about the Annual Plan and the National Toxicology Program should be addressed to: Dr. Larry Hart, National Toxicology Program, P.O. Box 12233, Research Triangle Park, NC 27709; (919-541-3971; FTS 629-3971).

If readers of the Annual Plan are aware of planned or ongoing studies on chemicals mentioned in the Plan, they are encouraged to make such information known to the NTP, so that unnecessary duplicative studies can be avoided or minimized.

*Errors or Omissions*

Although every effort is made to ensure that the Annual Plan is error free, mistakes may occur. Any errors or omissions noted by the reader in the body of the Annual Plan, or the index, should be called to the attention of Dr. Larrry Hart (see above for address).

*Index*

Numbers in the index refer to the number of the table in which the chemical is listed *except* where prefixed with a P. These entries are found in the text and P refers to the page number in the bound version of the Plan.

BILLING CODE 4140-41-M

TABLE 1

## CHEMICALS TESTED FOR MUTAGENICITY IN SALMONELLA ASSAYS IN FY 1982 FOR WHICH RESULTS ARE AVAILABLE FROM NTP

Acetonitrile
AF-2
Allyl isothiocyanate
9-Aminoacridine HCL H20
2-Aminoanthracene
P-Aminobenzoic acid
2-Amino-4-nitrophenol
2-Amino-5-nitrophenol
Ampicillin trihydrate
N-Amylamine
Anethole
P-Anisidine
Anthracene
Benzethonium chloride
Benzidine
Benzophenone
O-Benzyl-p-chlorophenol
4-Biphenylamine
2,2-Bis(bromomethyl)-1,3-propanediol
Bis(2-chloroethyl)ether
N,N'-Bis(1,4-dimethylpentyl)-p-phenylenediamine
1,2-Bis(2,4,6-tribromophenoxy)ethane
Boric acid
Bromoacetonitrile
Bromodichloromethane
2-bromo-4,6-dinitroaniline
Brucine
1,4-Butanediol diglycidyl ether
Tert-Butylamine
n-Butylamine
Butyl anthranilate
Butyl(2,4-dichlorophenoxy) acetate
Butyl methacrylate
o-sec-Butylphenol
Butyl(2,4,5-trichlorophenoxy) acetate
Butyraldehyde
gamma-Butyrolactone
Cadmium oxide
Carvyl acetate
Chlorambucil
Chlordane
Chlordecone (Kepone)
Chlordecone alcohol
Chloroacetonitrile
2-Chloroethyltrimethyl-ammonium chloride
2-Chloromethylpyridine hydrochloride
4-Chloro-2-nitroaniline
Chlorothen
3-Chloro-p-toluidine
5-Chloro-o-toluidine
Chlorpheniramine maleate
Choline chloride
C.I. Acid Red 114
C.I. Direct Blue 218
C.I. Direct Blue 1
C.I. Direct Blue 15
C.I. Direct Blue 53
C.I. Direct Blue 25
C.I. Direct Green 1
C.I. Direct Red 2
C.I. Pigment Violet 1
C.I. Vat Blue 1
C.I. Vat Brown 3
C.I. Vat Yellow 4
1,8- Cineol
Citral
Colchicine
Cresyl diphenyl phosphate
Curcumin
Cyclohexane
Cyclohexylamine
Diallylamine
Diallyl phthalate
1,4-Diamino-2,6-dichlorobenzene
4,4'-Diaminodicyclohexylmethane
1,3-Diaminopropane
Di-n-amylamine
Diarylanilide Yellow
Dibromoacetonitrile
2,3-Dibromo-2-butene-1,4-diol
Dibromomannitol
2,3-Dibromopropylmethacrylate
2,3-Dibromopropyl acrylate
Dibutyl phthalate
Dibutyltin diacetate
3,3'-Dichlorobenzidine dihydrochloride
2,7-Dichlorodibenzo-p-dioxin
Dichloroisocyanuric acid
1,3-Dichloropropene
2,3-Dichloroquinoxaline
Dicyclohexyl phthalate
Dicyclopentadiene
Diesel fuel marine
DI(2-ethylhexyl) phthalate
Diethylamine
(Diethylamino)ethanol
Diethylene glycol
Diethylenetriamine
DI(2-ethylhexyl)sebacate
DI(p-ethylphenyl)dichloroethane
N,N'-Diethylthiourea
Diglycidyl resorcinol ether
2,2'-Dihydroxy-4-methoxy-benzophenone
Diisobutyl phthalate
Diisodecyl phthalate
Diisononyl phthalate
Diisopropylamine
Dimenhydrinate
3-Dimethylamino-propylamine
N,N'-Dimethylaniline
Dimethylcarbamoyl chloride
Dimethylethanolamine
Dimethyl hydrogen phosphite
Dimethylol dihydroxyethyleneurea
Dimethyl phthalate
Dimethyl terephthalate
2,4-2,4-Dinitroaniline
2,4-Dinitrotoluene
Dioctyl phthalate
Dioxathion
DI(n-hexyl)phthalate
Ditridecyl phthalate
Diundecyl phthalate
Divinylbenzene
Dodecenylsuccinic anhydride
Endosulfan
Epibromohydrin
Epichlorhydrin
1,2-Epoxyhexadecane
1,2-Epoxy-3,3,3-trichloropropane
Erythromycin stearate
Monoethanolamine
2-2-Ethoxyethyl p-methoxy-cinnamate
Ethyl anthranilate
N,N'-Ethylene-bis(tetrabromo-phthalimide)
Ethylene thiourea
2-Ethylhexanol
Mono(2-ethylhexyl) adipate
2- Ethylhexyl 2-cyano-3,3-diphenylacrylate
2-Ethylhexyl diphenyl phosphate
2-Ethylhexyl-p-methoxycinnamate
Mono(2-ethylhexyl)phthalate
Ethylidenenorbornene
Ethyl ethanesulfonate
Ethylvanillin
4-Fluoro-dl-phenylalanine
5-Fluorouracil
Furfuryl acetate
Gibberellic acid
Glutaraldehyde
Halothane
Heptachlor
Hexabromocyclododecane
Hexamethyl-p-rosaniline chloride
Hexanamide
N-Hexane
1,6-Hexanediamine
Hexylresorcinol
Hydrochlorothiazide
Hydroquinone monomethyl ether
2-Hydroxy-4-methoxybenzophenone
L-5-Hydroxytryptophan
3.3'-Iminobis(propylamine)
Indomethacin
Beta-Ionone
Isoamyl nitrite
Isobutylamine
Isobutyl anthranilate
Isobutyl nitrite
Isobutyraldehyde
Isoeugenol
Isoprene
Isopropyl glycidyl ether
Isoproterenol hydrochloride

TABLE 1

CHEMICALS TESTED FOR MUTAGENICITY IN SALMONELLA ASSAYS
IN FY 1982 FOR WHICH RESULTS ARE AVAILABLE FROM NTP (CONT.)

Lead dioxide
Linoleic acid
Malathion
Mercaptobenzothiazole
Mercuric chloride
p-Methane-1,8-diamine
Methoxychlor
alpha-Methylbenzyl alcohol
alpha-Methyl cinnamaldehyde
N-Methyldiethanolamine
4,4'-Methylenebis(2-chloroaniline)
N-Methylethanolamine
Methyleugenol
O-Methylhydroxylamine HCL
Methyl isocyanate
Methyl methanesulfonate
N-Methyl-2-pyrrolidone
Mirex
Monoethylamine
Monuron
Myleran
o-Nitroacetophenone
p-Nitroacetophenone
p-Nitroaniline
o-Nitroanisole
4-Nitroanthranilic acid
p-Nitrobenzoyl chloride
p-Nitrobenzyl chloride
o-Nitrobenzyl chloride
o-Nitrophenethyl alcohol
o-Nitrophenol
4-Nitro-o-phenylenediamine
Oleic acid
O,O-Diethyl S-(1,1-dimethylethyl) thioOmethyl)phoshorodithioate
Parathion
Pentabromodiphenyl oxide
2,3,4,5,6-Pentabromoethylbenzene
Pentabromophenol
Pentabromotoluene
Phenthiazine
o-Phenanthroline
Phenramine maleate
Phenolphthalein
D-Phenylalanine
N-Phenylhydroxylamine
1-Phenyl-3-methyl-5-pyrazolone
Phthalamide
Phthalic anhydride
Picloram
Piperazine
Piperonalacetone
Potassium chloride
Prednisone
Promethazine hydrochloride
Propiolactone
Propionaldehyde
Propylenediamine
Pyriamine
p-Quinone
Resorcine blue
Saccharin
Sodium diethyldithiocarbamate
Stannous chloride
Sulfamethazine
Sulfamethizole
Sulfamethoxazole
Sulfan blue
Sulfathiazole
Tetrabromobisphenol A
Tetrabromophthalic anhydride
1,2,4,5-Tetrachlorobenzene
1,1,1,2-Tetrachloroethane
Tetracycline hydrochloride
Tetraethylenepentamine
Tetraethylthiuram disulfide
N,N,N',N'-Tetramethyl-1,3-butanediamine
N,N,N',N'-Tetramethylethylenediamine
4,4-Thiobis(6-tert-butyl-m-cresol)
Thonzylamine hydrochloride
Toluene diisocyanate
Toxaphene
Triamylamine
S-Triazine-2,4,6(1H,3H,5H)-trione, 1,3-dichloro-, potassium salt
2,4,6-Tribromophenol
Trichloroacetonitrile
Trichloroethylene
Trichlorofluoromethane
2,4,5-Trichlorophenol
2,4,5-T isobutyl ester
Triethylamine
Triethylenetetramine
Triethyllead chloride
Triethyl phosphate
Triisopropanolamine
Trimellitic anhydride
Trimetacresyl phosphate
Trimethoprim
2,4,5-Trimethoxybenzaldehyde
Trimethylamine
3,3,5-Trimethylcyclohexyl
Trimethylthiourea
Tripelennamine
Triphenyl phosphate
Tris(2-chloroethyl)phosphite
Tris(1,3-dichloro-2-propyl) phosphate
Trixylenyl phosphate mixed isomers
Turmeric oil
Vanillin
Veratraldehyde
Vinyl cyclohexene dioxide
Witch hazel
Wollastonite calcium silicates
Zinc pyrithione
Zirconium oxychloride

TABLE 2

CHEMICALS SELECTED FOR MUTAGENICITY TESTING IN SALMONELLA IN FY 1983

Acetaldehyde
Acetanilide
Acetic anhydride
Acetoacetanilide
2-Acetylamino-4-methylphenol
N-Acetyl-m-aminophenol
1-Acetyl-2-phenyl hydrazide
N-Acetyl-m-Toluidine
N-Acetyl-p-Toluidine
Acrylamide
Acrylic acid
Acrylonitrile
Adiponitrile
Agaritine
Alloxan
Allyl acrylate
Allylamine
Allyl anthranilate
Allyl propyl disulfide
Allylthiourea
p-Amino acetanilide
m-Aminoacetanilide
2-Aminoacetanilide
5-(4-Aminobenzamido)-2,3-cresotic acid
2-Aminobenzenesulfonic acid
3-Aminobenzenesulfonic acid
4-Aminobenzenesulfonic acid
2-Aminobenzimidazole
2-Amino-4-chloro-5-nitrophenol
2-Amino-4-chloro-6-nitrophenol
2-Amino-6-chloro-4-nitrophenol
2-Amino-4-chlorophenol
6-Amino-4-chloro-1-phenol-2-sulfonic acid
2-Amino-4,6-dichlorophenol
2-Amino-4,6-dinitrophenol
4-Amino-4'-hydroxy-3-methyl-diphenylamine
2-Amino-4-methylphenol
3-Amino-6-methylphenol
3-Amino-4-methylphenol
2-Amino-4-(methylsulfonyl)phenol
2-Amino-6-nitrobenzothiazole
2-Amino-5-nitro-4-methylphenol
2-Amino-3-nitro-4-methylphenol
4-Amino-2-nitrophenol
6-Amino-4-nitro-1-phenol-2-sulfonic acid
2-Amino-6-nitro-1-phenol-4-sulfonic acid
3-Aminophenol
4-Aminophenol
2-Amino-1-phenol-4-sulfonic acid
2-Aminopyridine
5-Amino-3-sulfosalicylic acid
3-Amino-5-sulfosalicylic acid
3-Aminotriazole

TABLE 2

CHEMICALS SELECTED FOR MUTAGENICITY TESTING IN SALMONELLA IN FY 1983 (CONT.)

2-Amino-3,4,6-trichlorophenol
Amphetamine sulfate
Amphotericin B
Amyl nitrite
Antergan hydrochloride
Anthralin
o-Anthranilic acid
Atrazin
Azathioprine
Azinphosmethyl
Benomyl
Benzamide
Benzene sulfonic acid
Benzimidazole
Benzimidazol-2-ylurea
Benzonitrile
Benzo(f)-quinoline
p-Benzoquinone monooxime
Benzothiazole, 2,2'-dithiobis
Benzotriazole
Benzoyl chloride
Benzoyl peroxide
Benzyl chloride
Benzyltrimethyl ammonium chloride
2-Biphenylol, sodium salt
2,4-Bis(p-aminobenzyl) aniline
1,3-Bis(2-benzothiazolylmercapto-methyl) urea
1,3-Bis(tert-butyldioxyiso-propyl)benzene
Bismuth subsalicylate
Bisphenol A diglycidyl ether
Bis(tributyltin)oxide
N-Bromoacetamide
p-Bromoaniline
3-Bromo-2,2-bis(bromomethyl) propanol
Bromochloroacetaldehyde
Bromochloroacetonitrile
2-Bromo-1-ethanol
2-Bromoethyl acrylate
Beta-bromo-beta-nitrosostyrene
3-Bromo-1-propanol
1-Bromo-2-propanol
2,3-Butanedione 2-oxime
Mono-sec-butanolamine
N-Butyl acrylate
sec-Butylamine
tert-Butyl chromate
Butyl cyclohexyl phthalate
tert-Butyl perbenzoate
tert-Butylphenyl diphenyl phosphate
Butyltin-tris(isooctyl-mercaptoacetate)
tert-Butyltoluene
Butyric acid
Cadinene
Caprolactam
Carbarsone
4-(3-Carbazoylamino)phenol
Carbendazim
((O-Carboxyphenyl)thio)ethyl-mercury sodium salt
Carisoprodol
Carminic acid
Carveol
Castor oil
Chloral
Chloramphenicol sodium succinate
Chlorinated trisodium phosphate
Chloroacetophenone (CN)
N-(3-Chloroallyl)hexaminium chloride
m-Chloroaniline
o-Chloroaniline
o-Chlorobenzalmalononitrile
4-Chloro-2-(2,4-dinitroanilino) phenol
Chloroethyl acrylate
3-Chloromethylpyridine hydrochloride
Chloroneb
4-Chloro-O-phenylenediamine
3-Chloro-1,2-propanediol
2-Chloro-1,3-propanediol
1-Chloro-2-propanol
2-Chloro-1-propanol
3-Chloro-1-propanol
o-Chlorostyrene
Chlorotrianisene
2-Chloro-6-(trichloro-methyl)pyridine
Chlorotrimethylsilane
C.I. Acid Blue 74
C.I. Acid Orange 10
C.I. Acid Orange 3
C.I. Acid Red 14
C.I. Basic Orange 2
C.I. Basic Red 9
C.I. Basic Violet 14
C.I. Direct Black 114
C.I. Direct Blue 2
C.I. Direct Blue 8
C.I. Direct Blue 10
C.I. Direct Brown 2
C.I. Direct Red 39
C.I. Direct Yellow 11
C.I. Disperse Blue 1
C.I. Disperse Yellow 3
C.I. Pigment Green 36
C.I. Pigment Orange 43
C.I. Pigment Orange 7
C.I. Pigment Red 2
C.I. Pigment Red 8
C.I. Pigment Red 69
C.I. Pigment Yellow 74
C.I. Solvent Red 5
C.I. Solvent Yellow 14
Cinnamaldehyde ethylene glycol acetal
Citral diethyl acetal
Clonitralid
Coconut diethanolamide
Codeine
Copper acetoarsenite
p-Cresidine
p-Cresol glycydyl ether
Cumene hydroperoxide
4-Cumylphenyldiphenyl phosphate (CPDPP mixed isomers)
Cyclohexanone cyanohydrin cyclohexlmide
Cyclohexyl anthranilate
Cytarabine
Cytarabine hydrochloride
Cytembena
Dacarbazine
Decyl methacrylate
Dehydroemetine hydrochloride
Diaminomaleonitrile
Diazoaminobenzene
Dibromoacetaldehyde
Dibromochloropropane
1,2-Dibromo-4-(1,2-dibromoethyl) cyclohexane
Dibromodulcitol
2-(Dibutylamino)ethanol
Di-tert-butyl peroxide
Dibutyl phenyl phosphate
Dibutyltin-bis(laurylmercaptide)
Dibutyltin dilaurate
Dichloran
Dichloroacetaldehyde
2,5-Dichloroaniline
3,4-Dichloroaniline
1,2-Dichloroethane
4,5-Dichloro-6-methyl-2-methyl-sulfonylpyrimidine
1,1-Dichloro-1-nitroethane
1,3-Dichloro-2-propanol
2,3-Dichloro-1-propanol
Dichlorvos
Dicumyl peroxide
Dicyclohexylamine
Dicyclohexylamine nitrite
5-Diethylamino-2-nitroso-4-methylphenol
5-Diethylamino-2-nitrosophenol
3-Diethylaminophenol
N,N-Diethyl aniline
Diethylbutylamine
Diethyldichlorosilane
Diethylene glycol bis-glycidyl ether
Diethylstilbestrol
2,4-Difluoroaniline
Dihexylamine
1,2-Dihydro-2,2,4-trimethyl-quinoline
3,3'-Dihydroxybenzidine
1,8-Dihydroxy-4,5-dinitro-anthraquinone
Dihydroxyurea
Diisobutylamine
2,6-Diisocyanatotoluene
Diisopropanolamine
Di(isopropylphenyl)phenyl phosphate (DIPP)
N,N-Dimethylacetamide
2-(Dimethylamino)ethyl acrylate
3-Dimethylamino-4-methylphenol
5-Dimethylamino-2-nitroso-4-methylphenol
3-Dimethylaminophenol
3,3'-Dimethylbenzidine
2,5-Dimethyl-2,5-bis(tert-butyl-peroxy)hexane
1,3-Dimethylbutylamine

TABLE 2

CHEMICALS SELECTED FOR MUTAGENICITY TESTING IN SALMONELLA IN FY 1983 (CONT.)

N-(1,3-Dimethlbutyl)-n-phenyl -p-phenylenediamine
Trans-1,3-Dimethylcyclopentane
1,1-Dimethyl-1-(2-hydroxpropyl- amine)methacrylimide
1,1-Dimethyl-1-(2-hydroxypropyl- amine)tetradecanimide
Dimethyl morpholinophosphonate
Dimethyl sulfoxide
2-(2,4-Dinitroanilino)phenol
4-(2,4-Dinitroanilino)phenol
2,4-Dinitro-6-(1-methyl- heptyl)phenol
2,4-Dinitrophenol
Di(n-octyl)tin-S,S'-bis (Isooctylmercaptoacetate)
Di(n-octyl)tin maleate
1,3'-Diphenylguanidine
Diphenylurea
Di-n-Propylamine
Direct Violet 32
Di-sec-butanolamine
Dodecyl alcohol, ethoxylated
N-Dodecylmercaptan
Doxylamine succinate
Econazole
Emetine hydrochloride
Ephedrine sulfate
Epinephrine
2,3-Epoxy-1,4-dichlorobutane
1,2-Epoxy-1,1,2,3,3,3- hexafluoropropane
Ergotamine tartrate
Estragole
N-(3-Ethoxyphenyl)acetamide
3-Ethylamino-4-methylphenol
3-Ethylaminophenol
N-Ethyl aniline
Ethylbenzene
Ethyl chloride
S-Ethyl dipropylthiocarbamate
2-Ethylhexyl acrylate
Ethyl methacrylate
N-Ethylmorpholine
N-Ethyl-N-phenyl benzylamine
Ethyl 3-phenylglycidate
N-Ethyl-O-toluenesulfonamide
FD and C Red No. 32
Formulated fenaminosulf
Formamide
Formanilide
Fumaric acid
Furfuralacetone
Furfuryl alcohol
Furosemide
beta-2-Furylacrolein
Glycidol
Griseofulvin
Halazone
HC Blue 1
HC Blue 2
HC Red 3
2-Heptadecyl-3-hydroxyethyl- Imidazoline
1,2,3,6,7,8-Hexachloro- dibenzo-p-dioxin
Hexachloronaphthalene
Hexadecylamine
Hexafluoroacetone
Hexafluoro-1-propanol
Hexahydro-1,3-tris(2-hydroxy- ethyl)triazine
1,6-Hexamethylene diacrylate
1,3,6-Hexanetricarbonitrile
n-Hexyl methacrylate
Hycanthone methanesulfonate
Hydrocyanic acid
Hydroxyacetonitrile
2-Hydroxybenzamide
N-Hydroxybenzamide
alpha-Hydroxybenzeneacetonitrile
N-(Hydroxyethel)ethylenediamine
Hydroxylamine, hydrochloride
2-Hydroxy-2-methylpropanenitrile
2-Hydroxy-1,4-naphthoquinone
3-Hydroxy-n-phenylaniline
2-Hydroxypropanenitrile
3-Hydroxypropanenitrile
8-Hydroxyquinoline sulfate
Iodinated glycerol
Iodoacetic acid
Iodochlorohydroxyquinoline
beta-Ionone
Isatin-5-sulfonic acid
Isobutyl acrylate
Isobutyl methacrylate
Isodecyl diphenyl phosphate
Isophorone diisocyanate
Monoisopropanolamine
Isopropylamine
N-Isopropylaniline
Isopropyl methacrylate
Isopropyl phenyl diphenyl phosphate (IPDP mixed Isomers)
N-Isopropyl-N'-phenyl-p- phenylenediamine
Lauric acid
Lauric acid diethanolamine
Laurylethanolamide
Linalyl anthranilate
Malaoxon
Maleic hydrazide diethanolamine
Malonic dinitrile
Maltol
Manganese sulfate
para-Menthane hydroperoxide
2-Mercaptobenzimidazole
Methacrylonitrile
Methapyrilene hydrochloride
Methdilazine hydrochloride
3-((Methoxycarbonyl)amino)phenyl N-(3-methylphenyl)carbamate
O-Methoxycinnamaldehyde
Methoxyethyl mercury chloride
Methoxyflurane
4-Methoxy-3-nitro-N-phenyl- benzamide
Methyl acrylate
Monomethylamine
3-Methylamino-4-methylphenol
N-Methyl aniline
Methyl anthranilate
N-Methylbenzamide
2-Methylbenzamide
cis-2-Methyl-2-butenenitrile
trans-2-Methyl-2-butenenitrile
2-Methyl-3-butenenitrile
Methyl 2-cyanoacrylate
Methyl demeton
Methyldopa
N,N'-Methylenebisacrylamide
Methylenebis(4-cyclohexyl Isocyanate)
Methylenedianiline
Methylglutaronitrile
Methyl mercuric chloride
Methylmercury hydroxide
Methyl methacrylate
4-Methyl-4-methoxy-2-pentanone
N-Methylolacrylamide
Methylphenidate
N-Methyltaurine
Methyltin-tris(Isooctylmercapto- acetate)
Methyltrifluoromethanesulfonate
Metronidazole
Mexacarbate
Mezerein
Monosodium glutamate
Musk ambrette
Musk ketone
Nalidixic acid
1,4-Naphthalenediamine
4-(2-Naphthylamino)phenol
2-Naphthyl lactate
Neohesperidin dihydrochalcone
N-Ethyl-N-butylamine
Nickel carbonyl
Ninhydrin
NTA(Nitrilotriacetic acid)
m-Nitroacetophenone
o-Nitroaniline
m-Nitroaniline
m-Nitrobenzamide
p-Nitrobenzamide
o-Nitrobenzamide
p-Nitrobenzoic acid
o-Nitrobenzoic acid
m-Nitrobenzoic acid
m-Nitrobenzoyl chloride
o-Nitrobenzoyl chloride
m-Nitrobenzyl chloride
p-Nitrophenethyl alcohol
p-Nitrophenethyl alcohol, acetate
o-Nitrophenethyl alcohol, acetate
m-Nitrophenol
(o-Nitrophenyl)acetonitrile
1-(4-Nitrophenyl)-2-chloropropane
N-Nitrosodiethanolamine
N-Nitroso-N-ethylurethane
Nonamethyleneimine
Nonanal
Nonylphenyl diphenyl phosphate (NPDPP mixed Isomers)
Noscapine
Ochratoxin A
Octachlorodibenzodioxin
Octachloronaphthalene
Octadecylamine
N-Octyl methacrylate
Oleic acid diethanolamine

TABLE 2

CHEMICALS SELECTED FOR MUTAGENICITY TESTING IN SALMONELLA IN FY 1983 (CONT.)

Olivetol
Oxethazaine
Papaverine hydrochloride
Pentabromochlorocyclohexane
Pentachloroanisole
Pentaerythritol triacrylate
Pentaethylenehexamine
cis-2-Pentenenitrile
trans-2-Pentenenitrile
3-Pentenenitrile
p-tert-Pentylphenol
Peracetic acid
Perchloromethyl mercaptan
Phenamiphos
Phenesterin
Phenethyl anthranilate
o-Phenetidine
p-Phenetidine
m-Phenetidine
Phenformin hydrochloride
Phenoxybenzamine hydrochloride
Phenylacetonitrile
N-Phenylbenzenamine
Phenylephrine hydrochloride
2-Phenyl-2-ethylmalondiamide
Phenylphosphine
Photodieldrin
Piperonyl acetate
2-Pivalyl-1,3-indandione
Polyethylene glycol 200
Polyethylpotassium 2-benzyl-4-chlorophenate
Polyvinylchloride latex
Polyvinylpyrrolidone polymers
Potassium p-tert amylphenate
Primaclone
Procarbazine hydrochloride
Propanedial, ion(1-), sodium
2-Propanol, 1-chloro-, phosphate (3:1)
Propantheline bromide
Propionitrile
Propylene
Propylene cyanohydrin
1,3-Propylene oxide
3-Propylidenephthalide
N-Propyl methacrylate
Quaternary ammonium compounds, benzyl-C8-18-alkyldimethyl, chlorides
Quinacrine dihydrochloride
Quinacrine mustard
Quinidine
D & C Red 9
Rhodamine 6G
Riddelline
Roxarsone
Salicylazosulfapyridine
Scopolamine
Seneciphylline
Sodium arsenilate
Sodium cyanurate
Sodium iodomethanesulfonate
Sodium mercaptobenzothiazole
Monosodium methane arsenate
Sodium methohexital
Stearatochromic chloride complex
Succinic anhydride
Succinonitrile
5-Sulfoanthranilic acid
Sunset Yellow FCF 6
L-Taurine
1,2,4,5-Tetrabromo-3,6-dimethylbenzene
O-Tetrabromoxylene
Tetrachlordiphenylethane
Tetrachloronaphthalene
Tetrachlorvinphos
Tetraethyldithiopyrophosphate
Tetraethylene glycol diacrylate
Tetrafluoroethylene
1-trans-Delta-9-tetrahydrocannabinol
Tetramethylsuccinonitrile
1,1,3,3-Tetramethyl-2-thiourea
Thenyldiamine hydrochloride
Theophylline
Thiabendazole
Thiazole
2,2'-Thiobis(4-chlorophenol)
2,2'-Thiobis(4,6-dichlorophenol)
Thiocid
Thioglycolic acid
Thiophanate M
Thiophen
Thiourea
D-alpha tocopheryl succinate
Tolazamide
o-Tolualdehyde
o-Toluidine
m-Toluidine
m-Toluidine hydrochloride
p-Toluidinium chloride
o-Tolunitrile
p-Tolunitrile
m-Tolunitrile
Tolytriazole
Triallylamine
Triamterene
Tribromoacetonitrile
2,4,6-Tribromophenyl carbonate
Tri-sec-butanolamine
Tributylamine
Trichlorfon
4,4,4-Trichloro-1,2-epoxybutane
Trichloromelamine
Triclorcarban
Triethanolamine stearate
Triethylene glycol diglycidyl ether
Trifluorothymidine
Triisobutylamine
Trimethyloxonium hexachloroantimonate
2,4,6-Trinitroaniline
2,4,6-Trinitrotoluene
Trioctyl phosphate
1,3,5-Trioxane (9Cl)
Triphenylamine
Triphenyl phosphite
Tri-n-Propylamine
Urethane
Urotropine
Valeronitrile
Vinylidene Fluoride
Vinyl Toluene
Vitamin D
Xylenes, commercial mixture
2,3-Xylidine
2,4-Xylidine
2,5-Xylidine
3,4-Xylidine
3,5-Xylidine
Zinc potassium chromate
Zineb

TABLE 3

CHEMICALS TESTED FOR MUTAGENICITY IN L5178Y MOUSE LYMPHOMA CELLS IN FY 1982 FOR WHICH RESULTS ARE AVAILABLE FROM NTP

Aldicarb
4-Amino-2-nitrophenol
2-Amino-5-nitrothiazole
Aniline
Anthracene
Benzo(e)pyrene
4,4'-Bis(dimethylamino) benzophenone
p-Chloroaniline
3-Chloromethylpyridine hydrochloride
C.I. Basic Red 9
N,N'-dicyclohexylthiourea
Diethylstilbestrol
Ethylene dibromide
Lead acetate
Lithocholic acid
Methyl carbamate
4,4'-Methylenebis(N,N'-dimethylaniline)
3-Nitropropionic acid
p-Phenylenediamine dihydrochloride
Pyrene
Sucrose
Thioacetamide
Thiourea

TABLE 4

CHEMICALS SELECTED TO BE TESTED FOR MUTAGENICITY IN L5178Y MOUSE LYMPHOMA CELLS IN FY 1983

2-Amino-4-nitrophenol
2-Amino-5-nitrophenol
Ampicillin trihydrate
Anilazine
o-Anthranilic acid
Benzidine, dihydrochloride
Benzyl alcohol
Bromoform
2-Butanone peroxide
Beta-Cadinene
Chloramphenicol sodium succinate
Monochloroacetic acid
p-Chloroaniline
o-Chlorobenzalmalononitrile
Chloroform
3-Chloro-2-methylpropene
2,4-Diaminophenol dihydrochloride
Dichlorodiphenyltrichloroethane
2,4-Dichlorophenol
Dichlorvos
3,3'-Dimethoxybenzidine dihydrochloride
4-Dimethylaminoazobenzene
3,3'-Dimethylbenzidine
Dimethylcarbamoyl chloride
Dimethylformamide
Dimethyl methylphosphonate
Dimethyl morpholinophosphonate
Dimethylvinyl chloride
Erythromycin stearate
Ethylene glycol
Ethylene thiourea
Fluorene, 2-nitro
Furfural
Geranyl acetate
Glutaraldehyde
Hexylresorcinol
Hydrochlorothiazide
Hydroquinone
Hydroxylamine, hydrochloride
Mercuric chloride
Methylazoxymethanol acetate
Methyl carbamate
Methyl methacrylate
Nalidixic acid
2-Naphthylamine
Nitrofurazone
p-Nitrosodiphenylamine
Oxytetracycline hydrochloride
Penicillin VK
Phenacetin
Phenylbutazone
o-Phenylphenol
Potassium chloride
Progesterone
Resorcinol
Safrole
Sodium fluoride
Tetrachloroethylene
Tetracycline hydrochloride
3,3',5,5'-tetramethylbenzidine
Titanium oxide
Toluene
Triamterene
1,1,1-Trichloroethane
1,1,2-Trichloroethane
Trichloroethylene
Triphenyltin hydroxide
Trisodium nitrilotriacetate monohydrate
Vinyl cyclohexene dioxide
Vinyl toluene

TABLE 5

CHEMICALS TESTED FOR CYTOGENETIC EFFECTS IN CHINESE HAMSTER OVARY CELLS IN FY 1982 FOR WHICH RESULTS ARE AVAILABLE FROM NTP

Acetonitrile
Acrolein
11-Aminoundecanoic acid
Benzidine
o-Benzyl-p-chlorophenol
Bis(2-chloro-1-methylethyl) ether
Bromobenzene
Bromoform
Butyraldehyde
Beta-Cadinene
Chlordecone (kepone)
Monochloroacetic acid
p-Chloroaniline
4-Chloro-2-nitroaniline
4-Chloronitrobenzene
m-Chloronitrobenzene
Choline chloride
C.I. Direct Blue 15
C.I. Direct Blue 6
Cinnamaldehyde
Cinnamyl anthranilate
Croton oil
2,4-Diaminophenol dihydrochloride
1,4-Dichlorobenzene
Dichlorodiphenylethylene
cis & trans 1,2-Dichloroethylene
2,4-Dichlorophenoxyacetic acid
1,2-Dichloropropane
3,3'-Dimethylbenzidine
Diphenylhydantoin
2-Ethoxyethanol
Formaldehyde
Glutaraldehyde
Halothane
Hydrazobenzene
Hydroquinone
Isoproterenol hydrochloride
Maleic hydrazide
Melamine
Methdilazine hydrochloride
p-Nitroaniline
o-Nitroanisole
2-Nitropropane
m-Nitrotoluene
p-Nitrotoluene
o-Nitrotoluene
Pentachlorophenol
Phthalic anhydride
Piperonyl butoxide
Promethazine hydrochloride
Propantheline bromide
Quinoline
Reserpine
2,3,7,8-Tetrachlorodibenzo-p-dioxin
1,1,2,2-Tetrachloroethane
2,3,5,6-Tetrachloronitrobenzene
Thiocarbanilide
Triamterene
Trichloroethylene
2,4,6-Trichlorophenol
2,4,5-Trichlorophenoxyacetic acid
1,2,3-Trichloropropane
Tricresyl phosphate
Triethanolamine
Trifluralin
Trimethoprim

TABLE 6

CHEMICALS SELECTED TO BE TESTED FOR CYTOGENETIC EFFECTS IN CHINESE HAMSTER OVARY CELLS IN FY 1983

Acetaldehyde
Acrylonitrile
Allyl isothiocyanate
2-Amino-4-nitrophenol
2-Amino-5-nitrophenol
Aniline
o-Anisidine
p-Anisidine
m-Anisidine
Benzoin
Benzo(a)pyrene
Benzyl acetate
Bisphenol A
2-Butanone peroxide
Butylated hydroxytoluene
Cadmium chloride
Caprolactam
Carbon disulfide
Chlordecone alcohol
Chlorobenzilate
2-Chloromethylpyridine hydrochloride
3-Chloromethylpyridine hydrochloride
2-Chloronitrobenzene
Chlorothalonil
3-Chloro-p-toluidine
5-Chloro-o-toluidine
4-Chlor-o-toluidine hydrochloride
Chlorpromazine hydrochloride
C.I. Acid Red 114
C.I. Direct Blue 218
C.I. Direct Brown 95
1,8-Cineol
Colchicine
Coumarin
Cyclophosphamide
o,p'-DDD
1,1-Dichloroethylene
1,1-Dichloroethylene
Dicofol
Dieldrin
N,N'-Diethylthiourea
Dimethoate
2,5-Dithiobiurea
Ethylene thiourea
2-Ethylhexanol
Ethyl-3-methyl-3-phenylglycidate
Ethyl tellurac
Eugenol
Fenthion
Geranyl acetate
Hexachlorobenzene
Hexachlorocyclopentadiene
Hexachloroethane
Hexamethyl-p-rosaniline chloride
Hexylresorcinol
Hydrochlorothiazide
Iodoform
Isoamyl nitrite
Isobutyl nitrite
Lead dimethyldithiocarbamate
Lindane
Malathion
Methyl parathion
Mirex
Monuron
N-(1-Naphthyl)ethylenediamine dihydrochloride
Nickelocene
4-Nitroanthranilic acid
Nitrobenzene
p-Nitrobenzoyl chloride
Nitrofurazone
1-Nitronaphthalene
4-Nitro-o-phenylenediamine
Parathion
Pentachlorobenzene
Pentachloroethane
Pentachloronitrobenzene
Phenazopyridine hydrochloride
Pheniramine maleate
Phenylbutazone
Piperonyl sulfoxide
Propionaldehyde
Pyrimethamine
Succinic acid 2,2-dimethyl-hydrazide
Sulfanilamide
4,4'-Sulfonyldianiline
1,1,1,2-Tetrachloroethane
Tetrachlorophthalic anhydride
Tetraethylthiuram disulfide
Tetrahydrofuran
O-Toluidine hydrochloride
1,1,1-Trichloroethane
tris(2-Chloroethyl) phosphate
Witch hazel
2,6-Xylidine
Zearalenone

TABLE 7

CHEMICALS TESTED FOR HERITABLE GENETIC EFFECTS IN DROSOPHILA IN FY 1982 FOR WHICH RESULTS ARE AVAILABLE FROM NTP

Acetoin
Allyl glycidyl ether
9-Aminoacridine HCL H20
o-Aminophenol
11-Aminoundecanoic acid
Aniline
o-Anisidine
Azodicarbonamide
p-Benzoquinone dioxime
tert-Butyl hydroperoxide
Calcium cyanamide
Chloral hydrate
Chlorobenzilate
Chlorothalonil
C.I. Direct Brown 95
Coumarin
Cyclophosphamide
Dibromochloropropane
2,3-Dibromo-1-propanol
3,4-Dichloronitrobenzene
2,4-Dichloronitrobenzene
2,3-Dichloronitrobenzene
Di(2-ethylhexyl) phthalate
3,3'-Dimethoxybenzidine
Dimethylcarbamoyl chloride
2,6-Dimethyl morpholine
N,N-Dimethyl-p-nitrosoaniline
1,4-Dioxane
1,2-Epoxybutane
1-Fluoro-2,4-dinitrobenzene
Glutaraldehyde
Hydrazine sulfate
Hydrazobenzene
Laslocarpine
Lead dimethyldithiocarbamate
Maleic hydrazide
2-Methyl-1-nitroanthraquinone
3-Nitro-p-acetophenetide
5-Nitro-o-anisidine
N-Nitrosopiperidine
Promethazine hydrochloride
Propanthelline bromide
Streptomycin sulfate
Sulfacetamide
2,3,5,6-Tetrachloronitrobenzene
Triethanolamine
Trifluralin
2,4,5-Trimethylaniline

TABLE 8

CHEMICALS SELECTED TO BE TESTED FOR HERITABLE GENETIC EFFECTS IN DROSOPHILA IN FY 1982

Acetaldehyde
Acetamide
Acetonitrile
AF-2
Alloxan
Allyl isothiocyanate
Allyl isovalerate
Amiben
2-Aminoanthracene
3-Amino-4-ethoxyacetanilide
3-Amino-9-ethylcarbazole
3-Aminotriazole
1-Aziridineethanol
Benomyl
Benzaldehyde
2-Biphenylamine
Bis(2-chloro-1-methylethyl) ether
Bromoform
Butyl benzyl phthalate
Butyraldehyde
Cadmium chloride
Carbendazim
Chlorambucil
2-Chloromethylpyridine HCL
3-Chloromethylpyridine HCL
Chloroneb
4-Chloro-2-nitroaniline
Chloropicrin
C.I. Acid Red 114
C.I. Acid Yellow 73
C.I. Direct Blue 15
C.I. Direct Blue 6
C.I. Direct Blue 53
Cinnamaldehyde
Colchicine
Crotonaldehyde
Croton oil
Cytembena
Diallyl phthalate
Dibromoacetonitrile
Dibutyltin diacetate
Dichloran
Dichloroacetonitrile
1,3-Dichloro-5,5-dimethyl-hydantoin
Dichlorodiphenylethylene
1,2-Dichloropropane
1,3-Dichloropropene
Dicofol
Di(2-ethylhexyl)adipate
N,N'-Diethylthiourea
Diglycidyl resorcinol ether
1,8-Dihydroxy-4,5-dinitro-anthraquinone
Dimenhydrinate
Dimethoxane
3,3'-Dimethylbenzidine
Dimethylformamide
Dimethyl hydrogen phosphite
2,4-Dinitroaniline
Diphenylhydantoin
1,2-Epoxypropane
1,2-Epoxy-3,3,3-trichloropropane
2-Ethoxyethanol
Ethyl acrylate
S-Ethyl dipropylthiocarbamate
Ethylene chlorohydrin
Ethylene thiourea
Ethyl tellurac
2-Fluorobenzoyl chloride
5-Fluorouracil
Formaldehyde
Furfural
Halothane
HC Yellow 4
Hexachlorobutadiene
Hexamethyl-p-rosaniline chloride
Hydrochlorothiazide
Iodoacetic acid
Isobutyl nitrite
Isobutyraldehyde
Isoproterenol hydrochloride
Manganese sulfate
3-Methylcholanthrene
2'-Methyl-4-dimethylaminobenzene
4,4'-Methylenebis(2-chloro-aniline)
Methylhydrazine
Methyl mercuric chloride
Mezerein
N-(1-Naphthyl)ethylenediamine dihydrochloride
Nickelocene
NTA(Nitrilotriacetic acid)
5-Nitroacenaphthene
P-Nitroaniline
4-Nitroanthranilic acid
5(6)-Nitrobenzimidazole
1-Nitronaphthalene
P-Nitrosodiphenylamine
Phenazopyridine hydrochloride
Phenol
O-Phenylphenol
Picloram
Piperonyl sulfoxide
Propanedial, ion(1-), sodium
Pyridine
Quinacrine dihydrochloride
Riddelliine
Sodium azide
Sodium (2-ethylhexyl)alcohol sulfate
Sulfanilamide
1,1,2,2-Tetrachloroethane
Tetrachloroethylene
Tetrachlorophthalic anhydride
Tetrahydrofuran
Titanocene dichloride
2,4,6-Trichlorophenol
1,2,3-Trichloropropane
Triethyllead chloride
Trihydroxybutyrophenone
Trimethoprim
Trimethylthiourea
Tris(2-chloroethyl)phosphite
Witch hazel

TABLE 9

HERITABLE TRANSLOCATION ASSAY - RESULTS OF THE POSITIVE CONTROL STUDY WITH TEM

FERTILITY TEST RESULTS
Tester Strains

| | ØN | ØR |
|---|---|---|
| N(x≥11) | 308 | 311 |
| (x>6) | 27 | 29 |
| (x≤6) | 36 | 31 |
| S(x=0) | 26 | 26 |
| | 397 | 397 |

CYTOGENETIC TEST RESULTS FOR MALES MATED TO ØN TESTER FEMALES

| | Cyto Pos | Cyto Neg |
|---|---|---|
| N(x≥11) | 4 | 304 |
| (x>6) PS | 14 | 13 |
| (x≤6) | 36 | 0 |
| S(x=0) | 26* | 0 |
| | 80 | 317 |

*5 of the 25 sterile males are suspected to be TH's but cytogenetic evaluations are inconclusive due to an absence of meiotic figures and incomplete mitotic analysis.

a-error = 13/317 = 0.033

b-error = 4/80 = 0.05

CYTOGENETIC TEST RESULTS FOR MALES MATED TO ØR TESTER FEMALES

| | Cyto Pos | Cyto Neg |
|---|---|---|
| N(x≥11) | 2 | 309 |
| (x>6) PS | 21 | 8 |
| (x≤6) | 31 | 0 |
| s(x=0) | 26* | 0 |
| | 80 | 317 |

*5 of the 26 sterile males are suspected to be TH's but cytogenetic evaluations are inconclusive due to an absence of meiotic figures and incomplete mitotic analysis.

a-error = 8/317 = 0.025

b-error = 2/80 = 0.025

TABLE 10

TOXICOLOGY AND CARCINOGENESIS BIOASSAYS COMPLETED IN FY 1982 FOR WHICH RESULTS ARE AVAILABLE FROM NTP

Allyl isovalerate
Asbestos, amosite
L-Ascorbic acid
Benzyl acetate
Bis(2-chloro-1-methylethyl) ether
Diallyl phthalate
Geranyl acetate
D-Mannitol
Melamine
Methylene chloride
4,4'Methylenedianiline dihydrochloride
Ortho-dichlorobenzene
Propyl gallate
Sodium (2-ethylhexyl) alcohol sulfate
1,1,1,2-Tetrachloroethane
Toluene diisocyanate
Tremolite
Trichloroethylene
2,6-Xylidine
Zearalenone
Ziram

TABLE 11

CHEMICALS IN PRECHRONIC PHASE OF TOXICITY TESTING AT THE END OF FY 1982

Acetonitrile
1-Amino-2,4-dibromoanthraquinone
Azodicarbonamide
o-Benzyl-p-chlorophenol
2,2-Bis (bromomethyl)-1,3-propanediol
Caffeine
Chloramphenicol sodium monosuccinate
C.I, Acid Red 114
C.I, Direct Blue 15
C.I. Direct Blue 218
1,8-Cineol (eucalyptol)
Cinnamaldehyde
3,3'-Dimethoxybenzidine
3,3'-Dimethylbenzidine
Dimethylol dihydroxyethyleneurea
Dimethylol dihydroxyethyleneurea
Doxylamine
HC Yellow 4
Isobutyl nitrite
Isoproterenol hydrochloride
Manganese sulfate
Mercuric chloride
Methapyrilene (acidified water)
Methapyrilene (neutral water)
Methdilazine
o-Nitroanisole
p-Nitroaniline
Nitrobenzene
Nitrobenzene
Palladium (II) chloride
Pentachloroanisole
Polybrominated biphenyl (FF-1)
Promethazine
Propantheline bromide
Pyrilamine
Riddelliine
Tetrahydrofuran
Thenyldiamine
Titanocene dichloride
Triamterene
1,2,3-Trichloropropane
Tricresyl phosphate
Trimellitic anhydride
Tripelennamine
Turmeric, oleoresin (curcumin)

TABLE 12

CHEMICALS IN THE CHRONIC PHASE OF THE BIOASSAY AT THE END OF FY 1982

Allyl glycidyl ether
2-Amino-4-nitrophenol
2-Amino-5-nitrophenol
Amphetamine sulfate
Ampicillin trihydrate
Asbestos, chrysotile (SR) + (IR)
Asbestos, crocidolite
Benzaldehyde
Benzene
Benzofuran
Benzyl alcohol
Benzyl chloride
Boric acid
Bromodichloromethane
Bromoform
1,3-Butadiene
2-Butanone peroxide
t-Butyl alcohol
n-Butyl chloride
gamma-Butyrolactone
d-Carvone
Castor oil
Chloramine
Chlorendic acid
Chlorinated trisodium phosphate
Chloroacetophenone
p-Chloroaniline
Chlorobenzene
o-Chlorobenzalmalonitrile
Chlorodibromomethane
3-Chloro-2-methylpropene
Chlorowax 40
Chlorowax 500C
Chlorpheniramine maleate
C.I. Acid Orange 3
C.I. Acid Yellow 73
C.I. Basic Red 9(p-rosaniline)
C.I. Disperse Blue 1
C.I. Pigment Red 3
C.I. Pigment Red 23
Coconut oil acid diethanolamin con (2/1)
Cyclohexanone
Decabromodiphenyl oxide
Diallylphthalate
2,4-Diaminophenol hydrochloride
2,3-Dibromo-1-propanol
p-Dichlorobenzene
2,4-Dichlorophenol
1,2-Dichloropropane
1,3-Dichloropropene (telone)
Dichlorvos
Diethanolamine
(DGRE)Diglycidylresorcinol ether
Diesel fuel marine
Dimethoxane
N,N-Dimethylaniline
DMBA(dimethylbenzanthracene)/TPA (Tetrad)
DMBA(dimethylbenzanthracene)/TPA (Tetrad)
N,N-Dimethylformamide
Dimethyl hydrogenphosphite
Dimethyl methylphosphonate
Dimethyl morpholinophosphoramidate
Dimethylvinylchloride
Diphenhydramine hydrochloride
Diphenyl hydantoin (phenytoin)
Ephedrine sulfate
Epinephrine hydrochloride
1,2-Epoxybutane
1,2-Epoxyhexadecane
Erythromycin stearate
Ethyl acrylate
Ethyl bromide
Ethyl chloride
Ethylene chlorohydrin
Ethylene glycol
Ethylene glycol monoethyl ether
Ethylene oxide
Ethylenethiourea
Furan
Furfural
Furosemide
Gentian violet
Gilsonite
Glutaraldehyde
Glycidol
HC Blue 1
HC Blue 2
HC Red 3
Hexachloroethane
Hexylresorcinol
Hydrochlorothiazide
Hydroquinone
4-Hydroxyacetanilide
8-Hydroxyquinoline
Iodinated glycerol
Isophorone
Lauric acid diethanolamine con (1/1)
d-Limonene
Malonaldehyde
2-Mercaptobenzothiazole
Methapyrilene (acidified water)
8-Methoxypsoralen
alpha-Methylbenzyl alcohol
Methyl carbamate
Methyl dopa
Methylene chloride
Methyl methacrylate
N-Methylolacrylamide
Mirex (A + B)
Monochloroacetic acid
Monuron
Nalidixic acid
Navy fuels JP5 (petroleum derived)
Nitrofurantoin
Nitrofurazone
p-Nitrophenol
Ochratoxin A
Oleic acid diethanolamine con (1/1)
Oxytetracycline HCL
Penicillin V potassium
Pentachloronitrobenzene
Pentachlorophenol, dowicide EC-7
Pentachlorophenol, technical
Pentaerythritol tetranitrate
Phenylbutazone
Phenylephrine hydrochloride
N-Phenyl-2-naphthylamine
o-Phenylphenol
Polysorbate 80
Probenecid
Propylene
Propylene oxide
Pyridine
Quercetin
Resorcinol
Rhodamine 6G
Rotenone
Rotenone
Roxarsone
Sodium azide
Sodium dodecyl sulfate
Sodium fluoride
Styrene oxide
Succinic anhydride
Succinic anhydride
Sulfamethazine
Tetrachloroethylene
Tetrachloroethylene (long evans rat)
Tetrachloroethylene (fisher rat)
Tetrachloroethylene (wistar rat)
Tetrachloroethylene (sherman rat)
Tetracycline hydrochloride
Tetranitromethane
THPC(Tetrakis(hydroxymethyl) phosphonium
THPS(Tetrakis(hydroxymethyl) phosphonium
Toluene, commercial
Tris(2-chloroethyl) phosphate
1,1,1-Trichloroethane
Trichlorfon
Trichloroethylene (marshall rat)
Trichloroethylene (ACI rat)
Trichloroethylene (august 28807 rat)
Trichloroethylene (osborne-mendel rat)
Tris(2-ethylhexyl)phosphate
4-Vinylcyclohexene
1-Vinyl-3-cyclohexene dioxide
Vinyl toluene
Witch hazel
Xylenes
Xylene sulfonic acid, Na salt

TABLE 13

CHEMICALS SCHEDULED TO START IN PRECHRONIC PHASE OF TOXICITY TESTING IN FY 1983

Barium chloride dihydrate
Carisoprodol
4-Chloro-2-nitroaniline
Hexachlorocyclopentadiene
1,6-Hexanediamine
Isobutyraldehyde
2-Mercaptobenzimidazole
Methyl bromide
Methylphenidate
Molybdenum trioxide
p-Nitrotoluene
Talc
1-Trans-delta9-tetrahydrocannabinol
Triprolidine
Tungsten carbide
Vinylidine fluoride

TABLE 14

CHEMICALS FOR WHICH CARCINOGENESIS BIOASSAYS WILL BE COMPLETED IN FY 1983

Asbestos, chrysotile (SR) + (IR)
Asbestos, crocidolite
Chlorobenzene
C.I. Acid Yellow 73
1,2-Dichloropropane
1,3-Dichloropropene (telone)
(DGRE)Diglycidylresorcinol ether
DMBA(dimethylbenzanthracene)/TPA (Tetrad)
DMBA(dimethylbenzanthracene)/TPA (Tetrad)
Dodecyl alcohol, ethoxylated
Ethyl acrylate
Ethylene chlorohydrin
Gilsonite
HC Blue 1
Mirex (A + B)
Monuron
Propylene
Propylene oxide
Rotenone
Sodium dodecyl sulfate
Tetrachloroethylene (long evans rat)
Tetrachloroethylene (fischer rat)
Tetrachloroethylene (wistar rat)
Tetrachloroethylene (sherman rat)
1,1,1-Trichloroethane
Tris(2-ethylhexyl) phosphate

TABLE 15

NCTR -- NTP-TYPE BIOASSAYS

Methapyrilene
Methapyrilene
Doxylamine
Pyrilamine
Tripelennamine
Thenyldiamine
Chlorothen
Caffeine
Cineole
Cinnamaldehyde
Trimellitic anhydride
Rotenone
Gentian Violet
Sulfamethazine

TABLE 16

SUMMARY OF THE NTP BENZIDINE CONGENER INITIATIVE

Benzidine
C.I. Direct Blue 6
o-Dianisidine
C.I. Direct Black 114
C.I. Direct Blue 8
C.I. Direct Blue 10
C.I. Direct Blue 15
C.I. Direct Blue 218
C.I. Direct Violet 32
o-Tolidine
C.I. Acid Red 114
C.I. Direct Blue 25
C.I. Direct Blue 53
C.I. Direct Orange 6
C.I. Direct Red 2
C.I. Direct Red 39

TABLE 17

SUMMARY OF COMPLETED METABOLISM STUDIES WITH BENZIDINE-CONGENER-BASED AZO DYES IN RATS

Direct Red 39
Direct Blue 8
Direct Blue 14
Direct Blue 53
Direct Orange 6
Direct Red 46
Direct Black 114
Direct Blue 10
Direct Violet 32
Direct Red 2
Direct Blue 15

TABLE 18

CHRONIC BIOASSAYS REVIEWED DURING FY 1982

Allyl isovalerate
Asbestos, amosite
Asbestos, chrysotile
Chlorobenzene
C.I. Acid Yellow 73
Cyclohexanone
Cyclohexanone
1,2-Dichlorobenzene
1,2-Dichloropropane
1,3-Dichloropropene
Diglycidyl resorcinol ether
DMBA-TPA
Dodecyl alcohol (ethoxylated)
Ethyl acrylate
Glisonite
HC Blue 1
Hexamethyl-p-rosaniline chloride
Malaoxon
Malathion
Methylene chloride
Methylene chloride
Methylene chloride
Monuron
Propylene
Propylene oxide
Propylene oxide
Sodium (2-ethyl hexyl) alcohol sulfate
Sodium dodecyl sulfate
Tetrachloroethylene
Tetrachloroethylene
Tetrachloroethylene
Tetrachloroethylene
2,4-Toluene diisocyanate
Tremolite
1,1,1-Trichloroethane
Trichloroethylene
Trichloroethylene
Trichloroethylene
2,6-Xylidine

TABLE 19

PATHOLOGY EVALUATION ON IMMUNOTOXICOLOGY STUDIES

Asbestos, chrysotile
Estradiol
Estradiol metabolites
Estradiol plus progesterone
Mercuric chloride
Ochratoxin A
Phenobarbital
Phorbol ester
Polyvinyl pyrrolidone
Promethazine
Urethane
Zearalenone

TABLE 20

PRECHRONIC BIOASSAYS REVIEWED BY A NTP PATHOLOGY WORKING GROUP DURING FY 1982

Prime Contract

Bromobenzene
Catechol
Chloramine
Chloroacetophenone
Chlorowax 40
o-Chlorobenzalmononitrile
2,3-Dibromo-1-propanol
Epinephrine HCL
1,2-Epoxybutane
Ethyl bromide
Ethyl chloride
Formaldehyde
Hydrochlorothiazide
Hydroquinone
1,5-Hydroxytryptophane
Pentachlorophenol-dow DP-2
Pentachlorophenol-dowicide EC-7
Pentachlorophenol-pure grade
Pentachlorophenol-technical grade
p-Quinone
Sodium floride
Sodium floride (dental study)
Succinic anhydride
Tetranitromethane
Trichloroethylene
Vinyl toluene

Master Agreement

Amphetamine sulfate
Azodicarbonamide
Benzaldehyde
Cadinene
d-Carvone
p-Chloroaniline
Chlorpromazine hydrochloride
Coumarin
2,4-Diaminophenol dihydro-chloride
4,4'-Diamino-2,2'-stilbenedi-sulfonic acid
Diethyl phthalate
3,4-Dihydrocoumarin
Dimethoxane
Ethylenediamine
Ethylene glycol
Furan
Furfural
Furfuryl alcohol
Gamma-Butyrolactone
Hexachlorocyclopentadiene
Hexachloroethane
4-Hydroxyacetanilide
6-Methylcoumarin
N-Methylolacrylamide
Monochloroacetic acid
Ochratoxin A
Pentaerythritol tetranitrate
Polysorbate 80
Probenecid
Resorcinol
Sodium azide
Titanium ferrocene
Toluene (inhalation)
Toluene (oral)
Tris(2-chloroethyl)phosphate
Vinylcyclohexane diepoxide (skin paint)

NIEHS Studies

Ethylenethiourea

TABLE 21

CHEMICALS UNDER STUDY BY THE SKIN APPLICATION ROUTE

2,2-Bis(bromomethyl)-1,3-propanediol
2-Butanone peroxide
2,3-dibromo-1-propanol
Coconut oil acid diethanolamine
Diesel fuel marine
DMBA/TPA
1,2-Epoxyhexadecane
Ethylene chlorohydrin
Glutaraldehyde
Lauric acid diethanolamine
Navy fuels JP-5 (petroleum derived)
Nitrobenzene
p-Nitrophenol
Oleic acid diethanolamine
o-Phenylphenol
1-Vinyl-3-cyclohexane dioxide
Witch hazel

TABLE 22

DEVELOPMENTAL TOXICITY STUDIES COMPLETED OR IN PROGRESS IN FY 1982 FOR WHICH RESULTS ARE AVAILABLE FROM NTP

Diphenhydramine hydrochloride
Ethylene oxide
Ethylene chlorohydrin
Hexamethyl-p-rosaniline
Isoproterenol
Sulfamethazine
Phenol
Carbon disulfide
Chlorpromazine hydrochloride
Di(2-ethylhexyl) phthalate
Hexamethyl-p-rosaniline
5-Hydroxytryptophan
Isoproterenol
Oxytetracycline hydrochloride
Sulfamethazine
Diphenhydramine hydrochloride
Di-(2-ethylhexyl)phthalate

TABLE 23

INHALATION TERATOLOGY STUDIES COMPLETED IN FY 1982 FOR WHICH RESULTS ARE AVAILABLE FROM NTP

n-Butyl acetate
Ethylene oxide
Propylene oxide

TABLE 24

CHEMICALS SELECTED FOR TESTING IN THE SHORT-TERM IN VIVO REPRODUCTIVE TOXICITY ASSAY IN FY 1982

Aniline
Benzyl alcohol
Diethylene glycol
Diethylene glycol dibutyl ether
Diethylene glycol diethyl ether
Diethylene glycol dimethyl ether
Diethylene glycol monobutyl ether
Diethylene glycol monoethyl ether
Diethylene glycol monomethyl ether
N,N-Dimethylaniline
Dimethylphthalate
2,4-Dinitrotoluene
Ethylenediamine
Ethylene glycol
Ethylene glycol diethyl ether
Ethylene glycol dimethyl ether
Ethylene glycol monobutyl ether
Ethylene glycol monoethyl ether
Ethylene glycol monomethyl ether
Ethylenethiourea
Naphthalene
p-Nitroaniline
Nitrofurazone
p-Nitrophenol
Sodium selenite
Toluene
2,4-Toluenediamine
Triethylene glycol
Triethylene glycol dimethyl ether
Trimellitic anhydride

TABLE 25

DEVELOPMENTAL TOXICITY OF GYCOL ETHERS: STUDIES COMPLETED IN FY 1982 FOR WHICH RESULTS ARE AVAILABLE FROM NTP

Ethylene glycol monobutyl ether
Ethylene glycol monoethyl ether
Ethylene glycol monoethyl ether acetate
Ethylene glycol monomethyl ether

TABLE 26

REPRODUCTIVE TOXICITY STUDIES COMPLETED IN FY 1982
FOR WHICH RESULTS ARE AVAILABLE FROM NTP

Acrolein
Allyl chloride
Bis (2-methoxyethyl) ether
n-Butyl acetate
Butylene oxide
Cyclohexanone
N,N-dimethylacetamide
Dimethylformamide
Ethyl benzene
Ethylene glycol monoethyl ether
Ethylene glycol monomethyl ether
Ethylene oxide
Hexachlorobutadiene
Methyl bromide
N-Methyl dicyclohexylamine
2-Nitropropane
Propylene oxide
Styrene oxide
1,1,2,2-Tetrachloroethane
Vinyl toluene

TABLE 27

CHEMICALS SELECTED FOR REPRODUCTIVE TOXICITY STUDIES IN FY 1982
FERTILITY ASSESSMENT BY CONTINUOUS BREEDING:

Bisphenol A
Caffeine
1,2-dibromo-3-chloropropane
Di(2-ethylhexyl)phthalate
Diethylstilbestrol
Lead acetate
Methyl salicylate
Sulfamethazine
Caffeine
Diethylstilbestrol
Ethylene glycol monoethyl ether
Ethylene glycol
Lead acetate
Methyl salicylate
Saccharin
Theobromine

TABLE 28

CHEMICALS SELECTED FOR REPRODUCTIVE TOXICITY STUDIES IN FY 1982:
SPERM MORPHOLOGY AND VAGINAL CYTOLOGY ASSAY

Acetonitrile
Barium chloride
Caffeine
4-Chloro-2-nitroaniline
Cinnamaldehyde
Dimethyl methyl phosphonate
Isoproterenol
Manganese sulfate
Methdilazine
Methylphenidate
Nitrobenzene
p-Nitroaniline
p-Nitrotoluene
Promethazine
Propanetheline bromide
Riddelliine
Tetrahydrofuran
Thenyldiamine
Toluene
1-Trans$^{9}$-tetrahydrocannabinol
Tricresyl phosphate
Trimellitic anhydride
Tris-(2-chloroethyl)phosphate

TABLE 29

NTP CHEMICAL NOMINATION ELEMENTS

I. Chemical Identification
   a. Chemical Abstracts Service (CAS) preferred name
   b. Common or generic name and synonyms
   c. CAS Registry Number
   d. Chemical class and related compounds
   e. Physical and chemical properties
      i. Physical description
      ii. Structural and molecular formula and molecular weight
      iii. Melting and boiling points
      iv. Solubility
      v. Stability and reactivity
      vi. Other relevant information
   f. Commercial product(s) composition
   g. References

II. Production, Use, Occurrences, and Analysis
   a. Production
      i. Source and synthesis, year and pathway of first production
      ii. Current production and pathway
   b. Uses
   c. Occurrence in the Environment
      i. Naturally occurring
      ii. Air, water, and soil
      iii. Occupational
   d. Analysis
   e. References

III. Toxicology
   a. Human data, case reports, and epidemiological studies
   b. Experimental animal information
   c. In vitro and other short-term tests
   d. Other relevant information
   e. References

TABLE 29

NTP CHEMICAL NOMINATION ELEMENTS (CONT.)

IV. Disposition and structure-activity-relations

a. Absorption, distribution, metabolism and excretion

b. Structure-activity correlations and considerations

c. References

V. Ongoing toxicological and environmental studies in the government, industry, and academia

VI. Rationale for Recommendation and Suggested Studies

TABLE 30

NTP CHEMICAL SELECTION PRINCIPLES

The NTP Executive Committee operates under the principle that industry will test chemicals for health and environmental effects as intended and mandated by the Congress under legislative authorities. Therefore, the NTP, acting under its chemical selection principles, will test:

1. Chemicals found in the environment that are not closely associated with commercial activities;

2. Desirable substitutes for existing chemicals, particularly therapeutic agents, that might not be developed or tested without Federal involvement;

3. Chemicals that should be tested to improve scientific understanding of structure-activity relationships and thereby assist in defining groups of commercial chemicals that should be tested by industry;

4. Certain chemicals tested by industry, or by others, the additional testing of which by the Federal government if justified to verify the results;

5. Previously tested chemicals for which other testing is desirable to cross-compare testing methods;

6. "Old chemicals" with the potential for significant human exposure which are of social importance but which generate too little revenue to support an adequate testing program (some of these may be "grandfathered" under FDA laws);

7. Two or more chemicals together, when combined human exposure occurs (such testing probably cannot be required of industry if the products of different companies are involved); and

8. In special situations, as determined by the Executive Committee, marketed chemicals which have potential for large-scale and/or intense human exposure, even if it may be possible to require industry to perform the testing.

The selection of a chemical by the Executive Committee does not automatically commit the NTP to testing the chemical. The NTP is committed to ascertain the specific toxicologic and regulatory concerns; evaluate the adequacy of existing data or current efforts in government, academic, or private laboratories; and then propose and conduct specific tests that are needed. Occasionally new information is obtained that answers the questions posed in the nomination and selection process. Sometimes testing is not done because chemicals are withdrawn by the nominator, because others are or will be testing the chemical, or because the chemical is not available, or no longer produced.

TABLE 31

CHEMICALS NOMINATED FOR TOXICOLOGICAL TESTING IN FY 1982

Arsine
Atrazine
Black newsprint inks
Butyl benzyl phthalate
C.I. Acid Yellow 151
C.I. Basic Red 18
C.I. Direct Red 80
C.I. Direct Yellow 4
C.I. Disperse Brown 1
p-Chlor-a,a,a-triflourotolune
Chromic acid mist
Cromolyn Sodium
1,3-Dinitropyrene
1,6-Dinitropyrene
1,8-Dinitropyrene
Formic acid
Linolelaidic acid
Luminol
Malathion
Methyl isobutyl ketone
Nitromethane
1-Nitropyrene
Ordram (molinate)
Picloram
beta-Pinene
Roundup (glyphosate isopropylamine salt)
1,2,4,5-Tetrachlorobenzene
2,3,4,6-Tetrachlorophenol
1,3,6,8-Tetranitropyrene
Thiophene
2,4,7-Trinitrofluorenone
1,3,6-Trinitropyrene

TABLE 32

CHEMICALS REVIEWED BY THE CHEMICAL EVALUATION COMMITTEE IN FY 1982 FOR WHICH TESTING RECOMMENDATIONS ARE AVAILABLE FROM NTP

2-Amino-6-nitrobenzothiazole
Benzonitrile
Benzo(f)quinoline
(4,4'-Bithiazole)-2,2'-diamine
Butyl benzyl phthalate
Carminic acid
Cholesterol
Cholesterol 5alpha, 6alpha-expoxide
1-Chloro-2-propanol
2-Chloro-1-propanol
C.I. Basic Red 29
Colchicine
Cromolyn sodium
L-Cysteine
Cytidine
5,6-Dichloro-2-benzothiazolamine
N,N-Diethyl-4-((5-nitro-2-thiazolyl)azo)benzenamine
2-Ethylhexanol
Ferrous sulfate
Folic acid
D-Fructose
Fumaric acid
Guanine
L-Isoleucine
Linoleic acid
Linolenic acid
L-Lysine
2-Mercapto-4-methyl-5-thiazolyl methyl ketone
6-Methoxy-2-benzothiazolyl)olamine
4-(6-Methyl-2-benzo thiazolyl-) benzenamine
3-Methyl-5-isothiazolamine
Methylene bis(2-chloraniline)
Mono(2-ethylhexyl) phthalate
m-Nitrobenzoyl chloride
p-Nitrobenzoyl chloride
2-Octyl-3-isothiazolone
Phenamiphos
5-Phenyl-2,4-diaminothiazole
Potassium iodide
Pyruvic acid
Riboflavin
Thiabendazole
Thiamin hydrochloride
2-Thiazolamine
Thiazole
L-Tyrosine
Vitamin E

TABLE 33

CHEMICALS REVIEWED BY THE NTP BOARD OF SCIENTIFIC COUNSELORS ON OCTOBER 23, 1981 FOR WHICH TESTING RECOMMENDATIONS ARE AVAILABLE FROM NTP

April 8 Chemicals

Benzethonium chloride
Benzotrichloride
Benzoyl chloride
t-Butyl perbenzoate
Butyric anhydride
m-Chloroaniline
Methyl trifluoromethane sulfonate
Ninhydrin
O-Phenanthroline
Tetrachlorophthalic anhydride
Triethanolamine
2,4,5-Trimethoxybenzal dehyde
Tumeric

May 19 Chemicals

Codeine
Gallium arsenide
Mercuric oxide, yellow
Methiodal sodium
Nickel oxide
N-Methyl-N-nitroso-p-toluene-sulfonamide
Salicylazosulfa-pyridine
Scopolamine
Sodium chromate
Sulfamethizole
Sulfanilamide
Sulfathiazole
Theophylline

TABLE 34

CHEMICALS REVIEWED BY THE NTP BOARD OF SCIENTIFIC COUNSELORS ON SEPTEMBER 24, 1982 FOR WHICH TESTING RECOMMENDATIONS ARE AVAILABLE FROM NTP

2-Amino-6-nitro-benzothiazole
Benzonitrile
Benzo(f)quinoline
Carminic acid
Cholesterol
Cholesterol 5 ,6 -epoxide
Colchicine
L-Cysteine
Cytidine
2-Ethylhexanol
Ferrous sulfate
Folic acid
Fumaric acid
Guanine
L-Isoleucine
Linoleic acid
Linolenic acid
L-Lysine
Methylene bis (o-chloroaniline)
Mono(2-ethylhexyl) phthalate
m-Nitrobenzoyl chloride
p-Nitrobenzoyl chloride
Phenamiphos
Potassium iodide
1-Chloro-2-propanol
2-Chloro-1-propanol
Pyruvic acid
Riboflavin
Thiamin hydro-chloride
L-Tyrosine
Vitamin E

TABLE 35

FY 1982 PRIORITY CHEMICALS FOR IN-DEPTH TOXICOLOGICAL EVALUATION

2-Bromo-4,6-dinitroaniline
beta-Bromo-beta-nitrostyrene
C.I. Direct Yellow 11
C.I. Vat Blue 1
Cadmium nitrate
Carisoprodol
1,3-Dichloro-5,5-dimethyl-hydantoin
1,8-Dihydroxy-4,5-dinitro-anthraquinone
2,4-Dinitroaniline
Estragole
Ethyl benzene
n-Hexane
1,6-Hexanediamine
Isobutyraldehyde
N-Isopropyl-N'-phenyl-p-phenyl-enediamine
2-Mercaptobenzimidazole
Methyl bromide
Molybdenum trioxide
d-Phenylalanine
Polyvinyl chloride latex
Sucrose
Talc
1-Trans-delta9-tetrahydro-cannabinol
Tocopherol
Vanadium pentoxide
Zinc oxide

TABLE 36

FY 1983 PRIORITY CHEMICALS FOR IN-DEPTH TOXICOLOGICAL EVALUATION

9-Aminoacridine hydrochloride
Benzethonium chloride
Benzoyl chloride
Bromobenzene
t-Butyl perbenzoate
m-Chloroaniline
Citral
Cobalt sulfate
Codeine
Crotonaldehyde
1,2-Dihydro-2,2,4-trimethyl-quinoline
2-Hydroxy-4-methoxybenzophenone
Methyleugenol
Nickel oxide
Salicylazosulfapyridine
Scopolamine
Sodium chromate
Tetrachlorophthalic anhydride
Tetrafluoroethylene
Theophylline
4,4'-Thiobis(6-tert-butyl-m-cresol)
Triethanolamine
2,4,5-Trimethoxybenzaldehyde
Zinc potassium chromate

TABLE 37

CHEMICALS PROCURED AND ANALYZED FOR TERATOLOGY STUDIES IN FY 1982

Bisphenol A
Chlorpromazine hydrochloride
Di(2-ethylhexyl)phthalate
Diphenhydramine hydrochloride
Methyl mercuric chloride

TABLE 38

CHEMICALS PROCURED AND ANALYZED FOR REPRODUCTIVE TOXICOLOGY STUDIES IN FY 1982

Bisphenol A
Caffeine
1,2-Dibromo-3-chloropropane
Di(2-ethylhexyl)phthalate
Diethylstilbestrol
Ethylene glycol
Ethylene glycol monoethyl ether
Lead acetate
Methyl salicylate
Saccharin
Sulfamethazine
Theobromine

TABLE 39

CHEMICALS PROCURED AND/OR ANALYZED FOR IMMUNOLOGY STUDIES IN FY 1982

Cadmium Chloride
Diethylstilbestrol
Pentachlorophenol, EC-7 Grade
Pentachlorophenol, Technical Grade

TABLE 40

CHEMICALS OBTAINED AND ANALYZED FOR PSORALEN STUDIES IN FY 1982

3-Carbethoxypsoralen
5-Methoxypsoralen
8-Methoxypsoralen
5-Methylisopsoralen

TABLE 41

SPECIAL CHEMISTRY RESOURCES SUPPORT FOR NTP STUDIES IN FY 1982

| | | |
|---|---|---|
| Allylisothiocyanate | Chlordecone (Kepone) | Diethylstilbestrol |
| Benzidine | C.I. Direct Blue 6 | Diethylstilbestrol derivatives |
| Cadmium chloride | C.I. Direct Blue 218 | Dimethylmethyl-phosphonate |
| Chloramphenicol | Di(2-ethylhexyl)-phthalate | Titanocene dichloride |

TABLE 42

NTP CHEMICAL REPOSITORY HOLDINGS AND ACTIVITIES IN FY 1982

| | Cellular and Genetic Toxicology Repository | Toxicology and Carcinogenesis Bioassay Repository |
|---|---|---|
| 1. Control chemicals in inventory | 17 | -- |
| 2. Total number of unique chemicals | 856 | 440 |
| 3. Test chemicals shipped for *Salmonella* testing in FY 1982 | 360 | -- |
| 4. Test chemicals shipped for *Drosophila* testing in FY 1982 | 90 | -- |
| 5. Test chemicals shipped for cytogenetics testing in FY 1982 | 90 | -- |
| 6. Test chemicals shipped for aneuploidy testing in FY 1982 | 15 | -- |
| 7. Test chemicals shipped for cellular and genetic toxicology testing other than 3, 4, 5, 6 | 350 | -- |
| 8. Allquots shipped in FY 1982 | 905 | 125 |
| 9. Chemicals synthesized | 1 | -- |
| 10. Purity analyses performed | 40 | -- |
| 11. Quality Assurance samples analyzed | 5 | 5 |
| 12. Allquots transferred to Cellular and Genetic Toxicology Repository | -- | 29 |
| 13. Chemicals selected for FY 1982 *Salmonella* testing | 140 | -- |
| 14. Chemicals selected for FY 1982 *Drosophila* testing | 55 | -- |
| 15. Chemicals selected for FY 1982 cytogenetics testing | 62 | -- |
| 16. Number of chemicals analyzed for flash point | 50 | -- |
| 17. Number of chemicals tested in glove permeability study | 20 | -- |
| 18. Number of chemicals analyzed for solubility | 330 | -- |

TABLE 43

CHEMICALS, SUBSTANCES AND MANUFACTURING PROCESSES INCLUDED IN THE THIRD ANNUAL REPORT ON CARCINOGENS

2-Acetylaminofluorene
Acrylonitrile
Aflatoxins
2-Aminoanthraquinone
4-Aminobiphenyl
1-Amino-2-methylanthraquinone
Amitrole
o-Anisidine hydrochloride
Aramite
Arsenic and certain arsenic compounds
Asbestos
Auramine, manufacture of
Benz(a)anthracene
Benzene
Benzidine
Benzo(b)fluoranthene
Benzo(a)pyrene
Beryllium & beryllium compounds
N,N-Bis(2-chloroethyl)-2-naphthylamine
Bis(chloromethyl)ether & TG chloromethylmethyl ether
Cadmium and certain cadmium compounds
Carbon tetrachloride
Chlorambucil
Chloroform
Chromium & chromium compounds
Coke oven emissions
p-Cresidine
Cupferron
Cycasin
Cyclophosphamide
2,4-Diaminoanisole sulfate
2,4-Diaminotoluene
Dibenz(a,h)acridine
Dibenz(a,j)acridine
Dibenz(a,h)anthracene
7H-Dibenzo(c,g)carbazole
Dibenzo(a,h)pyrene
Dibenzo(a,l)pyrene
1,2-Dibromo-3-chloropropane
1,2-Dibromoethane
Dichlorobenzidine
1,2-Dichloroethane
Diepoxybutane
Di(2-ethylhexyl)phthalate
Diethylstilboestrol
3,3'-Dimethoxybenzidine
3,3'-Dimethylbenzidine
4-Dimethylaminoazobenzene
Dimethylcarbamoyl chloride
Dimethyl sulfate
1,4-Dioxane
Direct Black 38
Direct Blue 6
Ethylene thiourea
Formaldehyde
Haematite underground mining
Hexachlorobenzene
Hydrazine
Hydrazine sulfate
Hydrazobenzene
Indeno(1,2,3-cd)pyrene
Iron dextran
Isopropyl alcohol
Kepone
Lead acetate
Lead phosphate
Lindane & hexachlorocyclohexane isomers
Melphalan
4,4'-Methylene bis(2-chloroaniline)
4,4'-Methylene bis(N,N-dimethyl) benzenamine
Michler's ketone
Mirex
Mustard gas
2-Naphthylamine
Nickel refining
Nitrilotriacetic acid
Nitrofen
5-Nitro-O-anisidine
N-Nitrosodi-n-butylamine
N-Nitrosodiethanolamine
N-Nitrosodiethylamine
N-Nitrosodimethylamine
p-Nitrosodiphenylamine
N-Nitrosodi-n-propylamine
N-Nitroso-N-ethylurea
N-Nitroso-N-methylurea
N-Nitrosomethylvinylamine
N-Nitrosomorpholine
N-Nitrosonornicotine
N-Nitrosopiperidine
N-Nitrosopyrrolidine
N-Nitrososarcosine
Oxymetholone
Phenacetin
Phenazopyridine hydrochloride
Phenytoin
Polybrominated biphenyls
Polychlorinated biphenyls
Procarbazine
Procarbazine hydrochloride
beta-Propiolactone
Reserpine
Saccharin
Safrole
Selenium sulfide
Soots, tars & mineral oils
Streptozotocin
Sulfallate
2,3,7,8-Tetrachlorodibenzo-p-dioxin
Thioacetamide
Thiourea
Thorium dioxide
o-Toluidine hydrochloride
Toxaphene
2,4,6-Trichlorophenol
Tris(1-aziridinyl)phosphine sulfide
Tris(2,3-dibromopropyl)phosphate
Urethane
Vinyl chloride

FIGURE 1

## NATIONAL TOXICOLOGY PROGRAM
### Agency origin and amounts of funding (millions)

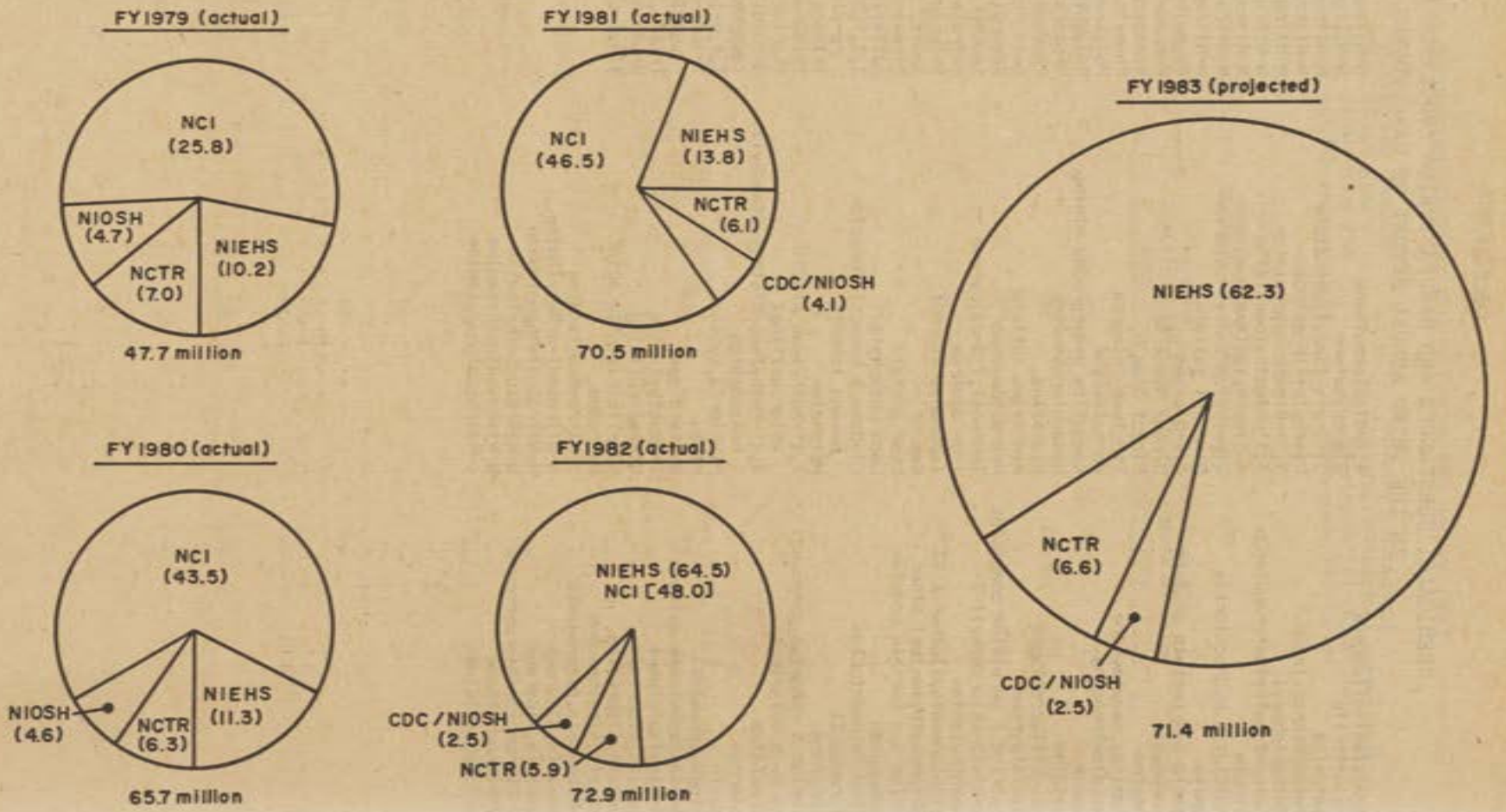
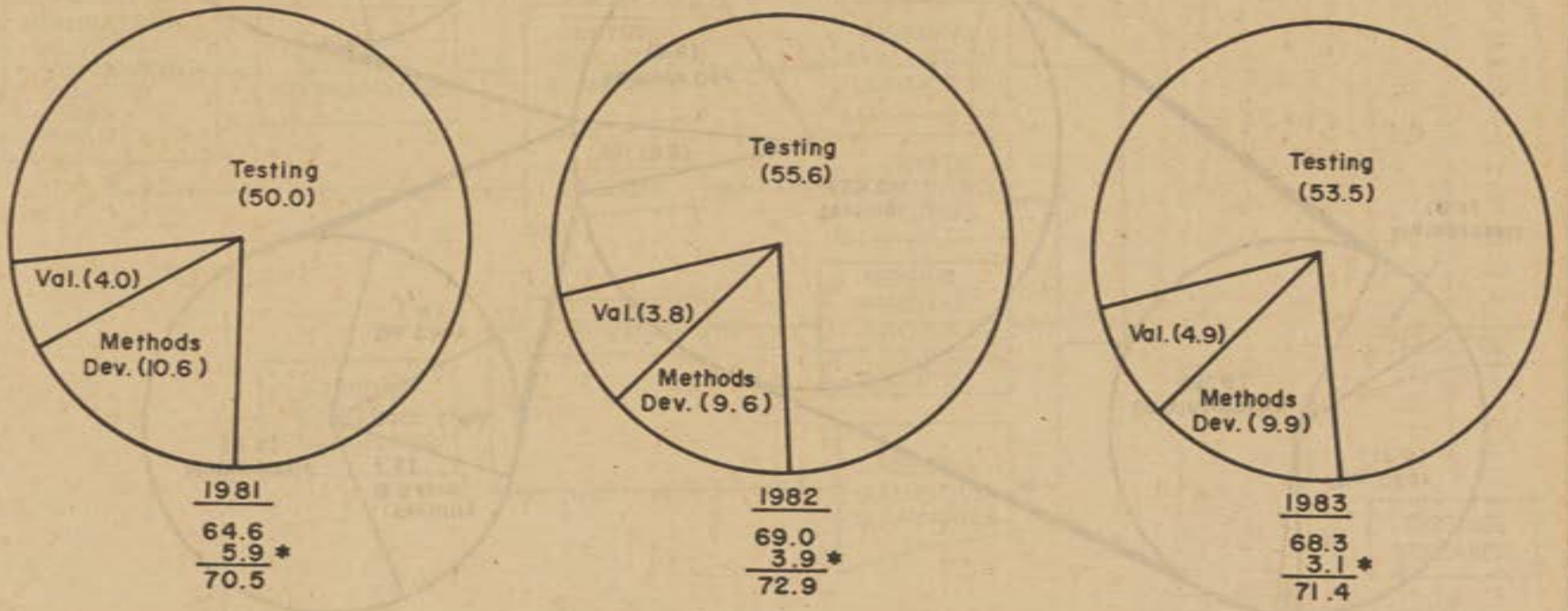


FIGURE 2

## NATIONAL TOXICOLOGY PROGRAM (millions)




*Other activities such as grants, WHO Cooperative Center, dioxin registry, core staff, indirect operational support, etc.

# NATIONAL TOXICOLOGY PROGRAM (millions)

## 1982

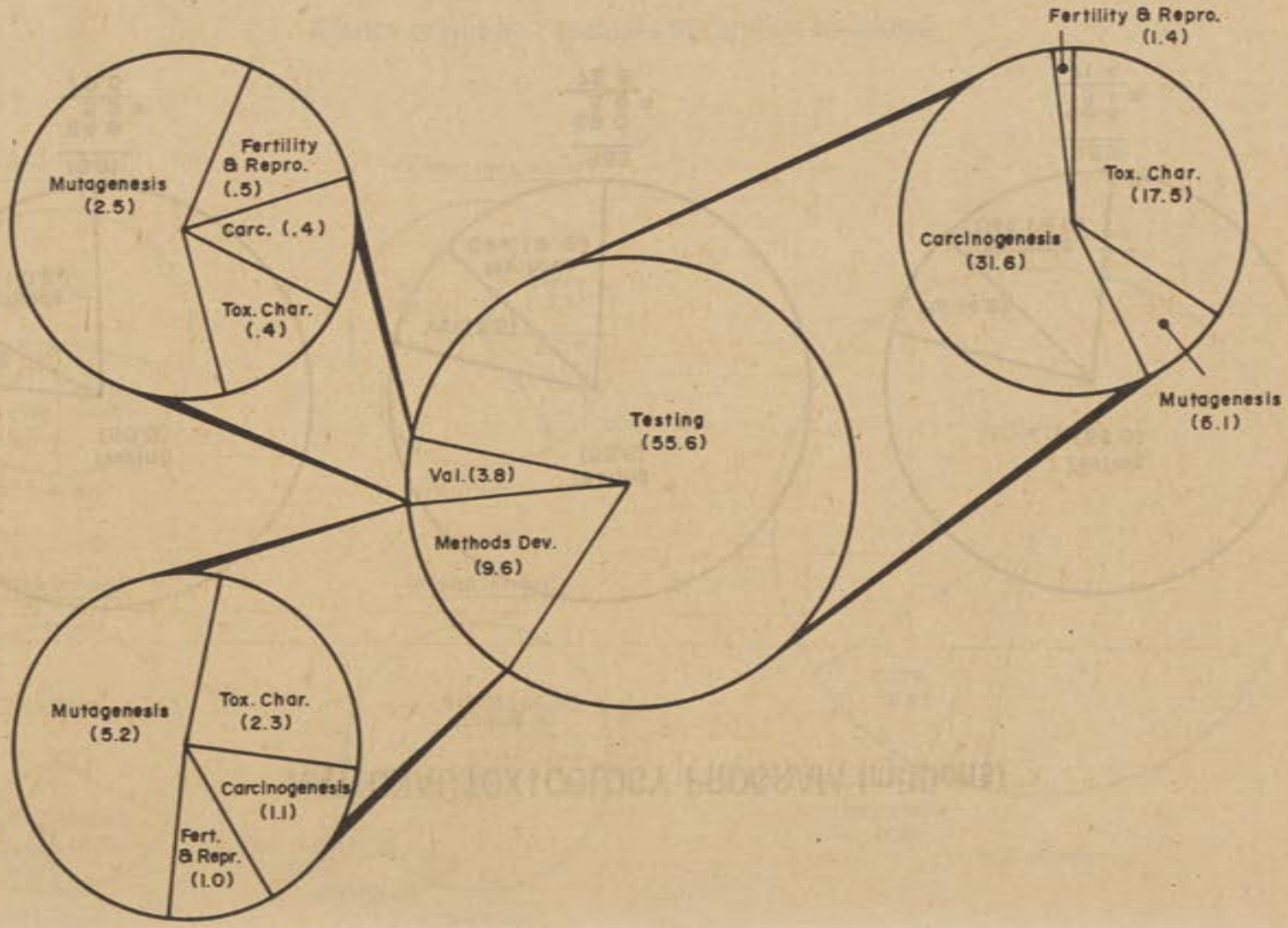
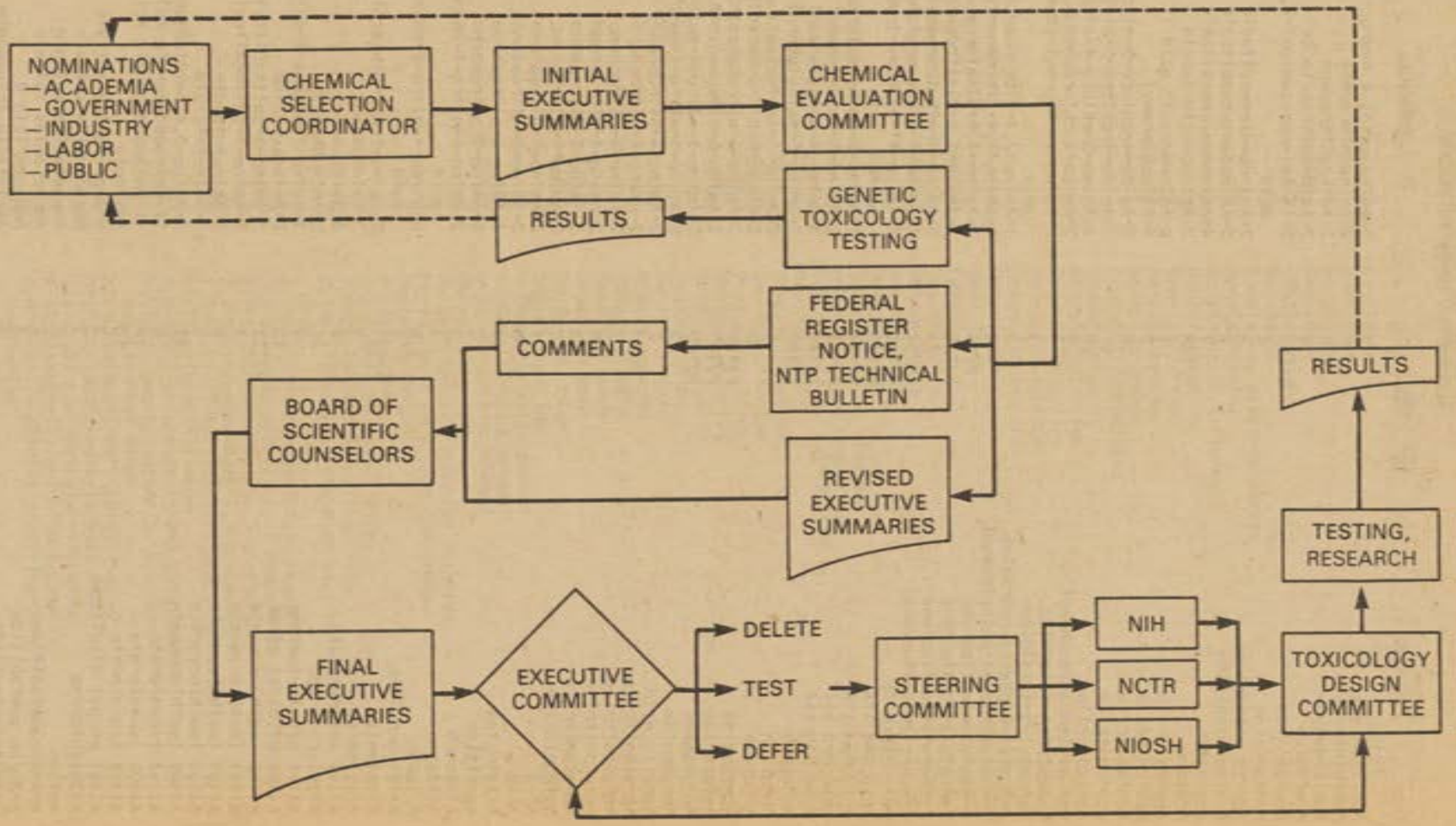


FIGURE 4

# NTP CHEMICAL NOMINATION AND SELECTION PROCESS



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[FR Doc. 83-9977 Filed 4-20-83; 8:45 am]
BILLING CODE 4140-41-C

federal register

Thursday
April 21, 1983

## Part III

# Department of Labor

**Occupational Safety and Health Administration**

**Occupational Exposure to Ethylene Oxide; Proposed Rule**

## DEPARTMENT OF LABOR

### Occupational Safety and Health Administration

### 29 CFR Part 1910

[Docket No. H-200]

### Occupational Exposure to Ethylene Oxide

**AGENCY:** Occupational Safety and Health Administration (OSHA), Department of Labor.

**ACTION:** Proposed rule and notice of hearing.

**SUMMARY:** By this notice, the Occupational Safety and Health Administration (OSHA) is proposing to amend its existing occupational standard that regulates employee exposure to ethylene oxide (EtO). The basis for this action is a determination by the Assistant Secretary, based on animal and human data, that exposure to EtO at OSHA's current permissible exposure limit (PEL) of 50 parts EtO per million parts of air (50 ppm) as an eight (8)-hour time-weighted average (TWA) is inadequate for employee health protection. OSHA proposes to reduce the PEL for EtO to a TWA of 1 ppm. An "action level" of 0.5 ppm as a TWA is included in the proposal as a mechanism for exempting an employer from the obligation to comply with certain requirements, such as employee exposure monitoring and medical surveillance, in instances where the employer can demonstrate that the employees exposures are at very low levels. The proposal would provide for among other requirements certain methods of exposure control, personal protective equipment, measurement of employee exposures, training, medical surveillance, signs and labels, regulated areas, emergency procedures and recordkeeping.

**DATES:** Comments concerning the proposed standard and notices of intention to appear at the informal rulemaking hearing must be postmarked on or before June 17, 1983. Parties requesting more than 10 minutes for their presentations at the hearing, and parties submitting documentary evidence at the hearing, must submit the full text of their testimony and all documentary evidence no later than July 1, 1983. The informal public rulemaking hearing is scheduled to begin July 19, 1983.

**ADDRESSES:** Comments are to be submitted to the Docket Officer, Docket No. H-200, Room S-6212, U.S. Department of Labor, Third and Constitution Avenue, N.W., Washington, D.C. 20210.

Notices of intention to appear at the informal rulemaking hearing, testimony and documentary evidence are to be sent to: Tom Hall, OSHA Division of Consumer Affairs, Docket No. H-200, Room N-3635, U.S. Department of Labor, Third Street and Constitution Avenue, N.W., Washington, D.C. 20210; telephone 202-523-8024. The informal public hearing will begin July 19, 1983, at 10:00 A.M. in the Auditorium, Frances Perkins Building, Third and Constitution Avenue, N.W., Washington, D.C. 20210.

**FOR FURTHER INFORMATION CONTACT:** Mr. James F. Foster, OSHA, U.S. Department of Labor, Office of Public Affairs, Rm. N-3641, 200 Constitution Avenue, N.W., Washington, D.C. 20210, Telephone (202) 523-8151.

**SUPPLEMENTARY INFORMATION:**

#### I. General

The preamble to the proposed standard on occupational exposure to ethylene oxide (EtO) discusses the events leading to the proposal, physical properties of EtO, manufacture and use of EtO, health effects of exposure to EtO, comments received in response to the Advance Notice of Proposed Rulemaking (ANPR) (47 FR 3566 January 26, 1982), and an analysis of the technological and economic feasibility and impact, and the rationale behind the specific provisions set forth in the proposed standard.

This proposed standard would apply to all employments in all industries covered by the Act, namely "general industry," construction, and maritime.

Public comment on the data discussed in this Notice and other relevant issues is requested for the purpose of assisting OSHA in its reevaluation of the adequacy of the present standard and the development of a new standard for exposure to EtO. OSHA also requests that interested parties submit any pertinent health data not discussed in this notice.

Comment is requested on the following issues relating to health effects, technological and economic feasibility, and provisions which should be considered for inclusion in a final EtO standard. Specifically, scientific and technical data and expert analysis and opinion are sought on the following issues:

1. Would the proposed provisions provide adequate worker protection from all health hazards associated with EtO exposure?

2. Are there additional, data or information on health care providers concerning the feasibility of complying with the proposed standard?

3. Is a short-term or ceiling exposure limit for EtO exposure necessary for the PEL or action level in view of recent information regarding increased spontaneous abortions and chromosome changes in workers exposed to EtO? What monitoring methods and control technology are available to meet such a short-term limit and what would be the economic burdens, if any, of such a limit?

4. What are the most suitable methods for determining compliance with EtO exposure permissible exposure limits (PEL's) of 0.5 and 1 ppm as 8-hour time-weighted averages and for ceilings ranging from 5 to 50 ppm for 30 minutes or less? What are the problems associated with such monitoring methods? Do they require special training or experience? Are there serious limitations as to the accuracy or precision of the available sampling techniques?

5. Are there other risk assessments besides that developed by OSHA that specifically deal with the risk of cancer or other disease at 50 ppm and the proposed PEL of 1 ppm? Can the risk of adverse reproductive effects resulting from exposure to 1 ppm or less be adequately quantified?

6. Is there any group of workers who, because of lifestyle, concurrent exposure to other chemicals, or physiological makeup, are likely to have an increased sensitivity to ethylene oxide? If so, what consideration, if any, should be provided for such workers in the final standard?

7. Are the proposed medical surveillance provisions, including the suggested examinations found in Appendix D to the proposal, adequate for the purpose of providing protective medical monitoring of affected employees? Should an examination also be required to be offered at the termination of employment? Should the standard be more specific in the elements required for medical examinations of exposed employees?

8. Specific provisions for skin and eye protection against contact with liquid EtO are not included in the proposal. Requirements found in § 1910.132 and 1910.133 require the employer to provide protective equipment (gloves, goggles, etc) where skin and eye exposure to hazardous liquids may occur. Is reliance on these two general provisions sufficient for protecting against potential dermal and eye hazards for liquid EtO? If not, explain and specify what additional provisions are necessary?

9. Should genetic screening, chromosome analysis, male fertility testing and pregnancy testing be provided as part of the routine physical examination? Should these tests be offered to employees exposed to emergency situations, or provided for these persons wishing to procreate? Should medical removal, protection (i.e., the employers shall maintain the earnings, seniority and other benefits and employment rights of an employee removed from exposure to EtO due to the risk of materials impairment to health; see OSHA lead standard 29 CFR 1910.1025) be provided for those wishing to procreate and, if so, under what circumstances?

10. In view of the uncertainty as to what constitutes an appropriate physical examination, should a mult-physician review be required if requested by the employee? Should employees who believe that they are suffering from symptoms associated with EtO overexposure be offered an interim medical examination?

11. What is the incidence of persistence of quadriradial or other chromosomal aberrations and sister chromated exchanges in peripheral lymphocytes over time after exposure to EtO ceases? Is this persistence or lack of persistence a function of dose and/or duration of exposure?

12. What length of time is needed for affected employers to reduce employee exposure to the proposed PEL through engineering and work practice controls? What technical and economic considerations form the basis for these time frames?

13. To what extent are hopitals and other health care facilities able to commit resources to obtain state-of-the-art monitoring equipment and plans?

14. Is it necessary for affected employers to develop written compliance plans as specified in paragraph (1)(2)(ii) of the proposal? Should only those employers with a large number of exposed employees (what number) or with high exposure conditions in the workplace be required to develop written compliance plans?

15. Are there conditions under which respirator use should be permitted in addition to those proposed? What respirator fit testing requirements should be included in the final standard and when should such testing be performed?

16. What additional information is available regarding the economic and technological feasiblity of complying with the proposal for small entities using EtO in the medical products manufacturing sector?

17. What has industry experience been in complying with the application and use requirements imposed by the Environmental Protection Agency's pesticides labeling? To what extent would those requirements conflict or overlap with the provisions of OSHA's proposed standard? What procedures are currently followed in complying with the requirements set forth on the labels for EtO pesticides?

## II. Pertinent Legal Authority

Authority for issuance of this standard is found primarily in sections 6(b), 8(c), and 8(g)(2) of the Occupational Safety and Health Act of 1970 (the Act), 29 U.S.C. 655 (b), 657(c), and 657(g)(2). Section 6(b)(5) governs the issuance of occupational safety and health standards dealing with toxic materials or harmful physical agents. Section 3(8) of the Act, 29 U.S.C. 652(8), defines an occupational safety and health standard as:

> (A) standard which requires conditions, or the adoption or use of one or more practice, means, methods, operations, or processes, reasonably necessary or appropriate to provide a safe or healthful employment and places of employment.

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 Department* v. *American Petroleum Institute*, 448 U.S. 607 (1980).

The "significant risk" determination constitues 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 is not unlike the threshold finding that a substance is toxic or a physical agent is harmful. *Id.* at 643, n. 48. A significant risk 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. 665(b)(5). Rather, the Agency may base its finding largely on policy considerations and has considerable leeway with the kinds of assumptions it applies in interpreting the data supporting it. *Id.* The Court's opinion indicates that risk assessments, which may involve mathematical estimates with some inherent uncertainties, are a means of demonstrating the existence of significant risk.

After OSHA has determined that a significant risk exists and that such risk can be reduced or eliminated by the proposed standard, it must set the standard "which most adequately assures, to the extent feasible on the basis of the best available evidence, that no employees will suffer material impairment of health * * *." Section 6(b)(5) of the Act. 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*, 452 U.S. 490 (1981). The Court held that "cost-benefit analysis is not required by the statute because feasibility analysis is." *Id.* at 509.

Authority to issue this standard is also found in section 8(c) of the Act. In general, this section empowers the Secretary to require employers to make, keep, and preserve records regarding activities related to the Act. In particular, section 8(c)(3) gives the Secretary authority to require employers to "maintain accurate records of employee exposures to potentially toxic materials or harmful physical agents which are required to be monitored or measured under section 6." Provisions of OSHA standards which require the making and maintenance of records of medical examinations, exposure monitoring, and the like are issued pursuant to section 8(c) of the Act.

The Secretary's authority to issue this proposed standard is further supported by the general rulemaking authority granted in section 8(g)(2) of the Act. This section empowers the Secretary "to prescribe such rules and regulations as he may deem necessary to carry out (his) responsibilities under the Act"—in this case as part of or ancillary to, a section 6(b) standard. The Secretary's responsibilities under the Act are defined largely by its enumerated purposes, which include:

> Encouraging employers and employees in their efforts to reduce the number of occupational safety and health hazards at their places of employment, and to stimulate employers and employees to institute new and to perfect existing programs for providing safe and healthful working conditions (29 U.S.C. 651 (b)(1);
>
> Authorizing the Secretary of Labor to set mandatory occupational safety and health standards applicable to business affecting interstate commerce, and by creating an Occupational Safety and Health Review Commission for carrying out adjudicatory functions under the Act; (29 U.S.C. 651 (b)(3);
>
> Building upon advances already made through employee and employer initiative for providing safe and health working conditions (29 U.S.C. 651(b)(5);

By providing for the development and promulgation of occupational safety and health standards; providing for appropriate reporting procedures with respect to occupational safety and health which procedures will help achieve the objectives of this Act and accurately describe the nature of the occupational safety and health problem; exploring ways to discover latent diseases, establishing causal connections between diseases and work in environmental conditions * * *. (29 U.S.C. 651 (b)(6);

Encouraging joint labor-management efforts to reduce injuries and diseases arising out of employment (29 U.S.C. 651 (b)(13);

And developing innovative methods, techniques, and approaches for dealing with occupational safety and health problems (19 U.S.C. 651(b)(5).

Because the ethylene oxide standard is reasonably related to these statutory goals, the Secretary finds that this standard is necessary to carry out his responsibilities under the Act. In addition to its status as a section 6(b) standard, therefore, it also falls within the broader class of section 8 regulations.

In addition, section 4(b)(2) of the Act provides for OSHA standards to apply to construction and other work places where the secretary determines these standards to be more effective than existing standards which otherwise apply to those workplaces.

### III. Physical Properties, Manufacture and Uses of Ethylene Oxide

Ethylene oxide (EtO), also known as 1, 2-epoxyethane, oxirane, and dimethylene oxide, is a colorless gas with a characteristic ether-like odor. Its chemical formula is $C_2H_4O$, molecular weight is 44.06 and CAS Registry Number is 75–21–8. Although several processes exist for the production of EtO, all United States producers currently manufacture EtO through the catalytic oxidation of ethylene in the presence of a silver catalyst. EtO is completely miscible with water, alcohol, acetone, benzene, ether, carbon tetrachloride and most organic solvents. It is also highly reactive and potentially explosive when heated or when in the presence of alkali metal hydroxides and highly active catalytic surfaces. EtO is relatively stable in aqueous solutions or when diluted with carbon dioxide ($CO_2$) or halocarbons. In order to reduce explosion hazards when EtO is used as a fumigant or sterilant, it is often used in gaseous mixtures (such as 10% EtO and 90% $CO_2$, or 12% EtO and 88% halocarbon).

Since its first domestic production in 1925, EtO has developed into a major industrial chemical and is presently one of the 25 chemicals of highest production volume in the United States. During the period from 1967 to 1978, for example, the average rate of growth in the EtO industry was 6.7 percent. In 1980, over 5.2 billion pounds of EtO were produced domestically. Current production capacity is about 6.7 billion pounds per year (Ex. 2–14).

The primary use of EtO is as an intermediate in the manufacture of other products. Over 99% of total EtO production is used in the manufacture of other products, and almost 90% is consumed by the EtO manufacturers themselves. On a volume basis, the largest use of EtO is as an intermediate in the production of ethylene glycol, a major component of automotive and other anti-freeze products and as an intermediate in the production of polyethylene terephthalate (PET) polyester fibers, bottles and films. Approximately 70% of all domestically produced EtO goes into the manufacture of ethylene glycol.

EtO is also widely employed in the production of non-ionic surface-active agents which are used in household detergents and as industrial surfactants. Other products manufactured from EtO include: (1) Ethanolamines, used in sweetening natural gas and in the production of specialty chemicals, detergents and cosmetics; (2) glycol ethers, utilized as a jet fuel additive and in the formulation of coatings, cleaners, automotive brake fluids and inks; (3) diethylene and triethylene glycol, used in drying natural gas and in the manufacture of polyester resins, emulsifiers, lubricants and plasticizers; (4) tetraethylene glycol, utilized to extract aromatic hydrocarbons from nonaromatic hydrocarbons; (5) polyethylene glycols, from which cosmetics, plasticizers, lubricants and dispersants are created; (6) polyethylene glycols, used for water-soluble packaging and for warp sizing, and (7) crown ethers, used for extraction of liquids.

A small fraction of EtO production (less than 0.5 percent) is consumed by sterilant or fumigant users. EtO is utilized as a sterilizing agent for heat and/or moisture sensitive materials by various facets of the health care industry and is employed as a fumigant for a number of miscellaneous items, such as spices, black walnut meats, books, furniture, textiles, empty bin equipment, empty cargo holds, cosmetics and dairy packaging.

### IV. Events Leading to the Proposed Standard

The present OSHA standard for EtO (29 CFR 1910.1000, Table Z–1) requires employers to ensure that the level of employee exposure to EtO does not exceed 50 parts per million parts of air (50 ppm), determined as an 8-hour time-weighted average (TWA). This standard was adopted in 1971 from an existing Walsh-Healey Federal standard. The source of the Walsh-Healey standard was the Threshold Limit Value (TLV) recommended in 1968 by the American Conference of Governmental Industrial Hygienists (ACGIH) (Ex. 2–2).

The documentation for the exposure level recommended by the ACGIH in 1968 consisted of limited data from 6 month inhalation animal studies which showed no adverse effects at levels below 50 ppm and one study of employees exposed for more than 10 years to EtO at levels of 5 to 10 ppm with no reported effects (Ex. 2–3). No indications of potential carcinogenicity were available at that time. Since that time, however, a substantial number of new studies have become available that have added significantly to the body of knowledge regarding potential health effects related to EtO exposure.

In 1977, the National Institute for Occupational Safety and Health (NIOSH) issued a "Special Occupational Hazard Review" (Ex. 2–5) on EtO, in which it recommended the adoption of a ceiling limit of 75 ppm (based on a 15-minute sampling period) for EtO in addition to the 50 ppm TWA (Ex. 2–4). Based upon observations of changes in the genetic material of cells in at least 13 biological species following EtO exposure and covalent chemical bonding between EtO and DNA, NIOSH also concluded that occupational exposure to EtO might increase the frequency of mutations in exposed populations. Although these observations raised concern regarding the potential carcinogenicity of EtO, no epidemiologic studies or long-term animal bioassays were available to assess it carcinogenic potential for humans.

In 1979, ACGIH published a Notice of Intended Change for EtO to 10 ppm TWA, with no proposal for a short-term exposure limit (STEL) ( Ex. 2–6). This change was adopted in 1981. ACGIH based its recommendation on a number of short-term, *in vitro* studies which provided positive mutagenic responses for EtO, and on a 1979 case report by Hogstedt et al. (Ex. 2–8) regarding the occurrence of 3 cases of leukemia in a group of 230 workers (more fully discussed below).

The 1981 ACGIH publication (Ex. 2–7) also designated EtO as a substance suspected of having carcinogenic potential in humans, and proposed to further lower the TLV for EtO to 5 ppm, based on the positive results from a two

year inhalation study on rats conducted at the Bushy Run Research Center (Ex. 2–9) (discussed below). On June 10, 1982, ACGIH adopted a proposal to lower the TLV to 1 ppm, such change to be effective in 1984. At that time, ACGIH decided not to recommend the adoption of an STEL.

On May 22, 1981, NIOSH issued a "Current Intelligence Bulletin" (Ex. 2–10) to inform employees and employers about the potential carcinogenic hazard of exposure to EtO. NIOSH recommended that EtO be regarded as a potential occupational carcinogen and that the current OSHA standard be reexamined in light of the information which had become available subsequent to the original adoption of that standard.

On January 26, 1982, OSHA published an ANPR (47 FR 3566) announcing its intention to conduct a reevaluation of the EtO standard. Interested parties were invited to submit data, views and comments with respect to the development of a new standard for EtO and particularly with respect to a number of specified questions. Responses to the ANPR are discussed in detail in Section VIII of this preamble. The data and views obtained through the ANPR as well as other information obtained by OSHA were used to develop this proposal.

In August 1981, prior to publication of the ANPR, Public Citizen Health Research Group (Public Citizen) petitioned OSHA to issue an Emergency Temporary Standard (ETS) reducing the permissible exposure limit for EtO to an eight-hour time-weighted average of 1 ppm (Ex. 2–11). OSHA denied Public Citizen's petition in September 1981 on the grounds that the available evidence did not indicate that an emergency situation existed to trigger the issuance of an ETS in accordance with section 6(c) of the Act (Ex. 2–12). Prior to the denial of the petition, Public Citizen brought suit in U.S. District Court for the District of Columbia to obtain an order requiring the Agency to issue an ETS *(Public Citizen Health Research Group et al.* v. *Auchter, D.C. Civil Action No. 81–02343). On January 5, 1983, the District Court Judge ruled that OSHA's determination not to issue an ETS represented a "clear error of judgment," and ordered the Agency to promulgate an ETS within 20 days of the Court's decision (Ex. 6–1). OSHA then sought and obtained a temporary stay of the District Court order pending review on the merits by the U.S. Court of Appeals for the District of Columbia Circuit.*

On March 15, 1983, the Court of Appeals rendered its decision on the merits in *Public Citizen Health Research Group et al.* v. *Auchter et al.*, No. 83–1071 (Ex. 6–2). In that decision, the Court ruled that the District Court had "impermissibly substituted its evaluation for that of OSHA" in ordering an ETS to be issued. Slip op. at p. 6. However, the Court then determined that because in the Court's terms a "significant risk of grave danger" exists with regard to EtO exposures, the failure of the Agency to publish a proposed standard on EtO for 18 months after the Advance Notice of Proposed Rulemaking constituted rulemaking action "unreasonably delayed," under section 6(g) of the OSH Act (29 U.S.C. 655(g)), and sections 555(b) and 706(1) of the Administrative Procedure Act (5 U.S.C. 555(b), 706(1)). Therefore, the Court ordered the Agency to expedite its development of a proposed rule on EtO, and to issue its proposal within 30 days of the Court decision. The publication of this proposed standard has been duly expedited to comply with the timeframe established by the Court.

In its January 5 decision, the District Court considered OSHA's assertions that the Environmental Protection Agency (EPA) had exercised its statutory authority over working conditions involving the application and use of EtO as a sterilant and fumigant under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.*, and that this exercise served to preempt OSHA regulation of these same working conditions pursuant to section 4(b)(1) of the OSHA Act. The District Court determined, and the Court of Appeals subsequently agreed, that OSHA coverage of EtO was not preempted in "areas—such as the health care industry—where EPA has apparently exercised *minimal, if any regulatory authority in an overlapping manner.*" (emphasis added) (District Court slip op. pp. 14–15; Court of Appeals slip op. p. 13, fn 23).

Pursuant to the court decision, the proposed rule being published today is intended to cover EtO exposures resulting from the application of EtO as a sterilant or fumigant, including hospital and health care uses.

In determining that OSHA retains authority to regulate working conditions involving the use of EtO as a pesticide, the Court stated that EPA's exercise of authority over working conditions under FIFRA did not "overlap" sufficiently to preempt OSHA regulation Because of OSHA's concern as to the interelationship between EPA pesticide labeling and OSHA regulation of EtO, the Issues section of this preamble contains several questions which are relevant to resolution of the problem. Comments and data on matters related to the interaction of EPA and OSHA regulation in this area are solicited for the rulemaking record.

## V. Health Effects

The ACGIH's TLV of 50 ppm was established in 1968 on the basis of toxic effects to EtO encountered in industry resulting from cutaneous contact with aqueous solutions of the compound (Ex. 6–3). These solutions cause primary irritation and sensitization of the skin. Chronic human intoxication of humans by EtO had not been reported up to 1968.

The 1966 documentation did discuss several experimental studies with laboratory animals that showed that exposure to high concentrations of EtO vapor (204–841 ppm) caused irritation of the respiratory passages, growth depression, and injury to various organs. Repeated exposures for 6 or 7 months (at 113 and 49 ppm) in rats caused no effects except for a growth depression and a moderate increase in lung weight at 113 ppm. The 1966 documentation also noted that repeated exposure of dogs, rats and mice at 100 ppm for six months caused no significant effects except for slight anemia in the dogs. The ACGIH's 1971 documentation for EtO (Ex. 6–4), however, described a 10 year study in an EtO production unit. Exposure concentrations were reported as ranging from 5–10 ppm with very few exposures exceeding 50 ppm. No adverse effects from exposure to EtO were seen in this study. The ACGIH concluded in 1966 and in 1971 that "the results from * * * these investigations of the chronic toxicity of ethylene oxide indicate that a threshold limit value of 50 ppm offers an adequate margin of safety from ostensible systemic effects."

New information regarding the possible occupational hazards of EtO has emerged over the past few years. These reports regarding the chronic toxicity, carcinogenicity, mutagenicity and possible reproductive hazards of EtO have been rviewed by OSHA to ascertain the extent to which any of these possible hazards may exist for employees exposed at the current PEL of 50 ppm to determine whether the current risks, if any, need to be reduced, and to estimate the effectiveness of various exposure limits in reducing risks. OSHA presents its review of the recent studies below.

a. *Carcinogenicity.* Morgan et al. (Ex. 6–5) reported on a mortality study of a cohort of 767 production workers potentially exposed to EtO. Industrial hygiene measurements revealed no detectable EtO levels in the production area. At the sources of EtO (pump,

valve, pipe flanges, spigots, and gauges), less than 10 ppm was recorded. Only during tank car loading operations were levels of approximately 6,000 ppm EtO recorded. All other measurements were below 50 ppm. The researchers saw fewer than expected deaths from all causes and fewer than expected deaths from total malignancies. The standardized mortality ratios were 58 and 79, respectively. No death from leukemia was observed as compared to 0.70 expected. There were, however, a total of 8 deaths reported for pancreatic cancer, bladder cancer, brain and CNS cancer and Hodgkin's disease compared to 2.16 expected for this group.

Hogstedt et al. (1979) (Ex. 2–8) reported 3 cases of leukemia, between 1972 and 1977, among 230 Swedish workers in a factory where a mixture of EtO and methyl formate had been used to sterilize hospital equipment; 0.2 cases would have been expected based on age- and sex-specific Swedish national rates for 1972. Though exposures were not well characterized, two of the cases (females) were estimated to have been exposed to EtO at an estimated eight-hour TWA of 20 ppm. The exposure history of the third case (male) was not specified, but he was also known to have had some occupational exposure to benzene in his laboratory work. The cases of leukemia were classified as acute myeloid leukemia and acute myelogenic leukemia in the women, and as macroglobulinemia in the man. The study is limited by the small size of the worker population, co-exposure of one of the cases to benzene (a human leukemia-inducing agent), and poor exposure histories.

Hogstedt et al. (1979) (Ex. 2–22) also reported the results of an historical prospective mortality investigation of workers in an EtO production facility. Workers who had been employed in 1961, had a minimum of one year of employment or exposure, and had achieved at least a ten year latency period from the start of exposure to EtO and the beginning of the observation period, were followed through 1977. Among the 89 full time workers in the EtO produciton areas, an excess of total mortality was observed (23 deaths observed, 13.5 expected, p less than 0.05). Significant excesses total cancer mortality (9 observed, 3.4 expected, p less than 0.01) and in deaths from diseases of the circulatory system (12 observed, 6.3 expected, p less than 0.05) were also reported. Site specific excess cancer mortality was noted for leukemia (2 observed, 0.14 expected, p less than 0.01) and stomach cancer (3 observed, 0.4 expected, p less than 0.01). No statistically significant excess mortality was noted among 86 maintenance workers from the same facility who had intermittent EtO exposure or among the 66 workers who never worked in EtO production areas, however, the statistical power to detect an effect was very low. One leukemia death was noted among the maintenance workers. Exposure to EtO in the EtO production areas was estimated to range up to the odor threshold of 700 ppm in the 1940's, 6–28 ppm during the 1950's and 1960's, and 0.6–6 ppm in the 1970's. Average exposure was believed to be below 14 ppm during the 1950's and 1960's.

The workers who were exposed to EtO were also exposed to ethylene, ethylene dichloride, ethylene chlorohydrin and bis 2-chloroethyl ether. Because of these multiple exposures, the authors were unable to attribute the excess cancer incidence to a specific chemical, although they speculated that EtO and ethylene dichloride were prime suspects.

After reviewing the two Hogstedt studies, NIOSH, in its Current Intelligence Bulletin on EtO concluded:

> These epidemiological investigations cannot be cited as definitive evidence of an excess risk of cancer resulting from ETO exposure, but they should be considered evidence that excess risk of cancer may exist for the EtO workers studied.

Taken singly, the two studies by Hogstedt and the study by Morgan are not remarkable. They attempted to characterize relatively rare events in small populations and might be disregarded because of small numbers regardless of statistical significance. Taken together with all their limitations, however, OSHA believes they suggest that exposure to EtO may increase the risk of malignancies, particularly leukemia.

The final report on the results of an inhalation toxicity study of EtO conducted at the Bushy Run Research Center was released in January 1981 (Ex. 2–9). This was a chronic two year inhalation study in which three groups of male and female Fischer 344 rats (120 rats per sex per group) were exposed to EtO concentrations of 100, 33 and 10 ppm, for 6 hours per day, 5 days per week. Two groups of rats were exposed to air only and served as controls.

Based on histological evaluation, the Bushy Run researchers concluded that the incidences of mononuclear cell leukemia and of peritoneal mesothelioma were significantly increased as a result of exposure to EtO. The incidence of mononuclear cell leukemia in female rats was dose-related, increasing with exposure concentration. A statistically significant increase in mononuclear cell leukemia was observed only in the group of female rats exposed at 100 ppm. For females exposed at 33 ppm, the cumulative percentage of animals developing leukemia was significantly higher than that for one control group and for both control groups combined, but was not higher than the incidence for the second control group. However, the incidence for the females exposed at 33 and 10 ppm did indicate a dose response. The regression analysis of leukemia incidence versus exposure concentration was significant with a correlation coefficient of +0.99, indicating that induction of the leukemia was highly correlated to exposure at each concentration.

An increase in peritoneal mesothelioma was reported in the male rats exposed at 33 and 100 ppm. Among the males exposed at 100 ppm, the cumulative percentage developing a tumor of this type was reported to be statistically significantly higher than that of the controls beginning with the 21st month of exposure. The incidence of these tumors in males exposed at 33 ppm was not appreciably higher than in the controls until the final month of the study. These peritoneal tumors originated in the testicular mesothelium and were confined to the abdominal cavity.

In addition, the Bushy Run investigators reported that EtO exposure was associated with a higher frequency and/or earlier onset of mononuclear cell leukemia in male rats. The researchers also reported that a mortality-adjusted trend analysis indicated that the normal occurrence of pituitary adenoma in male and female rats was significantly accelerated by exposure to EtO. They also concluded there was a dose-related increase in all other combined cancers.

Preliminary results from a two-year, NIOSH-conducted chronic inhalation study on male rats and male monkeys were reported at the 1982 meeting on the Society of Toxicology (Ex. 6–6). In that study, groups of 80 male Fischer 344 rats and 12 male Cynomolgus monkeys were exposed to 50 ppm and 100 ppm of EtO. Two groups, 80 rats and 12 monkeys, were used as controls and exposed to conditioned, filtered ambient air. During the study, all of the rat groups became infected with *Mycoplasma pulmonis* which, beginning with the sixteenth month, caused the death of a large segment of the rat population.

The preliminary results of the available histopathological evaluations of the spleen indicate an exposure-related increase of mononuclear cell

leukemia in male rats exposed to EtO at 50 ppm but not at 100 ppm. NIOSH has acknowledged that these preliminary results must be interpreted in light of the known spontaneous incidence of leukemia in Fischer 344 rats. It should be noted, however, that excess mortality has occurred in the 100 ppm group (19% survived as compared to 49% of the controls). At the terminal kill a significant higher frequency of leukemia was found only in the group exposed to 100 ppm of EtO. Of equal or greater importance, however, is the apparent dose-related finding of gliomas in the rats of the NIOSH study. This tumor is rare in Fischer 344 rats. Gliomas were found in 5 of 79 rats exposed at 100 ppm and 2 of 77 rats exposed at 50 ppm. There were none in the 76 control rats. A significant association of exposure and an occurrence of peritoneal mesothelioma was found for rats exposed to 100 ppm EtO, but not to 50 ppm EtO. These results parallel those from the Bushy Run study. A more comprehensive evaluation of the chronic studies is planned by NIOSH, but only after all of the data are statistically analyzed and interpreted.

None of the monkeys in the NIOSH study have demonstrated any evidence of leukemia. Two of the monkeys in each exposure group were sacrificed for neuropathological evaluation. The only significantly finding was an increase of axonal dystrophy in the nucleous gracilis of the experimental monkey as compared to the two controls and demyelination of portions of the gracile tract in one of the monkeys in each of the low and high dose groups. Based on this limited evidence, the researchers were not able to reach any conclusions as to the cause or significance of these findings, but they remain noteworthy in view of the findings of gliomas in the rats.

In 1979, Dunkelberg (Ex. 2–18) reported preliminary results of a long-term carcinogenicity bioassay in mice, in which EtO was administered by subcutaneous injection to 100 female NMRI mice in weekly dosages of 0.1, 0.3, or 1.0 mg per animal. Two control groups, 200 untreated and 100 tricaprylin treated mice, were used. After 91 weeks of treatment, it was reported that the number of sarcomas at the injection site increased in the experimental groups, but not in the control groups. The first tumor appeared in the fiftieth week of treatment. The number of subcutaneous tumors at sites distant from the injection sites were not significantly greater in the treated groups than in the control groups.

Three earlier studies of EtO carcinogenicity should also be noted. Walpole (1957) (Ex. 2–20) subjected 12 "stock" rats to repeated subcutaneous injections of a dose of 1 g/kg EtO in Archis oil for 94 days. The small sample of animals was observed for their lifetime and no tumors were observed. Van Duuren et al. (1955) Ex. 2–21) applied 0.1 ml of a 10% EtO solution in acetone to the dorsal skin of 30 female Swiss Millerton mice three times per week for life. No tumors were observed.

Reyniers et al. (1964) (Ex. 2–19) reported tumors in 63 of 83 female mice accidentally exposed to EtO-treated bedding for 150 days and then moved to untreated bedding for the remainder of their lifespans. In contrast, no tumors were reported in 83 female mice that had not been exposed to the EtO-treated bedding. This report was not of a scientifically designed study.

In summary, OSHA has determined that EtO is carcinogenic in laboratory animals and that a significant cancer risk exists for employees exposed to EtO. This finding is supported by the available epidemiological evidence of the effects of EtO in the workplace.

The Bushy Run study clearly indicates that EtO is carcinogenic in both male and female rats. This finding is buttressed by the epidemiological studies of Hostedt et al. which are considered to strongly suggest that excess risk of cancer may exist for workers exposed to EtO. The work of Morgan et al. is also supportive of this conclusion. In addition, other animal studies, though not necessarily as well reported or documented as the Bushy Run study, confirm the carcinogenic hazard of EtO. For example, the preliminary reports from the NIOSH rat study confirms the Bushy Run study results and indentifies the brain as another possible target site for cancer in animals. NIOSH has asked that the investigators at the Bushy Run Research Center review their slides with this finding in mind.

In the following section, reports on the mutagenic effects of EtO have been reviewed. The positive findings of a mutagenic hazard support the findings of potential risk by identifying the mechanism of cancer induction by EtO to be genotoxic in nature.

b. *Evidence of Reproductive Effects and Mutagenicity.* In 1982, Hemminki et al. (Ex. 6–7) published a report which suggests that women occupationally exposed to ethylene oxide may be at an increased risk of spontaneous abortion. With a postal questionnaire, women employed during 1980 in chemical sterilization of instruments using ethylene oxide, glutaraldehyde and formaldehyde were identified by nursing supervisors in all Finnish general hospitals (about 80 hospitals). Later, questionnaires were sent to all hospital staff engaged in sterilizing instruments and to an equal number of unexposed nurse auxiliaries (controls) who were selected from the same hospital's staff by the supervising nurses. The response rate was greater than 90% for both groups. Information collected on the questionnaires permitted the researchers to adjust the data for age, parity, decade of reported pregnancy, coffee and alcohol consumption, and smoking habits using a linear logistic regression model.

No effect on spontaneous abortion rate was observed when the crude rate for the entire sterilizing staff was compared to the crude rate for the nurse auxiliary controls. A significant increase (p less than 0.001) in the spontaneous abortion rate was observed when the experience of sterilizing staff exposed to sterilizing agents during pregnancy (adjusted rate 15.1) was compared to the experience of the sterilizing staff without exposure during pregnancy (adjusted rate 4.6). The controls had an intermediate spontaneous abortion rate (adjusted rate 10.5).

Hemminki et al. were able to stratify the sterilizing staff by exposure to specific sterilizing agents during pregnancy. Although the numbers in some of the categories were relatively small, significant increases (p less than 0.05) were observed in the adjusted spontaneous abortion rates for total pregnancies exposed to ethylene oxide (with and without other agents), ethylene oxide (or glutaraldehyde) or ethylene oxide alone compared to total pregnancies not exposed to these chemicals. (In the papers, the category "ethylene oxide (with glutaraldehyde)" should read "ethylene oxide (or glutaraldehyde)". Correction explained in "exhibit No. 6–25.)

The authors also noted that the rate of spontaneous abortion (adjusted for parity) among non-exposed sterilizing staff during the calendar time period 1961–70 was significantly lower than the rate for nurse auxiliary controls over the entire study period 1951–81. However, the analysis is not considered appropriate as adjustment for calendar time period of reported pregnancy, a factor associated with spontaneous abortion, was not made in this analysis. There did appear to be a slightly lower rate of spontaneous abortion among the non-exposed sterilizer operators as compared to the nurse auxiliary controls during each decade of pregnancy. This

difference was not explained by the authors. The appearance of a significantly reduced adjusted rate among the non-exposed sterilizers, which could not be determined from the study, might lead one to conclude that the control group was not comparable to the sterilizer operators.

Finally, the authors ascertained data on pregnancy outcome from the Finnish hospital discharge register for sterilizing staff and controls for the years 1973–79. The data demonstrated a significant excess in the crude rate of spontaneous abortion among only EtO exposed staff as compared to controls (22.6% vs. 9.2%, p less than 0.05). Since spontaneous abortion is known to affect subsequent pregnancy outcome, data were then eliminated for women who had more than one spontaneous abortion. One woman in the EtO exposed group and two women in the control group had two spontaneous abortions. When the data for these women were eliminated from the analysis, the crude abortion rates was 17.2% for EtO exposed as compared to 8.2% for the controls (Ex. 6–25). While these rates are based on small numbers, they indicate that the elimination of data for women with more than one spontaneous abortion did not change the trend seen in the analysis of the total data set. These findings from a second independent source tends to corroborate the findings observed in the questionnaire aspect of the study.

In response to OSHA's request for further information concerning the of the nature of EtO exposure, Dr. Hemminki responded:

> * * * ethylene oxide concentrations in sterilization units of the Finnish hospitals, measurements have been carried out only since 1976, independently from our study. In many hospitals, it was noted that immediately after opening of the sterilizing chamber, a 20 min average ethylene oxide concentration of 5 to 10 ppm was measured. This would amount to an 8 h TWA of probably less than 1 ppm. Some supervisors of sterilizing activity assume that in early 1970's the gas concentrations could have been higher, even though the same procedures and, in many instances, the same instruments were used. (Ex. 6–8)

Therefore, the available information suggests that the excess in spontaneous abortion among sterilizing staff exposed to EtO may have resulted from one short-term peak exposure per day, though the information on exposure is sparce.

The Hemminki et al. data provide suggestive evidence of increased risk of spontaneous abortions in women exposed to EtO. Other reproductive problems, such as decreased fertility, were not addressed by this study.

EtO has been evaluated for toxic and teratogenic effects in New Zealand white rabbits (Ex. 6–9). When EtO was administered intravenously at 0, 9, 18, or 36 mg/kg/day on gestation days 6–9, maternal toxicity was minimal and no evidence of fetotoxicity or teratogenicity was found. This may be because implantation in the rabbit does not occur until gestation day 7 or 8. Administered daily on gestation days 6–14 by intravenous injection, EtO at doses of 0, 9, 18, or 36 mg/kg/day failed to produce evidence of an exposure-related teratogenic effect, even at levels producing maternal and fetal toxicity. There was evidence of fetotoxicity directly related to increasing dose, including increases in the percentage of resorptions and nonlive fetuses per litter, and decreases in live litter size and in the percentage of males per litter. This study supports the work of Hemminki et al., in that it confirms the potential fetotoxicity of EtO.

The final report of a one-generation reproduction study in rats conducted at the Bushy Run Research Center (Ex. 2–23) is also available. Both male and female rats were exposed to EtO vapor at air concentrations of 100, 33, or 10 ppm for 6 hours per day, 5 days per week for 12 weeks prior to mating and for 6 hours per day, 7 days per week for two weeks during and after mating. The major treatment related adverse effect was that significantly fewer pups were born per litter for rats exposed to 100 ppm EtO. A dose-related decrease in fertility was observed at the 100 ppm and 33 ppm exposure levels, while no effect occurred following exposure to 10 ppm EtO.

Snellings et al. (Ex. 2–23) of the Bushy Run Research Center, also reported that no developmental effects occurred when female Fischer 344 rats were exposed by inhalation to 10, 33, and 100 ppm EtO for 6 hr/day on days 6 through 15 of gestation.

In a similar type of study sponsored by NIOSH, female rats and rabbits were exposed to 150 ppm ETO, 7 hr/day (Hackett et al. 1982, Ex. 6–10). There were no adverse reproductive effects observed in the rabbits. In litters from female rats exposed prior to mating and during gestation, there was an increase in fetal deaths (resorptions). Fetal growth indices were reduced in the ethylene oxide exposed rats, particularly those receiving both pregestational and gestational exposure. Reduced ossification in fetal skulls and sternebrae were higher in the EtO exposed rats than in the controls. These effects may be related to inhibited fetal growth which could have been caused secondarily by maternal toxicity.

LaBorde and Kimmel (Ex. 2–24) reported evidence of a teratogenic effect in CD–1 mice from intravenous exposure to EtO. They found that EtO was toxic to pregnant mice at doses of 150 mg/kg when administered intravenously during days 4–6, 8–10 or 10–12 of gestation, but not when administered during days 6–8. A significant increase in the percentage of malformed fetuses was noted as a result of EtO administration during days 6–8 and 10–12 of gestation.

Embree et al. (1977)(Ex. 2–35) have shown that EtO causes mutation in Long-Evans rats in the dominant-lethal assay. Male rats were exposed to 1000 ppm of EtO for 4 hours and each male was mated to 2 females each week for 10 weeks. A significant increase was observed in post-inplantation deaths at 1, 2, 3 and 5 weeks after treatment, indicating that gametes in various stages of development from spermatocyte through mature sperm were adversely affected.

Generoso et al. (1980) (Ex. 2–36) reported the induction of dominant-lethal effects in rats resulting from a single intraperitoneal injection of 150 mg/kg of EtO (maximum tolerated dose). In a heritable translocation assay, male rats were given intraperitoneal EtO injections of either 60 or 30 mg/kg body weight 5 days a week for 5 weeks. In addition to observed dominant lethal effects, an increased frequency of heritable translocation was reported or groups exposed to EtO.

An inhalation study on mice performed by Cummings et al. (1981) (Ex. 2–37) found that unscheduled DNA synthesis in the testis was increased after male (101 x C3H) F1 hybrid mice were exposed at 300 or 500 ppm EtO in a work-week type exposure regimen (8 hours per day for 5 days). EtO at doses of 600 and 800 ppm was found to inhibit the repair of DNA damage, as measured by a reduction in unscheduled DNA synthesis after 4 hours of exposure.

The mutagenicity of EtO has been observed or reported in a wide range of biological systems, including submammalian and mammalian species. An increased frequency of cell mutations has been reported in 13 different species, including *Salmonella, Neurospora,* barley, *Tradescantia, Drosophila,* and *E. Coli.* While these tests are not definitive determinants of chemical carcinogenesis, it is recognized that correlative and functional relations have been demonstrated between these two end points. For example, McCann et al. (1975) (Ex. 6–11) showed an extremely good correlation between the results of microbial mutagenesis tests and *in vivo* rodent carcinogenesis

assays. Futhermore, these types of studies establish that EtO acts directly on DNA and is to be considered genotoxic. Thus, the level of human exposure must be stringently evaluated.

The 1982 NIOSH chronic study on rats and monkeys (previously discussed) was also designed to explore the cytogenic effects from EtO exposure in the monkeys. Specifically, groups of Fischer 344 rats and Cynomolgus monkeys were exposed by inhalation to ethylene oxide for 7 hours/day, 5 days/week for 24 months. Each experimental group consisted of 80 rats and 12 monkeys. One group was exposed at 50 ppm ethylene oxide, a second group at 100 ppm ethylene oxide, and a third group, not exposed to ethylene oxide, was used for comparison to the exposed animals. Cytogenetic and spermatogenic evaluation of the monkeys was performed after the twenty-fourth month. Peripheral lymphocytes were cultured and examined for chromosomal aberrations and sister chromatid exchange.

NIOSH reported that exposure to ethylene oxide significantly increased the frequency of chromosomal aberrations in peripheral lymphocytes of monkeys in both exposed groups. In animals exposed at 100 ppm, 4.2 percent of the cells were found to be abnormal. At 50 ppm, the percent of abnormal cells was 2.2. This is about a 3 fold increase in abnormal cells for animals exposed at 50 ppm, and about a 5.6 fold increase in animals exposed at 100 ppm, compared to the rate of aberrations found in the unexposed animals.

NIOSH reported that the prevalence of sister chromatid exhanges (SCE) was also significantly increased in ethylene oxide exposed monkeys. The mean number of SCEs per 42 chromosomes was 5.7 in the unexposed group compared to 10.2 SCEs per 42 chromosomes in animals exposed at 50 ppm, and 16.8 SCEs per 42 chromosomes in monkeys exposed at 100 ppm ethylene oxide. There was also an increase in micronuclei in the polychromatic erythrocytes from bone marrow of EtO exposed monkeys (5 per 1000 cells) as compared to controls (1–2 per 1000 cells) in the monkeys examined per dose level. NIOSH stated that these results support the cytogenetic toxicity of ethylene oxide. The total sperm count and the percentage of motile sperm was reduced and sperm drive range was increased in primates exposed to either 50 or 100 ppm EtO for 24 months.

Pero et al. (1982) (Ex. 6–12) examined the effects of EtO exposure on unscheduled DNA synthesis, a step in the enzymatic repair of DNA lesions. Peripheral blood lymphocytes were obtained from five male workers expose to EtO at TWA concentrations of 0.5–1 ppm for 0.3–5 years. Control samples were obtained from 12 men employed in a nearby industry where no known mutagens were in use. The controls were matched for age and smoking habits. A significant decrease in DNA repair proficiency was associated with EtO exposure, indicating that EtO is genotoxic.

In another study, Pero et al. (1981) (Ex. 6–13) examined the effects of exposure to EtO on unscheduled DNA synthesis induced by N-acetoxy-2-acetylaminofluorene and on chromosomal aberrations in peripheral lymphoctyes of female employees at a Swedish factory manufacturing disposable medical equipment. Seventeen workers and 11 matched controls working at the same plant were examined. Group A consisted of 12 packers (mean age 40.6 years) exposed to an average of 0.5–1 ppm for 1–8 years. Group B was composed of 5 sterilizer/technicians (mean age 32.0 years) who had been exposed for 0.8–3.0 years for 1 hour/day at concentrations of 5–10 ppm. Chromosomal aberrations were scored for both breaks and gaps. A significant increase in both total aberrations and breaks was found for group B and for groups A and B combined as compared to controls. Unscheduled DNA synthesis was inhibited significantly in group A. When this test was repeated 9 months after measures had been taken to lower exposure to EtO to 0–0.5 ppm, results for the group of exposed workers had returned to normal. From these tests and *in vitro* studies of EtO, the authors suggested that EtO, inhibits DNA repair.

Johnson and Johnson submitted preliminary results of an ongoing chromosome study being conducted at three of their facilities (Ex. 4–17) The worksites selected were chosen on the basis of potential exposure to EtO prior to September 1980, with one site representing high exposure (5–200 ppm, 8-hour TWA), another representing moderate exposure (1–10 ppm, 8-hour TWA) and the third low exposure (less than 1 ppm, 8-hour TWA). All participants exposed to EtO were employed in sterilizing areas and they were classified within each plant according to whether their potential for exposure to EtO was high or low. Controls were randomly selected from other areas of the plant on the basis of sex and age. At two plants, a dose related trend was observed for increases in sister chromatid exchanges, and at the highest exposure plant, the increase in the frequency of complex aberrations was also dose-related.

After preliminary experimental studies with rats, Ehrenberg and Hallstrom (1967) (Ex. 2–38) conducted hematologic studies among personnel of a factory manufacturing and using ethylene oxide. In 1960, they conducted medical examinations and compared the results of hematologic studies for 31 EtO exposed personnel with those for 26 unexposed employees from other departments of the same factory. Significantly lower ($p=0.05$) hemoglobin values were found for the exposed group. Three cases of anisocytosis and one case of chronic lymphatic leukemia were identified in the EtO exposed group, whereas none were identified among the controls. When currently ill persons were excluded from the analysis, the EtO exposed group had a significantly higher average white cell count. Subsequent to these findings, ventilation and safety measures in the factory were improved, and in 1961, further study was conducted. Lymphocyte counts were still significantly higher in the exposed than in the unexposed group among those persons who had participated in the 1960 study, indicating that the control measures were inadequate or that the effects were persistent. When additional employees were added to the study, including those who were intermittently exposed to EtO or had been exposed to EtO at some time in the past, the overall differences between the enlarged exposed and control groups in lymphocyte counts decreased so that they were not significantly different from each other. This effect would be expected with the addition of persons with poorly defined EtO exposure to the exposed group.

Ehrenberg and Hallstrom (1967 also examined blood values for 8 factory workers accidentally exposed to high concentrations of EtO. Exposure that resulted when a tube burst in the factory during repair work led to acute adverse health effects, with two persons hospitalized for respiratory difficulties. Blood values were followed for these 8 subjects for six weeks after the accident. Large variations in the numbers of lymphocytes and neutrophils were noted. No control group was studied. Eighteen months after the accident, chromosome studies were conducted for seven of the acutely exposed persons and ten unexposed personnel from the same factory. The authors concluded that acute exposure to EtO for approximately two hours induced significantly greater numbers of chromosomal aberrations (breaks, gaps, and exchanges) than in a comparable control group (p less than 0.05). It was

not stated whether the accidentally exposed workers had additional exposures to EtO prior to or subsequent to the accident.

Garry et al. (1979) (Ex 6–14)) studied a group of 15 employees who worked in an EtO sterilization facility. Most of these employees reported clinical symptoms of the upper respiratory tract and central nervous system. Twelve exposed employees and 12 unexposed individuals were studied for SCE's. Four chronically exposed persons who reported upper respiratory and neurologic symptoms showed a significantly increased number of sister chromatid exchanges at 3 weeks and again at 8 weeks after the last known exposure. Another group of eight persons with fewer complaints studied as late as the ninth week of exposure showed a significant increase in the number of exchanges. The measured concentrations of ethylene oxide were repeated to be less than 50 ppm.

A company using EtO in manufacturing and distributing health care products has reported the results of a medical examinations that included cytogenetic evaluations, of 75 workers with potential EtO exposure at nine facilities (Abrahams, 1980) (Ex. 2–39)). Workers were exposed for an average of 2.9 years. A group of 37 workers with no known EtO exposure served as a comparison group for the cytogenetic evaluation. The data indicated that the facilities had complied with the OSHA PEL of 50 ppm as an 8-hour TWA, although there were instances then the NIOSH recommendation for a maximum 15-minute exposure of 75 ppm had been exceeded. The physical examination revealed no unusual findings among exposed persons. A statistically significant increase in the number of chromosome abberrations in peripheral lymphocytes among the exposed workers was noted when compared to the number in the nonexposed group. Some workers had an increased incidence of sister chromatid exchanges compared to nonexposed workers. Data from the sperm analysis were inconclusive.

The significance of this investigation is difficult to evaluate because of the manner in which the data are presented and the design of the study. However, the chromosomal aberrations in exposed workers included quadriradial chromosomes; the occurrence of this rare type of aberration should be viewed with concern.

*Conclusion*

OSHA's determination that EtO is a potential occupational carcinogen was generated by the positive findings of the chronic inhalation study performed at the Bushy Run Research Center. This is supported by the strongly suggestive epidemiological findings of Morgan et al. and Hogstedt et al. Many positive effects from *in vitro* mutagenic investigations establish the genotoxic mechanism of cancer induction. The work of Callaman et al. suggest that EtO may elicit this action by alkylation of DNA.

The work of Pero et al. and the data submitted by Johnson and Johnson establish that EtO exposure at relatively low levels produce effects in man related to its probable carcinogenic mechanism.

The recent report of Hemminki et al. suggests the EtO exposure may cause an increase in spontaneous abortions. The fetotoxic hazard of EtO with regard to exposure of the female is supported by positive findings in the animal studies performed by Hackett et al., Jones-Price et al., and La Borde and Kimmel. This type of an effect could be induced by changes in the DNA and many alkylating agents are known to induce them. OSHA feels that the adverse spermatogenic effects of EtO on the primates alone, which are consistent with effects on DNA, are suggestive of an effect on the male reproductive capacity. This conclusion is supported by the one generation study in rats conducted at the Bushy Run Research Center. Furthermore, the establishment of the dominant lethal effect by Embree et. al., the heritable translocations by Generoso et al., and alteration of DNA in testes of experimental animals establish the hazard of heritable changes following exposure to the male.

In summary, findings in humans and experimental animals exposed to EtO are indicative of damage to the genetic material (DNA). These include hemoglobin alkylation, unscheduled DNA synthesis, sister chromatid exchange, chromosomal aberrations, and functional sperm abnormalities. In addition, evidence from *in vivo* studies shows that in animals and man, DNA damage may occur in the form of increased incidence of cancer, mutation in offspring, and spontaneous abortions following exposure to EtO.

c. *Risk Assessment.* The United States Supreme Court, in the recent *Benzene* and *Cotton Dust* cases, (*Industrial Union Department, AFL–CIO* v. *American Petroleum Institute*, 448 U.S. 607 (1980); and *American Textile Manufacturers Institute* v. *Donovan*, 452 U.S. 490 (1981), respectively), has ruled that OSHA may not promulgate a standard unless it has determined, based on substantial evidence in the record considered as a whole, that there is a significant risk of health impairment at existing permissible exposure levels and that issuance of a new standard is necessary to achieve a significant reduction in that risk. Although the Court in the *Cotton Dust* case rejected the use of cost-benefit analysis in setting OSHA standards, it reaffirmed its earlier holding in *Benzene* that a risk assessment relating to worker health is not only appropriate, but is in fact required in order to identify a significant worker health risk and to determine whether a proposed standard will achieve a reduction in that risk. Although the Court did not require OSHA to perform a *quantitative* risk assessment in every case, the Court implied, and OSHA as a policy matter agrees, that such assessments should be put in quantitative terms to the extent possible.

1. *Preliminary Quantitative Risk Assessment: Data Base for Quantitative Risk Assessment.* In order to estimate the potential risk of cancer to workers exposed to EtO, OSHA performed a quantitative risk assessment. OSHA extrapolated the data from the two year inhalation study on rats performed at the Bushy Run Research Center (Snellings et al., 1981, Ex. 2–9) in an effort to quantify the lifetime excess risk of cancer to humans. OSHA chose lifetime EtO exposure levels of 50, 10, 5, 1, and 0.5 ppm as possible scenarios to examine. The following discussion summarizes the data and conclusions of OSHA's preliminary quantitative risk assessment. The full text of the assessment, including technical appendices, has been placed in the EtO docket, and is available for review and copying at the OSHA docket office (Ex. 6–18).

In the Bushy Run study, Fischer 344 rats were exposed to airborne concentrations of 100, 33 or 10 ppm of ethylene oxide vapor for 6 hours per day, 5 days per week for approximately two years. Two control groups were exposed to air only under similar conditions. Initially, 120 rats per sex per group were exposed, and at each 6-month interval a portion of the animals was sacrificed to determine possible treatment-related effects. Interim evaluations included hematology, serum clinical chemistry, urinalysis, body weight, organ weight, bone marrow cytogenetic, and gross and histologic examinations.

Two different neoplastic lesions were observed to have significantly increased incidence over the controls: peritoneal

mesothelioma in the male rats, and mononuclear cell leukemia in the females. No other types of malignant neoplasms were observed. The investigators employed two independent control groups (air only) in the study to gain a better assessment of variability in the non-treated animals. Results in the two control groups (for the tumors of interest) were not significantly different and the two groups were combined for purposes of the quantitative risk assessment.

The Bushy Run study was selected for the quantitative risk assessment because it provided, by far, the best quantitative information available from any study on EtO and it had the following characteristics:

1. There was a statistically significant increase in the incidence of malignant neoplastic changes.
2. A dose-response relationship was observed.
3. The study was run with a concurrent control group.
4. The dosing regimen was completely specified including route of exposure, duration of exposure, observation period and age of animals.
5. This study had the added advantage that the routes of exposure are identical for both the animal experiments and the major occupational exposure.

*General Assumptions*

The following general assumptions were carried through in performing the quantitative risk assessment:

1. The mathematical model fit to the measured data is assumed to hold for doses outside the range of measurement.
2. There is no threshold effect assumed.
3. The absorption rate for both rats and humans is assumed to be 100 percent.
4. Estimation of risk factors for a particular malignancy in animals is not assumed to correlate directly to a risk for that particular tumor in humans. The predicted risk simply indicates an excess risk of cancer to humans at a given level.
5. Experimental doses were scaled to "equivalent human doses" using milligrams of EtO inhaled per kilogram of body weight per day (mg/kg/day). This scaling procedure has been shown empirically to accurately predict human carcinogenic potency for several chemical substances (Crump and Howe, 1980, Ex. 6–17). Additional scaling factors were applied to correct for differences in length of lifetime exposure, though, calculations on the length of exposure also show that the rats and humans are exposed for approximately the same proportion of their lives (approximately 18% of the lifetime). Details of the calculations of scaling factors can be found in Appendix B of the Preliminary Quantitative Risk Assessment which has been submitted to the OSHA docket.

Incidence and dose data are presented in Table 1.

TABLE 1.—PATHOLOGIES IN RATS AFTER EXPOSURE TO ETHYLENE OXIDE

| Tumor type | Animal | 100 ppm [1] | 33 ppm | 10 ppm | Control I + II |
|---|---|---|---|---|---|
| Peritoneal Mesothelioma | Males | 22/96 [2] | 7/82 | 3/88 | 4/187 |
| | P value [3] | <.0001* | .0213 | .3983 | |
| | Females [4] | | | | |
| Mononuclear cell Leukemia | Males | 26/98 | 25/77 | 21/77 | 38/193 |
| | P value | .1192 | .0202 | .1163 | |
| | Females | 28/73 | 24/72 | 14/71 | 22/186 |
| | P value | <.0001* | .0001* | .0791 | |

[1] Dose used in risk assessment was expressed in mg/kg/day. Dose was calculated as d(mg/kg/day) = d(ppm) x S, where S is a scaling factor. For male rats S = 0.1930324; for female rats S = 0.2393601; for humans S = 0.129696.
[2] Number of tumor-bearing animals/Effective number of animals at risk.
[3] P value from Fisher's Exact test, (upper tail probability) when compared to combined controls. A Bonferroni correction was used in evaluating the significance at the .05 level of the probabilities for use in the quantitative risk assessment * indicates P less than .05/r where r is the number of test doses.
[4] Data not available.

TABLE 2.—EXCESS LIFETIME RISK OF CANCER PER 10,000 WORKERS FROM EXPOSURE TO ETHYLENE OXIDE [1]

| Exposure level [2] | Multistage [3] | | One hit [4] | | Multistage [5] | |
|---|---|---|---|---|---|---|
| | MLE [6] | UCL [7] | MLE | UCL | MLE | UCL |
| 50 | 634 | 1,008 | 746 | 1,018 | 1,093 | 1,524 |
| 10 | 118 | 211 | 154 | 213 | 229 | 326 |
| 5 | 58 | 106 | 77 | 107 | 115 | 164 |
| 1 | 12 | 21 | 15 | 21 | 23 | 33 |
| 0.5 | 6 | 11 | 8 | 11 | 12 | 16 |
| $\chi^2$ [8] | 0.0579(1) | | 0.2360(2) | | 4.3255(2) | |
| P [9] | 0.81 | | 0.89 | | 0.12 | |

[1] Extra risk per 10,000 workers $[P_s = (P(d)-P(0))/(1-P(0))]$. Lifetime exposure is assumed to be 8 hours per day, 5 days per week, 46 weeks per year for 45 years in a 54 year lifespan since initial exposure.
[2] Multistage model with 3 parameters: $q_o = 0.020965$, $q_1 = 0.008905$, $q_2 = 0.000184$. Extrapolated from male rats.
[3] One hit model with parameters $q_o = 0.019682$, $q_1 = 0.011943$. Extrapolated from male rats.
[4] The multistage model fit a one hit model in this case, with parameters $q_o = 0.14700$ and $q_1 = 0.017841$. Extrapolated from female rats.
[5] ppm.
[6] Maximum Likelihood Estimate of Excess Risk.
[7] 95% Upper Confidence Limit On Excess Risk.
[8] One-tailed Chi-squared goodness-of-fit test. (Degrees of freedom are in parentheses)
[9] -value associated with $\chi^2$.

*Statistical Methods and Predictions*

The predictions of risk from two mathematical models for cancer initiation are presented in Table 2. The multistage model is a mathematical model for carcinogenesis based on the biological theory that carcinogens induce cancer through a series of stages. The multistage theory was proposed by Armitage and Doll in 1916 and is in wide use for performing quantitative risk assessments. The onehit model is a special case of the multistage model where there is only one stage. The estimates were produced using the computer program GLOBAL 82, a program used to extrapolate dichotomous animal carcinogenicity data to low doses (Howe and Crump, 1982, Ex. 6–17).

The curvefitting and predictions of risk are based on assumptions discussed above and a worker's lifetime exposure scenario of 8 hours per day, 5 days per week, 46 weeks per year for 45 years. Predictions of risk from the male and female rats are listed separately, and can be used to formulate a range of predicted risk. As can be seen from the table, the multistage model predicts a lifetime excess risk of cancer from occupational exposure to ethylene oxide at the current PEL of 50 ppm as 634 to 1093 per 10,000 workers, with 95% upper confidence limits on the excess risk of 1008 to 1524 deaths per 10,000 workers. Upper confidence limits are useful in assessing the amount of statistical variation found in the data being used for the quantitative risk assessment. A reduction in the PEL from 50 ppm to 1 ppm would constitute a 98% reduction in the estimated risk. lastly, Chi-squared goodness-of-fit test results are given in order to judge the fit of a given model to the data. The closer the P value

associated with a chi-square goodness-of-fit statistic is to one, the better the fit. (The lack of fit of the multistage model (and other models) to the female rat data is discussed in more detail in the full text, Exhibit 6–18.)

*Other Models*

In addition to the multistage and onehit models, four other models were considered for the data: the probit, logit, Weibull, and gamma multihit models. Each of these curves is signoid in shape and was formulated in terms of tolerance to a given toxic agent. These models have the property that, at lower doses, the curves tend to approach zero more quickly than the multistage model, though the probit model, by far, most strongly exhibits this characteristic.

The estimates of risk from the other models agree generally with those from the multistage model (a three-fold difference in estimates from different models falls well within the range of "acceptable" discrepancy. See Tables V(i) and V(ii) of Preliminary Risk Assessment). Thus, the estimates from the multistage model, though slightly conservative, generally represent the level of risk predicted by all of the models but the probit model.

Information and comment are sought on all aspects of the quantitative risk assessment, including aspects of risk assessment not explicitly addressed in this proposal.

*Other Risk Assessments*

Calleman and colleagues (1978 Ex. 6–19) have presented a risk assessment for ethylene oxide based on a comparison of the degree of alkylation of histidine in hemoglobin in EtO-exposed workers and workers exposed to ionizing radiation. By such comparisons the authors calculated the "rad-equivalence" for certain alkylating agents, that is, the number of rads of acute gamma radiation that gives the same effect as a unit dose of the chemical.

Calleman et al. employed data from epidemiologic studies of populations exposed to EtO and those exposed to ionizing radiation. The authors speculated that compounds such as EtO would induce a "spectrum of cancers similar to that observed following whole body exposure to penetrating low-LET [linear energy transfer] radiation." Since radiation-induced leukemias tend to have shorter latency times (approximately 10 years) than most solid tumors median latency of 25 years) the authors recommend that special attention should be directed toward the incidence of leukemia in EtO-exposed populations.

Based on EtO exposure profiles, Calleman and his co-workers estimated that exposure to 1 ppm per hour of ethylene oxide resulted in a risk of 10 mrad-equivalents of effects in a genetic mechanism. Thus, in industrial work environments with an average exposure level in the range of 5–10 ppm of EtO, Calleman et al. estimated that the mid-point of the range would correspond to approximately 120 rad-equivalents per year. On this basis they predicted that a group of 100 workers exposed at the 5–10 level for 10 years could expect 3.6 cases of leukemia, one of which would be expected to appear before the end of the 10-year period.

Expanding upon these findings, Rantanen et al. (1982, Ex. 6–20) point out that the limit of occupational risk recommended by the International Commission on Radiological Protection corresponds to whole body exposure of 5 rads per year of low LET radiation. The comparative exposure dose of EtO would be an average concentration of 0.25 ppm (using conversion formula of Calleman et al.).

The EPA Carcinogen Assessment Group (CAG) performed a preliminary risk assessment (October 16, 1979, Ex. 6–21) based on the report of leukemia in three out of 230 workers in Sweden (Hogstedt et al., 1979, Ex 2–8).

The CAG estimated the lifetime probability of death from leukemia from breathing 1 ppm of EtO is:

$$P=\{a[R-1)X_1]/X_2$$

where a is the background lifetime probability of dying from leukemia in the U.S., R is the relative risk, $X_1$ is the exposure at 1 ppm and $X_2$ is the exposure experienced by the workers. After converting from ppm to $mg/m^3$ (1 ppm = 1.80 $mg/m^3$), the CAG predicted a lifetime probability of dying from leukemia from breathing 1 $mg/m^3$ of EtO as 0.00012 (.12 per 1000) based on an occupational exposure of 9 years as reported in the study.

The CAG noted that this might be an underestimate of the risk for two reasons: (1) There might have been insufficient latency in the study to detect the total number of potential cancers (only 9 years); and (2) since the number of person-years of exposure was not reported, the CAG assumed that all workers were exposed for 9 years, an assumption which also underestimates the risk of exposure over a working lifetime. In making its estimates the CAG noted that it could not definitively judge the effect that the mixed exposures to EtO and methyl formate reported in the Swedish study would have on the CAG risk estimates for EtO alone.

2. *Dose-Response Analysis.* OSHA performed its preliminary quantitative risk assessment on the carcinogenic response in the Bushy Run animal study. OSHA believes this study provided the most appropriate data on which to base the risk assessment, particularly since most low-dose extrapolation methods currently in use rely on theories of carcinogensis.

The data on other adverse health effects discussed earlier were determined to be not as suitable for quantitative risk assessment for a variety of reasons including: (1) Lack of a well-defined endpoint, suitable for risk determination; (2) exposure levels are not defined well enough for predictive purposes; and (3) the small numbers of subjects limit determination of statistical significance and generalizations to a larger worker population. Nonetheless, the demonstration of a dose-response relationship for such adverse health effects in these studies can be used as qualitative supportive evidence in establishing a potential hazard.

There are several studies in humans and other species which demonstrate strong positive dose-response relationships between exposure and noncarcinogenic effects. Such relationships have been displayed within the range of current exposure including adverse effects at and below the current PEL of 50 ppm. Details of the dose-response analysis can be found in Exhibit 6–18. Some observations are summarized below.

In humans, a strong dose-response relationship has been shown between exposure to EtO and the frequency of sister chromatid exchange (Yager, 1982, Ex. 4–61, and Yager, 1983, (Ex. 6–15)). In addition, the Johnson and Johnson (Ex. 4–17) data also showed a dose-effect relationship with mean complex chromosomal aberrations. A similar result has been demonstrated in monkeys exposed to 50 and 100 ppm (NIOSH, 1982 Ex. 6–16). The findings of chromosomal aberrations are qualitative evidence supporting the epidemiologic demonstration of leukemia in EtO-exposed worker populations.

Strong dose-response relationships were also displayed with adverse reproductive effects in rats (Bushy Run Reproductive study Ex. 2–23). Again, this finding comports with a demonstrated association between EtO-exposed sterilizer workers and spontaneous abortion (Hemminki, et al., 1982, Ex. 6–7).

d. *Significance of Risk.* OHSA's overall analytic approach for setting worker health standards is a four-step

process consistent with recent court interpretations of the OSH Act and rational, objective policy formulation. In the first step, quantitative risk assessments are performed where possible and considered with other relevant factors to determine whether the substance to be regulated poses a significant risk to workers. In the second step, OSHA considers which, if any, of the proposed standards being considered for the substance will substantially reduce the risk. In the third step, OSHA looks at the best available data to set the most protective exposure limit that is both technologically and economically feasible. In the fourth and final step, OSHA considers the most cost-effective way to achieve the objective.

In the Benzene decision, the Supreme Court indicated when a reasonable person might well consider the risk significant and take steps to decrease it. The Court stated:

> It is the Agency's responsibility to determine in the first instance what it considers to be a "significant" risk. Some risks are plainly acceptable and others are plainly unacceptable. If, for example, the odds are one in a billion that a person will die from cancer by taking a drink of chlorinated water, the risk clearly could not be considered significant. On the other hand, if the odds are one in a thousand that regular inhalation of gasoline vapors that are 2% benzene will be fatal a reasonable person might well consider the risk significant and take the appropriate steps to decrease or eliminate it. (*IUD* V. API 448 U.S. at p. 655).

The Supreme Court's language indicates that the examples given were of excess risk over a lifetime. It speaks of "regular inhalation" which implies that it takes place over a substantial period of time and refers to the "odds * * * that a person will die," obviously a once in a lifetime occurrence.

The Court indicated, however, that the significant risk determination required by the OSH Act is "not a mathematical straitjacket," and that "OSHA is not required to support its finding that a significant risk exists with any thing approaching scientific certainly." The Court ruled that "a reviewing court [is] to give OSHA some leeway where its findings must be made on the frontiers of scientific knowledge [and that] * * * the Agency is free to sue conservation assumptions in interpreting the data with respect to carcinogens, risking error on the side of overprotection rather than underprotection" (488 US at pp. 655, 656).

In this proposed standard, OSHA has presented data establishing a dose response relationship with regard to cancer in experimental animals, chromosomal changes in man and experimental animals, and reproductive effects in experimental animals. Unlike the data on carcinogenesis, however, OSHA is not confident that the data on mutagenic and reproductive effects have established a sufficient dose response relationship to enable OSHA to perform a *quantitive* risk assessment for effects of EtO exposure other than cancer. Nonetheless, OSHA believes that there is sufficient qualitative evidence of an experimental or laboratory nature to demonstrate that EtO acts to cause alterations in the cellular genetic material and that sufficient clinical evidence is present to indicate that these changes may or do produce adverse reproductive effects, chromosomal changes, as well as cancer.

As discussed in detail earlier, OSHA has performed a quantitive risk assessment for EtO based on the Bushy Run inhalation study on rats. The risk assessment performed resulted in a maximum likelihood estimate of risk of 63 to 109 cancer cases per 1,000 workers exposed at the current permissible exposure limit (50 ppm) assuming such employees have regular exposure to EtO for the period of a working lifetime. Furthermore, upper 95 percent estimates of risk at the current exposure limit were 100 to 152 cancer cases per 1,000 workers. OSHA feels that this upper 95 percent estimate is a conservative assumption allowing error on the side of maximum worker protection.

These estimates of risk for EtO at the current exposure limit are well above the one per thousand guideline suggested by the Supreme Court in the Benzene Decision as representing a "significant risk". The risk for EtO at the current PEL is also comparable to the risk of byssinosis of approximately 13 cases per hundred workers exposed to cotton dust. By comparison, the recent supplemental statement of reasons for the final rule for occupational exposure to arsenic, (43 FR 19548) OSHA determined that the risk at the former permissible exposure levels of 148–425 cases of cancer was significant. The upper confidence limits for risk from EtO exposure are within this range. The risks from EtO exposure are, in turn, far higher than those for coke oven workers (over 10 cancer cases per 1,000 workers) which OSHA determined were sufficient to justify lowering the standard.

While OSHA ultimately relied on the multistage and one hit model to determine risk from exposure to EtO at the current and proposed permissible exposure limit, the Agency did explore the results from other mathematical models. At the current exposure limits, the other models used all gave maximum likelihood estimates from 63 to 173 cancer cases per 1,000 workers. The agency points out that with regard to the estimates of risk based on the finding of leukemia in female rats, these models gave a higher maximum likelihood estimate of risk that the one hit model. These models support OSHA's determination that significant risks exist from exposure to EtO at the current PEL.

Public response to the ANPR indicated general agreement that the current permissible exposure limit for EtO should be lowered and that, indeed, many industries have already voluntarily established limits well below 50 ppm. OSHA believes that these industries have reduced exposures on the basis of recommendations from their scientific staff and on basis of available health data. The agency thus believes that the voluntary action taken by industry and their having recommended a reduction in OSHA's PEL indicate an acceptance by the scientific community of OSHA's determination that there is a significant risk to the health of employees exposed at the current PEL.

OSHA's risk assessment projects that a maximum likelihood estimate of risk of 1 to 2 cancer cases per 1,000 workers will occur from regular occupational exposure at 1 ppm over a working lifetime. The upper confidence limit of this assessment is 2 to 3 cases per 1,000 workers. In addition, at least one study (Hemminki, et at.) has suggested that spontaneous abortions in women may occur when they are exposed to approximately half of the proposed PEL, or 0.5 ppm. OSHA believes that the proposed exposure limit of 1 ppm will not totally eliminate risk from cancer and perhaps not the risk of fetal death, although with regard to the latter, OSHA seeks additional information on these and other health effects and the risk to which employees are exposed.

OSHA's preliminary conclusion is that significant risk is not eliminated at a 1 ppm PEL, with a projected 1 to 2 excess cases of cancer per 1,000 exposed workers. Guidance for the Agency in evaluating significant risk is provided by an examination of occupational risk rates and legislative intent. For example, in the high risk occupations of fire fighting and mining and quarrying the average risk of death from an occupational injury or an acute occupationally related illness from a lifetime of employment (45 years) is 27.45 and 20.16 per 1,000 employees respectively. Typical risk in occupations of average risk are 2.7 per 1,000 for all manufacturing and 1.62 per 1,000 for all

service employment. Typical risks in occupations of relatively low risk are 0.48 per 1,000 in electric equipment and 0.07 per 1,000 in retail clothing. These rates are derived from 1979 and 1980 Bureau of Labor Statistics data from employers with 11 or more employees adjusted to 45 years of employment for 48 weeks per year.

There are relatively few data on risk rates for occupational cancer as distinguished from occupational injury and acute illness. The estimated cancer fatality rate from the maximum permissible occupational exposure to ionizing radiation is 17 to 29 per 1,000. (47 years at 5 rems; Committee on the Biological Effects of Ionizing Radiation (BEIR) III predictions.) However, most radiation standards require that exposure limits be reduced to the lowest level reasonably achievable below the exposure (the ALARA principle). Approximately 95% of radiation workers have exposures less than one-tenth the maximum permitted level. This risk at one-tenth the permitted level is 1.7 to 2.9 per 1,000 exposed employees. (BEIR I estimates are 30 to 60 per 1,000 at 5 rem per year and 3 to 6 per 1,000 at one-tenth that level.)

Congress passed the Occupational Safety and Health Act of 1970 because of a determination that occupational safety and health risks were too high. Based on this it is clear that Congress gave OSHA authority to reduce risks of average or above average magnitude when feasible. OSHA believes that the proposed standard for EtO will reduce risk from a hundred per thousand to nearly one per thousand and, therefore, the Agency is carrying out the Congressional intent within the limits of feasibility and is not attempting to reduce insignificant risks.

Under both the congressional intent and the Supreme Court rationale, OSHA must, if it feasible, seek to reduce risks below those estimates by the risk assessment to persist at a PEL of 1 ppm. However, OSHA expects that the proposed rule as drafted can be expected to reduce the risks of EtO below those estimated using the mathematical model. The estimates of risk only consider the PEL, and do not take into account the other protective provisions of the proposed standard such as respirators and medical surveillance. The decrease in risk to be achieved by these additional provisions cannot be adquately quantified beyond a determination that they will add to the protection provided by the lower PEL alone. OSHA has determined that employers who fulfill the provisions of the standard as proposed will provide protection for their employees from the hazards presented by occupational exposure to EtO well beyond those which would be indicated solely by reduction of the PEL.

In determining the level to which the permissible exposure limit should be lowered, several alternative 8-hour TWA's (10, 5, 1 and 0.5 ppm) were considered by the Agency. OSHA currently believes that compliance with a 1 ppm TWA is technologically and economically feasible based on data that indicate that several industries or industry segments are presently controlling exposures to or very near this level. Regarding the feasibility of compliance with a PEL of 0.5 ppm, however, OSHA does not have sufficient data to demonstrate that a substantial portion of the EtO industry could control exposures to that level. In addition, OSHA is unable to determine what the economic impact would be of establishing a 0.5 ppm PEL. OSHA's preliminary analysis of technological and economic feasibility of the proposal is discussed in the following section of the preamble.

## VI. Summary of Regulatory Impact and Regulatory Flexibility Analysis

*Introduction*

Executive Order 12291 (46 FR 13197, February 19, 1981) requires that a regulatory 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 seq.) similarly requires the Occupational Safety and Health Administration (OSHA) to consider the impact of the proposed regulation on small entities.

In accordance with these requirements, OSHA has prepared a Preliminary Regulatory Impact and Regulatory Flexibility Analysis for the proposed EtO standard. This analysis describes the industries affected by the standard, the non-regulatory environment and regulatory alternatives considered, the costs of compliance with the proposed standard, the technological feasibility of the proposed provisions, and some of the potential benefits that will occur to employees exposed to EtO at their places of work.

The Secretary has determined that this action would not be major as defined by Section 1(b) of Executive Order 12291. The Secretary also certifies that this action would not have a significant impact on a substantial number of small entities as defined by the Regulatory Flexibility Act. The Preliminary Regulatory Impact and Regulatory Flexibility document is available in the rulemaking docket for inspection and copying.

Under Executive Order 12291, OSHA is required, in general, to submit notices of proposed rulemaking for "all rules other than major rules" to the Director of the Office of Management and Budget (OMB) at least ten days prior to publication in the **Federal Register.** However, section 89(a)(2) of the Executive Order provides an exemption from this requirement under the following circumstances:

> (a) The procedures prescribed by this order shall not apply to: * * * (2) Any regulation for which consideration or reconsideration under the terms of this Order would conflict with deadlines imposed by statute or by judicial order, *provided that,* any such regulation shall be reported to the Director together with a brief explanation of the conflict, the agency shall publish in the **Federal Register** a statement of the reasons why it is impracticable for the agency to follow the procedures of this Order with respect to such a rule, and the agency, in consultation with the Director, shall adhere to the requirements of this Order to the extent permitted by statutory or judicial deadlines.

As was discussed in the Background section of this preamble, OSHA has expedited the publication of its proposed EtO standard pursuant to an order issued by the U.S. Court of Appeals for the D.C. Circuit in *Public Citizen Health Research Group* v. *Auchter,* No. 83–1071 (March 15, 1983), which directed the Agency to issue a proposed rule within 30 days. For this reason, it is impracticable for OSHA to submit the notice of proposed rulemaking to OMB for consideration ten days prior to its publication in the **Federal Register.** To the extent permitted by judicial deadlines, OSHA will comply with the Executive Order in the assessment of the regulatory impact of the proposal, and in the development of the final rule.

On March 31, 1983, the Office of Management and Budget 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 becomes effective on April 30, 1983, sets forth procedures for agencies to follow in obtaining OMB clearance for collection of information requirements in proposed and final rules. In particular, §1320.13 requires agencies to submit information requirements contained in proposed rules to OMB not later than the date of publication of the proposal in the **Federal Register.** It also requires agencies to include a statement in the

notice of proposed rulemaking, indicating that such information requirements have been submitted to OMB for review under Section 3504 (h) of the Paperwork Reduction Act.

In accordance with the abovementioned provisions of both Paperwork Reduction Act and the regulations issued pursuant thereto, OSHA certifies that it has submitted the information collection requirements contained in its proposed rule on occupational exposure to ethylene oxide to OMB for review under section 3504(h) of that Act. Comments on these information collection requirements may be submitted by interested persons to the Office of Information and Regulatory Affairs of OMB, Attention: Desk Officer for OSHA.

*Summary of Industry and Exposure Profiles*

OSHA estimates that the proposed EtO standard would cover approximately 80,000 directly exposed employees and 144,000 incidentally exposed workers in five industry sectors. Directly exposed workers are defined as those exposed to EtO as part of their regular work assignments. Incidentally exposed employees are defined as those exposed only occasionally. For example, an incidental exposure would occur when an employee inhales airborne EtO that is off-gassing from a product previously sterilized with EtO, or when a poorly functioning ventilation system permits EtO to accumulate in an area normally free of EtO.

The employees covered by the proposed standard work in five industry sectors: EtO producers, EtO ethoxylators (firms using EtO to manufacture other chemical products), health care providers (hospitals that use EtO as a sterilant) manufacturers and sterilizers of medical products (hereafter termed medical products manufacturers), and spice manufacturers. The producer industry is comprised of 13 large firms, only 3 of which had annual sales under $1 billion. OSHA has identified 36 of the 50 firms estimated by the Ethylene Oxide Industry Council (EOIC) (Ex. 4–33) to be in the ethoxylator industry. The 36 ethoxylator firms and 13 producers identified use approximately 98 percent of all EtO produced in the United States to synthesize other chemicals, such ethylene glycol used in antifreeze, and polyester resins and fibers. The smallest ethoxylator firm by revenue had annual sales of $15 million and employs 350 workers. A total of 3,676 employees are currently directly exposed in the producer and ethoxylator sectors.

Three of the industries affected by the proposed standard use EtO to sterilize or fumigate other products: hospitals, medical products manufacturers, and spice manufacturers. Approximately 2 percent of all EtO produced is used to sterilize or fumigate other products but this 2 percent results in most of the employee exposures to EtO. OSHA estimates that EtO is used as a sterilant in 7,700 sterilizers in 6,300 hospitals. Approximately 62,370 employees are estimated to be directly exposed and 25,000 are estimated to be incidentally exposed in U.S. hospitals.

In addition, 14,000 and 116,900 employees are directly and incidentally exposed to EtO, respectively, in the 300 to 400 medical products manufacturing firms that are estimated to use EtO. According to the Health Industry Manufacturers' Association (HIMA), 8 to 10 firms are dominant in this sector. OSHA could not determine the number of small firms in this industry sector and solicits additional information on small business users of EtO in this industry sector. Finally, an estimated 27 spice manufacturing firms use EtO to fumigate spices. These firms have a total of 160 directly exposed employees. Sixty percent of the firms identified in this industry sector have more than 1,000 employees. The two smallest firms identified have 28 and 95 employees and annual sales of $20 and $14 million, respectively.

*Summary of Costs*

OSHA has examined both the annualized and present value costs (in 1982 dollars) of compliance with the following regulatory alternatives for EtO permissible exposure limits (PELs): 10 ppm, 5 ppm, 1 ppm, and 0.5 ppm. (Ex. 6–22). These costs were determined for all affected industry sectors. The present value of the costs were estimated using a 10 percent discount rate and a 50-year time period. Costs are presented in the regulatory analysis both for the engineering controls necessary to achieve exposure levels of 1 and 0.5 ppm and for other provisions of the standard, such as medical surveillance, exposure monitoring, training, and recordkeeping. This summary presents combined costs only for the proposed 1 ppm PEL and the remaining provisions of the proposed standard.

OSHA estimates that total annualized costs for the proposed standard would be $72.4 million. The total annualized costs for the five industry sectors are: producers, $1.56 million; ethoxylators, $1.03 million; health care providers, $23.65 million; manufacturers of medical products, $45.99 million; and spice manufacturers, $0.17 million. The present value of the costs of the proposed standard over the next 50 years, assuming a 10-percent discount rate, is estimated to be $720.19 million for all affected industry sectors.

The average annualized cost per directly exposed employee by industry sector are: health care providers, $379; producers, $594; ethoxylators, $980; spice manufacturers, $1,050; and medical product manufacturers, $3,282. Most of the employees in the medical manufacturing industry are incidentically exposd. The average annualized cost per employee (including both directly and incidentally exposed employees) for medical product manufacturers is estimated to be approximately $400 per year.

It is not expected that the cost of this proposed standard would have a negative impact on the viability of firms in these five industries or on employment, balance of payments, inflation, or any specific communities.

*Summary of Benefits*

The reduction in the occurence of occupational illnesses that would result if the proposed EtO standard is promulgated represent the fundamental benefit of the proposed standard. Some aspects of these benefits can be qualified, such as the excess risk of cancer due to direct exposure to EtO. Other impacts, such as the effect of chromosome damage, cannot be quantified due to limited data.

Among the non-quantifiable health impairments attributable to EtO exposure are several types of chromosomal damage including sister chromatid exchanges (faulty exchanges of genetic material among chromosomes), chemical alteration of DNA caused by unscheduled DNA synthesis (a failure of the DNA repair mechanism), and quadriradials (a visually detectable, rare, and complex chromosome aberration). Mutagenic and reproductive effects of EtO exposure that have been observed in experimental animal studies include increases in the frequency of resorption, stillbirths, and deformed offspring. In addition to these animal studies, increases in the number of spontaneous abortions have been observed in an epidemiological study of exposed hospital sterlizer technicians in Finland.

Using a quantitative risk assessment, OSHA has estimated the number of excess cancer cases that are expected to occur among directly exposed workers during the next 50 years. The risk assessment assumes exposures of 6 hours a day, 5 days per week, and 46 weeks a year for 45 years. The directly

exposed population accounts for approximately 80,000 of the estimated 224,000 employees exposed to EtO. OSHA estimates that compliance with its proposed 1 ppm PEL would reduce the number of excess EtO-related cancers over the next 50 years from 958, based on current exposures, to 95, a 90 percent reduction.

This regulatory action would significantly reduce the number of EtO-related cancer cases and the occurrence of the other EtO-related health impairments such as spontaneous abortions and chromosomal abnormalities.

*Technological Feasibility*

OSHA had determined that the proposed standard is technologically feasible. The methods that can be used to reduce employee exposure to EtO are conventional technology such as air monitoring, exhaust ventilation, double mechanical seals, leak detection, and use of respiratory protection for intermittent exposures. This technology is commonly known and presently used by the affected industries and is discussed in detail in the section of the Regulatory Impact document dealing with costs of compliance.

*Regulatory Flexibility Analysis*

OSHA has evaluated the expected cost of compliance for relatively small firms in each affected industry sector. In all cases, the annualized cost per firm, expressed as a percent of its annual sales, is less than 0.5 percent. The producers and ethoxylators are generally large chemical corporations. Differential size impact is therefore not a factor in these industries. Because of the price-inelasticity of demand for products that require the use of EtO as a sterilant and fumigant, it is expected that the costs of compliance for the medical product manufacturer, health care provider, and spice manufacture industries would be passed forward to consumers.

Because few medical manufacturers responded to OSHA's ANPR for EtO, little information on the relative impacts on small entities in this sector could be obtained. OSHA expects to obtain additional information on the potential impacts on small entities in the medical product manufacturing industry during this rulemaking.

Pursuant to the Regulatory Flexibility Act, OSHA certifies that the proposed standard would not have a significant adverse economic impact on a substantial number of small entities.

**VII. Environmental Assessment—Finding of No Significant Impact**

In OSHA's January 26, 1982 AMPR for occupational exposure to EtO, information was solicited from the public on a variety of issues including possible environmental impacts of a proposed revised standard. The information and comments submitted in response to the ANPR have been reviewed in accordance with the requirements of the National Environmental Policy Act (NEPA) of 1969 (42 U.S.C. 4321, et seq.), the Guidelines of the Council on Environmental Quality (40 CFR Part 1500), and OSHA's DOL NEPA Procedures (29 CFR Part 11). As a result of this review, the Assistant Secretary has determined that the proposed rule will not have a significant impact on the external environment. Impacts on the workplace environment are discussed in other portions of this preamble.

EtO is used primarily as an intermediate in the production of several industrial products, such as antifreeze, polyester fibers, films, and bottles. EtO is also used as a pesticide, fumigant, and antimicrobial sterilant for medical products and spices, and in limited applications for items such as cosmetics, books, railcars, etc.

The Environmental Protection Agency (EPA) has the authority to regulate the use and application of sterilant and fumigants under the Federal insecticide, Fungicide and Rodenticide Act (FIFRA) as amended (7 U.S.C. 136 et seq.). EPA regulations on the enforcement of FIFRA are founded in 40 CFR Part 162. As a sterilant or fumigant, EtO is regulated under FIFRA, and formulations of EtO pesticides are registered with EPA and are required to be labelled properly as to their toxicity to humans, their particular hazards, their route(s) of exposure, and the precautions to be taken to avoid accident, injury, or damage. Application of these pesticides may only be performed in accordance with the precautions set forth on the label. Under the Clean Air Act (42 U.S.C. 1857 et seq.), and the National Ambient Air Quality Standards for Total Suspended Particulated, EPA is responsible for maintaining ambient air quality by preventing or controlling air pollution. Under the proposed OSHA standard, the current PEL of 50 ppm would be reduced to 1 ppm as an 8-hour, time-weighted average (TWA). This reduction in the exposure limit is not anticipated to impact significantly on the external environment because: (1) The process equipment containing EtO generally consists of tightly closed and highly automated systems; (2) any emissions that occur to the external atmosphere would dissipate and disperse rapidly; and (3) no solid waste is directly associated wht EtO fumigation and sterilization.

Although the removal of increased amounts of EtO from the workplace air might seem to contribute to the pollution of ambient air surrounding EtO operations and applications, this is not anticipated because direct exhaust to the external environment is regulated under EPA air quality standards. In cases where worker exposure is reduced by the use of improved control methods such as chamber ventilation and purge systems, atmospheric emissions of EtO would remain constant, having an insignificant impact on the external environment.

Only mimimal amounts of EtO are released from manufacturing processes as wastewater effluents. Treatment of EtO containing wastes usually involves degradation in water (producing ethylene glycol). Wastewater treatment must comply with the requirements of the Clean Water Act of 1977, and under this standard, conventional biological wastewater treatment would effectively remove EtO from water effluents.

In cases where liquid EtO is transported or stored, there may be some potential for spills or leaks. Because of the nature of EtO, however, such occurrences are not anticipated to impact on the environment, since EtO quickly volatilizes and dissipates. Although instances of waste disposal have not been presented to the record, such disposal would be covered by EPA regulations and transportation would be regulated by the Department of Transportation. The requirements of the proposed standard, therefore, will not alter present methods for waste disposal or transportation of EtO.

Based on this discussion and other information presented in this Notice, OSHA concludes that there will be no significant impact on the general quality of the human environment external to the workplace, particularly in terms of ambient air quality, water quality, or solid waste disposal. OSHA, of course, reserves the right to perform additional environmental analyses based on the information and comments received in response to this Notice.

**VIII. Response to the Advance Notice of Proposed Rulemaking (ANPR)**

OSHA's ANPR for EtO sought public comment on issues such as appropriate permissible exposure levels, health effects, feasibility of available control methods, current exposures, number and classification of workers exposed,

available exposure measurement methods, and appropriateness of requirements for medical surveillance, protective clothing and equipment, respirators, hygiene facilities, training, and signs and labels. The comments on the ANPR's major issues are summarized briefly in the section. Not every comment received will be alluded to in this discussion. However, for each issue several representative comments will be cited by exhibit number.

There was widespread agreement from commentors that OSHA's existing standard should be revised based on available health data dealing with carcinogenic, reproductive, and cytogenic effects (Exs. 4–9, 13, 17, 19, 21, 23, 24, 25, 26, 28, 38, 47, 52, 60). Concern was expressed by some, however, that the preponderance of data was from high-dose animal experiments rather than human studies (Exs. 4–5, 22, 23, 31, 37). New human and other data have become available to OSHA since publication of the ANPR, however, and are discussed in the "Health Effects" section in this preamble.

Recommendations for a revised permissible exposure limit for EtO generally ranged from 0.5 ppm (Exs. 4–52, 58) to 10 ppm (Exs. 4–2, 23, 45). In addition, many commentors reported that their firms had voluntarily established internal exposure limits below OSHA's existing exposure limit of 50 ppm. For example, Lincoln General Hospital (Ex. 4–2), St. Joseph Hospital (Ex. 4–6), and 3M (Ex. 4–23) have adopted a 10 ppm internal limit; Shell (Ex. 4–28), Union Carbide (Ex. 4–39), and BASF Corp. (Ex. 4–53) have adopted a 5 ppm limit; UpJohn (Ex. 4–46) a 3 ppm limit; Texaco (Ex. 4–46) a 2 ppm limit; and Johnson & Johnson (Ex. 4–17), Dow (Ex. 4–31), the University of Arizona (Ex. 4–36), Celanese (Ex. 4–40), Monsanto (Ex. 4–41), the Smithsonian Institute (Ex. 4–43), and Lederle Laboratories, (Ex. 4–55) have adopted an internal exposure limit of 1 ppm.

The feasibility of achieving compliance with an exposure limit at or below 10 ppm is detailed elsewhere in this preamble and is based on public comment and JRB Associates study of the EtO industry (Ex. 6–20). The views of industry representatives who responded to the ANPR on this issue were generally similar to those expressed in the submission of the Ethylene Oxide Industry Council (EOIC) (Ex. 4–33). The EOIC, a broad based coalition of producers and users of EtO, surveyed its member companies on many issues regarding regulation of EtO, including feasibility. Their conclusions on feasibility, as reflecting by the survey results, were presented as follows:

> With respect to technological feasibility, several producers and non-producer converters have achieved targets of 1 pm (TWA) or below, so that level may be technologically feasible for most producers and converters if respirator protection can be used for certain operations. With respect to the non-producer converters, however, it must be emphasized that the EOIC survey responses constitute a relatively small sample of a diverse industry and that 1 ppm may not be technologically feasible for some members of that industry. There is considerable doubt among most producers and converters as to whether 0.5 ppm (TWA) is technologically feasible and whether available monitoring equipment is sufficiently reliable at that level to determine compliance.
>
> The majority of health product manufacturers have achieved levels of 10 ppm (TWA) or below, so that level may be technologically feasible for most health product manufacturers, if respirator protection can be used for certain operations. There is substantial doubt among most health product manufacturers as to whether 1 ppm (TWA) is technologically feasible by engineering controls alone.

The Health Industry Manufacturers Association (HIMA), a trade organization representing 270 domestic medical device and diagnostic product manufacturers, distributed the EOIC's questionnaire to its members interested in EtO. Regarding prevailing exposure limits in the industry HIMA indicated that:

> 25 out of 28 companies (90%) stated that they have an internal standard. 17 out of 25 companies (68%) are at 10 ppm or below. 18 companies with internal standards (ranging from 1 ppm to 50 ppm) indicated that their internal ETO standard is under review. 3 companies at 1 ppm were not reviewing their internal standard. Of the 18 companies reviewing their internal standard, 10 anticipate lowering that standard. (Ex. 4–51).

HIMA also noted that a total capital cost of $44 million and a period of 3 to 4 years were reported by 17 responding companies as being necessary to achieve compliance with a 1 ppm TWA (Ex. 4–51).

Lederle Laboratories (Ex. 4–55), a major producer of pharmaceutical products, provided specific exposure data for employees engaged in sterilization operations and for other employees present who were not engaged in the actual application of EtO. Lederle reported that the exposure levels of 218 directly exposed employees ranged from 0.2 to 1 ppm for various sterilant operations where exposure duration ranged from 1 to 8 hours per day, 5 days per week. These operations include: chamber operations, maintenance, and validation (use of air supplied respirators which effectively reduces exposure to less than 1 ppm was noted for operation personnel engaged in these activities); sterile room operations (0.5 to 1 ppm); finishing and sterile kitchen operations (0.2 to 1 ppm); surgical supplies packaging (0.2 pmm); and quality control (1 ppm). for incidentally exposed employees Lederle stated that:

> Approximately 165 employees may be exposed to EtO but not engaged in the actual application of the EtO. These employees may be exposed up to 8 hours per day, on normal work shifts to EtO concentrations ranging 0.2 to 1.0 ppm. The work environment is controlled through general ventilation and local exhaust, degassing of sterilized products prior to introduction to the work areas, and administrative controls and schedules to ensure unloading of sterilization chambers during off-shifts to reduce possible exposure to adjacent non-applicators.

A number of commentors provided data on the ability of hospitals and other health care providers to control exposure where EtO was being used as a sterilant in their facilities. St. Annes' Hospital reported that its chamber sterilizer, processing 3 loads per week, resulted in 8-hour TWA readings averaging 2.5 ppm (Ex. 4–8). St. Joseph's Hospital (Ex. 4–6) and Lincoln General Hospital (Ex. 4–2) stated that they have voluntarily adopted an internal exposure limit of 10 ppm. Council Shared Services (CSS) (Ex. 4–14) conducted an EtO hazard survey from 1978 to 1982 in 100 southern California hospitals. Of a total of 278 surveys at 121 different sites in 100 hospitals, CSS reported that personal breathing zone 8-hour TWA exposures were below 5 ppm in all but 7 of the 121 sites. Doylestown hospital (Ex. 4–18) reported that their sterilizer operation TWA exposures ranged from 3 to 6 ppm. The Veterans Administration reported exposure in many of their medical centers to be below 5 ppm (Ex. 4–35). ECRI, an independent nonprofit corporation, provided exposure data from 27 hospitals they surveyed (Ex. 4–53). ECRI reported only 5 out of the 27 hospitals had 8-hours TWA's exceeding 10 ppm during sterilant operations. Nine of the 27 were found to have TWA's at or below 1 ppm. Breathing zone concentrations for aeration activities ranged from 0 to 10 ppm, with one exposure of 19 ppm. Sixteen of the 27 hospitals surveyed revealed exposures to be below 4 ppm. The highest exposure found (19 ppm) was described as involving use of an aerator vented directly into the room surveyed.

Though hospital and health care facility exposure data discussed above

alludes primarily to 8-hour TWA's, it is evident that the exposure profile for their sterilant operations is greatly influenced by the pattern and frequency of EtO sterilization. It is relatively common for sterilizer operators to be exposed to very high breathing zone concentrations of EtO for very brief periods while unloading freshly sterilized materials. The data suggest that stringent control of brief exposures of this nature through engineering or work practice controls may be critical if the health care industry is to reduce their TWA's to a level approaching 1 ppm or below.

Comment regarding the issue of the necessity of establishing a short-term or ceiling limit varied widely. Reasons given in support of inclusion of a short-term exposure limit varied. One commentor suggested that a short-term limit should be established for all carcinogens (Ex. 4–47). Others suggested that such a limit is necessary in order to reduce background exposures for all employees (Exs. 4–28, 36, 55). One commentor (Ex. 4–24) stated that a short-term limit based on the concept of one equivalence (concentration times exposure duration) to the 8-hour TWA may be appropriate in establishing a limit and acceptable duration of exposure. This participant, who has established an internal workplace exposure limit of 3 ppm stated:

> We believe that a short-term exposure limit (STEL) of 40–50 ppm averaged over any 15 minute period in an 8-hour workday, and allowing for no more than two of these 15 minute periods would be sufficient to protect our employees from any adverse health effects due to exposure to EtO.
>
> This STEL is based on the concept of dose equivalence which is the product of concentration (ppm) times exposure duration (minutes). Therefore:
>
> 3 ppm (8-hour TWA)×8 hrs. (480 min.)=1440 ppm minutes.
>
> 50 ppm (STEL)×15 min.×2 (# of 15 min. periods in 8 hrs.)=1500 ppm minutes.

A 5 ppm ceiling for 15 minutes was also suggested based on available health data (Ex. 4–52). Additional rationale for establishment of a short-term limit was suggested by the Amalgamated Clothing and Textile Workers Union as follows:

> ACTWU strongly recommends that a protective short term limit be established as part of the standard. Such a limit is needed to allow proper assessment of the intermittent exposure conditions that characterize most EtO user situations. It is doubtful that employer will be able to successfully control their TWA exposures unless they fully understand the contribution made by peak exposures. Glasser (1980) recommended that a ceiling value be used in describing EtO exposures because of the inadequacies of a TWA to indicate the exposure situation. He provides an example where a typical sterilizer operator TWA of 3.18 ppm was produced through a 2 minute, 600 ppm peak; along with some residual exposure and 7 hours at 0 ppm. However, without the 2 minutes of 600 ppm exposure, the resulting TWA is 0.7 ppm. This illustrates the lack of sensitivity of a TWA.
>
> A ceiling limit is also justified in light of the known health effects of EtO. Darby, Martis, and Northrup (1980) note that because of its solubility in blood, it is likely that *all* inhaled ethylene oxide is taken up by the body. Ehrenberg and Hallstrom (1967) report chromomsomal aberrations in humans accidentally exposed to high concentrations of EtO. A TWA standard of 1 ppm without a short-term limit would allow 15 minute exposures as high as 96 ppm. Given the carcinogenic risk from EtO, it is important that exposures be kept as low as possible. A short-term limit is the most effective way to insure that worker health is protected. (Ex 4–25).

Those opposing establishment of a short-term limit contended that the need was not indicated by the health data inasmuch as no acute effects from exposure to EtO have been demonstrated (Exs. 4–31, 33, 40), and that the control necessary to achieve a TWA as low as 5 ppm (or 1 ppm) would tend to preclude the occurrence of high excursions for most EtO operations (Ex. 4–39).

Participants who indicated uncertainty over the appropriateness of a short-term limit suggested that the need and level for such a limit should be based on quantitative assessment of risk of associated health effects.

Though OSHA has not proposed to include a short-term exposure limit for EtO, the Agency is not convinced that there is no need for such a limit. OSHA is closely scrutinizing the implications of the results of the study by Hemminki et al. which reports an increased incidence of spontaneous abortions with high short-term exposures but low 8-hour exposures (see health effects section), and the suggestion by Yager et al. that the increases in observed sister chromatid exchanges among another group of workers may have been caused by high short-term exposures. OSHA is also aware of the common occurrence of high, short duration exposure during sterilization operations. In addition, for some operations, short-term limits may be a good practical engineering and compliance approach for controlling the overall exposure OSHA is seeking full discussion on this issue from all interested parties.

The issue of which work practice and engineering controls are available to the EtO industry for exposure reduction was raised in the ANPR. Comments discussed a variety of controls available to control different EtO operations.

Production and ethoxylation processes were reported to utilize double mechanical seals, double seated valves, check valves, local exhaust systems, recovery systems, pump seal vents, flanged leak seals, plugged vents, closed loop quality control, scrubbers, vent treating systems, nitrogen purge, low temperature storage, emergency dilution, all welded construction where possible, and magnetic level gauges and recovery systems for tank car operations.

Engineering and work practice controls available for use for sterilization and fumigation operations were described by commentors as including: local exhaust above the chamber door; continuous purge after end of cycle; post-vacuum purge; liquid gas separator; 6–10 room air changes per hour; one-way tank connection line valve; exhaust to outside of building; containerization of loads; remote material handling; conveyer system from chamber to off-gassing area; use of isolated sterilization area under negative pressure; ventilation of off-gassing areas; automatic remote chamber door opening devices; automatic chamber door locks until after flushing; preconditioned temperature and humidity in room or chamber; handling of sterilized items with gloves; keeping employees upwind of cart when moving sterilized items; and if manual opening of the door of the sterilization chamber is necessary, opening the door only at the end of cycle and having employees leave the area for several minutes prior to removing items from the chamber.

Regarding the issue of respiratory protection, air supplied respirators and self-contained breathing apparatus (SCBA) were acknowledged by participants as being available for use with EtO (Exs. 4–25, 31, 33, 47). NIOSH-approved air purifying (chemical cartridge/canister) respirators are not available. Commentors expressed concern that air supplied and "SCBA" may not be feasible where extended wearing time or mobility are major considerations, and that employers would be placed in a difficult position if the use of air-purifying respirators were not permitted due to lack of NIOSH approval (Ex. 4–40, 55). (As discussed in the section dealing with respirators under "Summary and Explanation of the Standard" below, however, the proposal would allow for the use of such respirators under certain exposure conditions were stringent sorbent replacement requirements are followed).

The question of the availability of measurement and analytical methods for determining the level of employee exposure to EtO was also raised in the ANPR. Commentors have indicated that methods available for measuring EtO concentrations include the use of charcoal tubes, passive dosimeters, gas sampling bags, impingers, detector tubes, and direct reading instruments. Charcoal tube methods appear to be the most frequently used. As indicated in the EOIC survey (Ex. 4–33) and the HIMA survey (Ex. 4–51), however, all of the methods are employed to some extent.

The proposed standard would permit the use of any of the methods described above or any other method if the employer can demonstrate that the method chosen is capable of determining an employees' 8-hour TWA (breathing zone) with an accuracy of within plus or minus 25% at the PEL (1 ppm) and plus or minus 35% at the action level of 0.5 ppm.

A discussion of EtO sampling methodology was presented in Chicago, Illinois, October 4 and 5, 1982, at the Ethylene Oxide Worker Safety Seminar sponsored by HIMA and EOIC. Edward Zimowski, of the OSHA Health Response Team, attended the seminar and provided a report on the advantages and disadvantages of presently available procedures (Ex. 6–24).

Many commentors provided a description of the sampling methodology and devices they were presently using and, in some cases, a statement of their experience with such devices. The concerns over the deficiencies in the available sampling methods were alluded to by a number of participants who also noted that charcoal tube methodology represents the most throughly validated and accurate method for personal monitoring of EtO exposure (Ex. 4–24, 28, 39, 47). OSHA is aware that industrial hygiene services or commerical sampling devices that are capable of accurately determining an employee's exposure at the proposed PEL of 1 ppm must be available in sufficient quantities in order for the standard to be effective. The OSHA charcoal method (See Appendix D) has been validated at 1 ppm. Submissions to the record indicate that at least two other methods also may be capable of measuring an employees personal 8-hour TWA exposure with acceptable accuracy at the 1 ppm level. Union Carbide reports that its charcoal tube method developed in 1977 (Qazi-Ketchem) has been validated in the laboratory over a range of 0.5–5.00 ppm (Ex. 4–39). 3M Company reports that its passive diffusion monitor is also capable of accurately measuring 1 ppm (Ex. 4–23). 3M states that the method using its monitor has a detection limit of 0.3 ppm for an 8-hour TWA with a working range of up to 75 ppm. Laboratory validation tests performed by 3M were reported as demonstrating the recovery precision of the method to be plus or minus 5% with a mean value of 100% when 14 spiked monitors were compared to 14 matching standards. Field test comparison of the 3M monitor to jumbo charcoal tubes with pumps in a plant environment that was very humid with high ambient temperatures resulted in the charcoal tube/pump method giving much lower values than the 3M monitors.

Some commentors, however, have expressed reservations about passive diffusion samplers. The EOIC states: "This monitoring method using diffusion samplers is subject to the same interference and break through problems as charcoal tubes" (Ex. 4–33). One company stated in the EOIC submission, without discussion, that it had investigated using the 3M diffusion monitor and "was not pleased with them."

Problems associated with charcoal tube methods were also alluded to by other commentors. They included: interference from vinyl chloride, acetaldehyde above 50 ppm, and other organic compounds; limited sample size (affects flow rate and time) because of breakthrough; high relative humidity reducing usable sample volumes, charcoal tubes being large and inconvenient for workers; samples requiring refrigeration to avoid EtO loss; the need to analyze tubes in 3 to 7 days; difficulty of calibration and desorption; and complexity of analysis requiring sophisticated training of laboratory personnel (Ex. 4–33). Comment on the experience of those employing these devices to determine employee exposure and the ability of these and other sampling devices to meet the requirements of the proposed standard is solicited by OSHA.

Finally, as noted previously, OSHA is evaluating the necessity of including a short-term exposure limit for EtO. The Agency's judgment at this time is that such a limit, if established, would probably be between 5 and 50 ppm as measured over a period of up to 30 minutes. The capability of available measurement methodology would be one element in the determination of an appropriate specific short-term limit and sampling duration. Thus, OSHA is seeking data and comment on monitoring methods that reliably characterize an employee's exposure for periods less than 30 minutes at levels ranging up to 50 ppm.

### IX. Summary and Explanation, of the Proposed Standard

The proposed requirements set forth in this notice are those which, based on currently available data, OSHA believes are necessary and appropriate to provide adequate protection to employees exposed to EtO. In the development of the proposal, OSHA has considered all recommendations received in response to the ANPR as well as numerous reference works, journal articles, and other data accumulated by OSHA since initiation of this rulemaking.

1. *Paragraph(a). Scope and application.* This proposed standard would apply to all workplaces in all industries, including construction and maritime as well as general industry, where EtO is produced, released, stored, handled, used, or transported, and over which OSHA has jurisdiction. An exemption provision, however, has been provided in the proposal.

This section does not apply to the processing, use, and handling of products containing EtO where objective data demonstrate that the product cannot release EtO above the action level under the expected conditions of processing, use, and handling which will cause the greatest possible release. It is likely that in a number of products made from, containing, or treated with EtO, there may be insignificant residual EtO present to the extent that minimal exposure would be expected. This determination (that air concentrations will not exceed the action level) need not be based on data generated by the processor but may, for example, be based upon information provided by the manufacturer. The provision enables fabricators or users of products made from, containing, or treated with EtO to avoid the burdens of compliance with the standard where exposures are minimal.

It should be noted that where objective data are not available to satisfy the condition for exemption, the employer is required to perform, at the very least, initial monitoring of employee exposures to EtO. If the results of initial monitoring indicate employee exposures are below the action level, the employer may discontinue monitoring for those employees and is relieved of other obligations under the proposal. Thus, even if operations are not specifically exempted from the proposal, exposure

levels below 0.5 ppm will relieve many employers from further duties under the standard, except with respect to labelling. This provision has been incorporated in a number of OSHA standards (acrylonitrile, arsenic).

2. *Paragragh (b). Definitions.* An "action level" of 0.5 ppm (8-hour time-weighted average), is provided in the proposal. The purpose of the action level is to relieve the burden on employers by providing a cut-off point for required compliance activities under the standard. The broad scope of the proposal necessarily encompasses many employers whose employees are exposed to levels of EtO below the permissible exposure limit. Such employers are required either to perform initial monitoring to determine to determine the extent of their employees' exposure to EtO or otherwise to document the employees' exposure by other objective data. If, on the basis of the results of the initial monitoring or other data, an employer can demonstrate that an employee is exposed to EtO below the action level, the employer may then discontinue compliance activities for that employee. The action level concept thus provides an objective means for an employer to determine what further actions are required for compliance with the standard.

The statistical basis for determining the action level has been discussed in connection with several other OSHA health standards (see, for example, acrylonitrile). In brief, although all measurements on a given day may fall below the permissible exposure limit, some possibility exists that on unmeasured days the employee's actual exposure may exceed the permissible limit. Where exposure measurements are above one-half of the permissible exposure limit, i.e. the action level, the employer cannot reasonably be confident that the employee may not be overexposed. (Leidel, N.A. et al., "Exposure Measurement Action Level and Occupational Environmental Variability." DHEW, PHS, DCD, NIOSH, DLCK (August 1975)) (Ex. 6–26). Therefore, requiring periodic employee exposure measurements to begin at the action level provides the employer with a reasonable degree of confidence in the results of his measurement program.

A definition of the term "emergency" is included in the proposed standard. For the purposes of the standard, emergencies are occurrences such as, but not limited to, equipment failure, rupture of containers, or failure of control equipment which are likely to, or do, result in unexpected high exposure to EtO.

3. *Paragrah (c). Permissible exposure limit.* OSHA proposes to revise the PEL for EtO by deleting the current 50 ppm standard contained in 29 CFR 1910.1000, Table Z–1 and setting an 8-hour exposure limit of 1 ppm in paragraph (c) of section 1910.1047. This proposed PEL is based on underlying findings by OSHA that occupational exposure to EtO under current permissible exposure levels presents a significant risk to employees and that the new standard will achieve a significant reduction in that risk.

In making a determination of significant risk, it is appropriate for OSHA to consider a number of different factors. The Supreme Court in the *Benzene* decision provided some general guidance as to the process, stating that "while the Agency must support its finding that a certan level of risk exists with substantial evidence, we recognize that its determination that a particular level of risk is 'significant' will be based largely on policy considerations." 448 U.S. at 655, 656 n. 12. Consistent with rational policy judgment, OSHA has recently identified the following factors as being among those which should be considered: (1) the quality of the underlying data; (2) the reasonableness of the risk assessment; (3) the statistical significance of the findings; (4) the type of risk presented, and (5) the signifioance of the numerical risk relative to other risk factors. 47 FR 15358, 15365 (April 9, 1982).

These factors have been considered with respect to the EtO risk assessment performed (see Risk Assessment section of this preamble).

OSHA has determined that exposure to EtO at the present standard of 50 ppm clearly presents a significant risk of material impairment to employees. The significance of this risk has already been informally acknowledged by industry, which had reacted to the developing information regarding the potential health effects of EtO by voluntarily reducing exposure among its employees. As previously noted, all producers currently maintain internal exposure guidelines of 5 ppm (TWA) or less, and most converters and other industry segments are also well below the current 50 ppm PEL.

OSHA must also give consideration to the economic and technological feasibility of the proposed new PEL. In order to obtain the information necessary to allow OSHA to perform this analysis, OSHA contracted for the services of JRB Associates of McLean, Virginia. Based on this data, and data provided to the record in response to the ANPR, OSHA believes that achieving compliance with a PEL of 1 ppm is both economically and technologically feasible. (see Regulatory Analysis section).

4. *Paragraph (d). Exposure monitoring.* The exposure monitoring provisions require the employer to determine the exposure for each employee exposed to EtO. This does not require separate measurements for each employee. If a number of employees perform essentially the same job under the same conditions, it may be sufficient to monitor a fraction of such employees to obtain data that are representative of the remaining employees. Representative personal sampling for employees engaged in similar work and exposed to similar EtO levels can be achieved by measuring that member of the exposed group reasonably expected to have the highest exposure. This result would then be attributed to the remaining employees of the group.

In many specific work situations, the representative monitoring approach can be more cost-effective in identifying the exposures of affected employees. However, employers may use any monitoring strategy which correctly identifies the extent to which all employees are exposed.

Because of the nature of the EtO exposure hazard, it is necesary that the scope of the proposal be as broad as possible to protect potentially exposed employees. However, many employers will be required only to perform initial monitoring to determine employee exposures. If the results of initial monitoring demonstrate that an employee's exposure to EtO is below the action level (0.5 ppm), the employer may discontinue monitoring and other activities under the standard for that employee. OSHA anticipates that this provision will greatly reduce the burden on employers, while providing them with an objective means of determining whether they must take additional steps for compliance with the standard.

Where exposure measurements are determined to be above the permissible exposure limit, the employer must monitor every 3 months. Where exposure measurements are above the action level but below the PEL, monitoring need only be repeated at 6 month intervals. "Exposure" here means the airborne concentration in the employee's breathing zone, with no adjustment for the protection provided by any respirator the employee may be wearing.

The employer is also required to perform monitoring again for a

particular job position if any changes in production, processes, control measures, or personnel may result in new or additional exposure to EtO.

A primary concern connected with any health standard is the availability of methods of monitoring and analysis of employee exposures. It is clear from data in the record in that there are several off-the-shelf methods of monitoring for EtO in the range of exposures addressed by the proposal and that many employers are already carrying out periodic monitoring activities. Among methods which have been noted in the comments are the use of charcoal tubes, personal badge-type dosimeters, gas bag "grab samples," detector tubes, and fixed point monitoring systems. The proposal does not require the use of one specific monitoring method, but it does specify that whatever method is chosen must meet the criteria for sensitivity and accuracy set forth in the standard.

The proposed standard requires an employer to notify each employee in writing of his/her exposure within ten (10) working days of obtaining the results of measurement. This requirement can be a written communication to each employee, or other means, such as posting of monitoring results in an appropriate location, so that the employee will definitely be advised of his/her exposures.

5. *Paragraph (e)—Regulated areas.* Where EtO concentrations are in excess of permissible exposure limits, the employer must establish a regulated area. The purpose of establishing regulated areas is to limit EtO exposure to as few employees as possible.

The proposal requires the employer merely to identify, by the posting of signs, for example, and to control access to regulated areas. Comment is requested as to whether demarcation and sign posting of the regulated area are sufficient to restrict access to authorized personnel.

6. *Paragraph (f)—Methods of compliance.* The proposed standard would require the employer to institute engineering and work practice controls to reduce employee exposures to or below the permissible limit. In situations where engineering and work practice controls that can be instituted immediately will not reduce exposures to the permissible exposure limit, these controls must nonetheless be used to reduce exposures to the lowest feasible level and be supplemented by the use of respirators. In addition, a compliance program to reduce exposures to within the permissible exposure limits solely by means of engineering and work practice controls must be developed and implemented. Written plans for this program must be developed and furnished upon request for examination and copying to representatives of the Assistant Secretary, representatives of the Director, and affected employees. These plans must be reviewed and updated annually to reflect the current status of the program. OSHA solicits comments on whether an annual review of the program will be sufficient to assure that engineering and work practice controls are implemented as they become available.

Engineering controls are the preferred means of compliance because they reduce exposure hazards in the workplace environment by removing the airborne contaminant. Engineering controls may include the installation of local exhaust ventilation, modification of a process so as to reduce emission of the contaminant into the workplace, or substitution of another substance. Work practices are often necessary for the effective operation of engineering controls, and they are also a preferred means of controlling exposures.

Respirators are the least satisfactory means of control because of certain difficulties inherent in their use. Respirators are capable of providing adequate protection only if they are properly selected for the concentrations of airborne contaminants present, properly fitted to the employee, properly worn by the employee, properly maintained, and replaced when they have ceased to provide adequate protection. While theoretically it is possible for all of these conditions to be met, it is more often the case that they are not. As a consequence, the protection of employees by respirators is not always effective.

OSHA recognizes that there are certain activities, often involving certain maintenance and repair operations, as well as in emergency situations in which the use of engineering controls to control exposures will not be feasible, regardless of the permissible exposure limits in the standard. Where the employer can show that engineering controls for such operations are not feasible, respirators shall be permitted as a primary means of control.

It has been OSHA policy to require that employers use feasible engineering and work practice controls to prevent excessive employee exposures and that respirators be used as an alternative only when other methods are not adequate, are not feasible, or have not yet been installed. This policy is, in particular, stated in the OSHA Respiratory Protection Standard, 29 CFR 1910.134(a)(1), which applies to all exposures to airborne toxins, and in the Air Contaminant Standard, 29 CFR 1910.1000(e), which applies to exposures to all substances listed in Tables Z-1, Z-2, and Z-3. The policy was inherent in national consensus standards which were adopted by OSHA in 1971 pursuant to the section 6(a) rulemaking provisions of the OSH Act 1970, without public comment.

All of the other health standards in Subpart Z, which were developed through section 6(b) rulemaking proceedings reflect the same preference for engineering and work practice controls over respirators. Each of these latter standards applies only to a specific substance and was developed on the basis of a public record. OSHA recently published an ANPR (48 FR 7473) requesting comments on all relevant issues related to whether OSHA should allow greater reliance on respirators. Comment on the issue of respirators to control EtO exposures is also requested by OSHA.

7. *Paragraph (g). Respiratory protection.* The proposal provides that where respirators are necessary to limit employee exposures to below the permissible exposure limit, the employer must provide the respirators at no cost to the employee, and assure that the employees use them.

Most companies working with EtO are aware of the high toxicity of this chemical, and many have developed respiratory protection programs to deal with the exposure hazard. OSHA has determined, on the basis of information in the record concerning these on-going respirator programs that the provisions in the proposal concerning respirators should pose no undue burden to companies in their compliance efforts, particularly in light of the ready availability of the prescribed equipment.

In the proposal, OSHA has included a table of respirators for use with EtO. The primary basis for the selection and evaluation of respirators in this table (Table I) is experience gained during other rulemakings (e. g., acrylonitrile) regarding this issue. In addition to the table, several other requirements for respirator usage are included concerning approval of respirators, replacement of sorbents and cleaning of respirators.

The proposal does not require, as do some other OSHA standards that where air-purifying respirators are to be used, they must be jointly approved by NIOSH and MSHA specifically for use with EtO. NIOSH does not grant such approval for substances with poor warning qualities. It is not possible for the respirator wearer to detect leakage or breakthrough within the facepiece

until clearly overexposed and there are no end-of-service indicators presently available for use with air-purifying respirators. OSHA has determined, however, that air-purifying respirators, when used in a rigidly controlled program of proper fitting and frequent sorbent replacement, should be permitted for protection against low concentrations of EtO, as prescribed in Table 1 of the standard. When the protection factors in the respirator table are followed, organic vapor canisters may provide adequate protection for employees.

Therefore, under these conditions the proposal would permit full facepiece organic vapor respirators to be used for EtO in concentrations up to 50 ppm. These respirators must be approved by NIOSH for use with organic vapors. We must note however, that there are numerous factors which affect the performance of air-purifying respirators, including the sorbent material itself and the fit of the facepiece on the wearer. Other important factors include wearer acceptance and training.

Proper fit of the respirator is critical. A negative pressure is created within the facepiece when the wearer breathes. This may result in workplace air entering the facepiece through gaps and leaks in the facepiece seal, instead of passing through the sorbent material. Obtaining a proper fit on each employee may require the employer to provide two or three different mask sizes so the employee can select the facepiece with the least leakage around the faceseal.

The employee must be properly trained to wear the respirator, to know why the respirator is needed, and to understand the limitations of the respirator. An understanding of the hazard involved is necessary to enable the employee to take steps for his or her own protection. The respiratory protection program implemented by the employer must conform to that set forth in 29 CFR 1910.134 which contains basic requirements for proper selection, use, cleaning, and maintenance of respirators.

Under § 1910.134, the employer must check to see that the employees' respirators fit properly and that leakage is at a minimum. A rapid simple fit-test can be performed at the start of each shift by each employee wearing a negative-pressure respirator. This test can be either a positive pressure test, in which the exhalation valve is closed and the wearer exhales into the facepiece to produce a positive pressure, or a negative pressure test, in which the inlet is closed and the wearer inhales so that the facepiece collapses slightly. Employees must be trained to perform this test. OSHA requests comments on whether the standard should provide specific quantative or qualitative fit testing provisions to supplement the general requirements of § 1910.134.

The critical issue of frequency of replacement of cartridges and canisters not approved for a specific substance (such as EtO), was discussed in the preamble to the final standard for acrylonitrile (AN) (43 FR 45803). As with EtO, no air-purifying respirators had been approved by NIOSH specifically for use with acrylonitrile for similar reasons that there are no ETO approved cartridges and canisters. Therefore, the discussion in the acrylonitrile standard replacement frequency appears relevant to this proposal and is presented below (record citations are to exhibits in the AN rulemaking record):

> Perhaps the most controversial element of the proposed respirator section involved the frequency of replacement of cartridges or canisters. It was contended by many in industry that the daily replacement of cartridges or canisters was wasteful, particularly if they were only used briefly during the workshift. A system of labeling of cartridges, it was argued, would assure that cartridges and canisters were replaced before the expiration of their service life (Ex. 92). OSHA does not agree with these contentions. As noted earlier, the very use of organic vapor cartridges and canisters for AN, which does not have good warning properties, runs totally counter to the respirator decision logic, and to good industrial hygiene practice. However, OSHA has determined that it is necessary to allow their use under a limited set of circumstances, provided that use is very narrowly restricted. The lack of end-of-service-life indicators for organic vapor cartridges used with AN makes it necessary for OSHA to require the replacement of the sorbent at the completion of each shift (Ex. 11:(6)).
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> It should be noted, in addition, that even changing the sorbent container each shift may not assure protection. Testing data submitted by a respirator manufacturer and by NIOSH indicate that some organic vapor cartridges used for AN may not last for 8 hours, and that they may last for only 4 hours under humid conditions (Ex. 11:(12L); 11:(13L); 11:(14L)). This finding is particularly important in the context of this standard, since there are numerous monomer and polymer production facilities which operate under conditions of high humidity. It is clear that where the service life of a cartridges or canister is less than 8 hours, that cartridge or canister may have to be replaced again at some time during the workshift. The standard allows for such a situation by requiring the employer to replace cartridge or canisters before the end of their service life or at the completion of each shift, whichever comes first. The employer has the obligation to ascertain the service life of the cartridges and canisters to be used in his workplace, in order to assure that they are replaced as required by the standard.

Again, this discussion relative to the situation with acrylonitrile parallels the case with EtO and serves as the rationale for the requirement in this proposal. It is emphasized that the employer must carefully evaluate the conditions under which air-purifying respirators would be used. Relative humidity, temperature, exposure level, presence of other organic vapors, and employee activity level all act to affect the service life of the canister or cartridge being used. Workplace environmental conditions may render the respirator canister or cartridges ineffective after a relatively short period of use. For example, test data gathered by OSHA (Ex. 6–27) on the service life of MSA canisters designed for EtO use showed breakthrough in less than 8 hours in some instances. The canisters were evaluated at 25°C, 85% relative humidity, and at a flow rate of 64 liters per minute. Two chin style canisters (one with an end-of-service life indicator window) and 2 supersize canisters (one also with an indicator window) were tested. MSA is planning to submit the indicator canisters to NIOSH for approval in the near future. The chin style canister with the indicator, challenged with a 100 ppm EtO test atmosphere, showed a 1% breakthrough at 90–120 minutes with the indicator changing color at 60–70 minutes. The other chin style canister challenged at 10 ppm EtO has a 1% breakthrough after 6 hours. The supersize canister with a window indicator showed a 1% breakthrough after 460 minutes when challenged with 1,000 ppm EtO; the indicator changed color at 300 minutes. The other super size canister also tested at 1,000 ppm, had a 1% breakthrough at 12–13 hours. It is apparent from data such as this that employers who choose to use air purifying respirators must fully evaluate and monitor their conditions of use in order to assure that they are adequately protecting the employee.

OSHA is interested in receiving canister test data such as that described above as well as additional comment regarding experiences in using air-purifying respirators and the efficacy of permitting the use of such respirators in the EtO standard.

Finally, the proposal requires that respirators required for protection from exposure to EtO shall be provided at no cost to the employee. OSHA views this allocation of costs to control employee exposure to EtO as being necessary to effectuate the purposes of the Act. The requirement makes explicit an agency position which has long been implicit in

health standards proceedings under section 6(b) of the Act.

8. *Paragraph (h). Emergency situations.* Available health data suggest that elevated short-term exposure to EtO should be viewed with concern. OSHA believes that an unexpected high exposure must be viewed as an emergency situation. The proposed requirements include development of a written plan where there is a possibility of an emergency and means to alert employees in the event that an emergency occurs. Employees involved in correcting the emergency conditions would be required to be provided with appropriate respirators and other protective equipment. Employees not involved in correcting the emergency conditions must be evacuated from area.

OSHA believes that these minimal requirements will provide the necessary means to ensure that affected employees are substantially protected against hazardous exposures.

9. *Paragraph (i). Medical surveillance.* The proposal requires, in paragraph (i)(1), each employer to institute a medical surveillance program for all employees who are or will be exposed at or above the action level for at least 30 days per year. Providing medical surveillance for employees exposed at or above the action level in consistent with other health standards which incorporate an action level and is considered by OSHA to be appropriate for monitoring the adequacy of the exposure limit specified.

Some employees may be assigned to work areas where they may be exposed to EtO at or above the action level on a temporary or short term basis. A cut-off point is, therefore, needed for the required medical surveillance program, since it would not be practical to require medical surveillance for every employee regardless of duration of exposure. It is important that the surveillance period selected be sufficiently inclusive but not administratively impractical. As a result of OSHA's experience gained in the inorganic arsenic and coke oven proceedings, the Agency has determined that 30 exposure days per year is an appropriate cut-off point for deciding which employees will be included in the medical surveillance program.

The proposal requires that the medical surveillance program provide each covered employee with an opportunity for a medical examination. Paragraph (i)(1)(ii) provides that all examinations and procedures be performed by or under the supervision of a licensed physician and be provided without cost to the employee. Clearly, a licensed physician is the appropriate person to be supervising and evaluating a medical examination. However, certain parts of the required examination do not necessarily require the physician's expertise and may be conducted by another person under the supervision of the physician.

The proposal requires that exams must be given at a reasonable time and place. It is necessary that exams be convenient and be provided without loss of pay to the employee to assure that they are taken.

The proposal allows the examining physician to prescribe the specific tests to be included in the medical surveillance program. Information presently available to OSHA is insufficient for the Agency to justify specification of the precise tests to be administered. Thus, it is believed that the examining physician is best qualified to make this judgment. Certain elements of an examination, however, are suggested in Appendix C as being appropriate considering the health data regarding carcinogenic, mutagenic, and reproductive effects. Thus, the proposal lists these elements and suggests that the physician consider their inclusion.

These elements include the following:

(i) Comprehensive medical and work histories with special emphasis directed to symptoms related to eyes, blood, blood forming organs, lungs, nervous and reproductive systems, and skin;

(ii) Comprehensive physical examination, with particular emphasis given to pulmonary, neurologic, reproductive, and ophthalmologic systems, blood forming organs, and the skin;

(iii) Complete blood count to include at least a white cell count, a differential count, hemoglobin, and hematocrit;

(iv) Screening for chromosome damage.

It is important to note that the employer is required to make any prescribed tests available more often than specified if recommended by the examining physician.

The proposal requires the employer to provide physician-recommended examinations to any employee exposed to high EtO exposures under emergency conditions. While little is known about the effects of high short-term exposures, it appears prudent to monitor such affected employees in light of existing health data.

The employer is required, in paragraph (i)(6), to provide the physician with the following information: a copy of this standard and its appendices; a description of the affected employee's duties as they relate to the employee exposure level; and information from the employee's previously medical examinations which is not readily available to the examining physician. Making this information available to the physician will aid in the evaluation of the employee's health in relation to assigned duties and fitness to wear personal protective equipment, when required.

The employer is required to obtain a written opinion from the examining physician containing the results of the medical examinations; the physician's opinion as to whether the employee has any detected medical conditions which would place the employee at increased risk of material health impairment from exposure to EtO; any recommended restrictions upon the employee's exposure to EtO or upon the use of protective clothing or equipment such as respirators; and a statement that the employee has been informed by the physician of the results of the medical examination and of any medical conditions which require further explanation or treatment. This written opinion must not reveal specific findings or diagnoses unrelated to occupational exposure to EtO, and a copy of the opinion must be provided to the affected employee.

The purpose in requiring the examining physician to supply the employer with a written opinion is to provide the employer with a medical basis to aid in the determination of initial placement of employees and to assess the employee's ability to use protective clothing and equipment. The requirement that a physician's opinion be in written form will ensure that employers have had the benefit of this information. The requirement that an employee be provided with a copy of the physician's written opinion will ensure that the employee is informed of the results of the medical examination. The purpose in requiring that specific findings or diagnoses unrelated to occupational exposure to EtO not be included in the written opinion is to encourage employees to take the medical examination by removing the concern that the employer will obtain information about their physical condition that has no relation to present occupational exposures.

10. *Paragraph (j). Employee information and training.* The proposed standard requires that all employers provide a training program for all employees exposed to airborne EtO at or above the action level.

OSHA has determined during other rulemakings that an information and training program is essential to inform employees of the hazards to which they are exposed and to provide employees with the necessary understanding of the

degree to which each employee can contribute toward minimizing health hazard potentials.

The content of the training program is intended to inform employees of: (1) The hazards to which they are exposed; (2) the necessary steps to protect themselves, including those to be taken during emergency situations; (3) limitations and the proper use of respirators and protective equipment; (4) a description of medical examinations and their purpose; (5) implementation of work practices and the use of available engineering controls; and (6) the contents of this standard. Section 6(b)(7) of the Act makes it clear that these are appropriate goals for an employee training program, and the proposed standard includes such provisions.

The employer is required to make a copy of the standard and its appendices available to affected employees and their representatives. This requirement, in combination with the review provided for as part of the training program, is intended to ensure that employees understand their rights and duties under this standard.

The employer is also required to provide, upon request, all materials relating to the training program to the Assistant Secretary and Director. This is intended to provide an objective check of compliance with the requirements under this paragraph.

OSHA recognizes that EtO may be only one of a number of substances to which an employee may be exposed simultaneously in the workplace. The education and training requirements in this standard contain those elements OSHA has determined to be basic. The format and content of the required training and information program are neither rigid nor extensive. An employer, may, if desired, incorporate the required information for EtO into a comprehensive program of training and education to be provided to employees.

The proposed standard requires that the training program be provided at least annually. OSHA believes that an annual training program is both necessary and sufficient to ensure that employees maintain a continuing awareness of the hazards of EtO and their rights and duties under the standard.

To increase the effectiveness of training goals the proposed standard requires that the training material be made available, without cost, to all affected employees or their representatives.

11. *Paragraph (k). Precautionary labels and signs.* The proposed standard requires that regulated areas be posted with signs stating: "Danger, Cancer and Reproductive Hazard, Authorized Personnel Only, Respirators and Protective Clothing May Be Required To Be Worn In This Area". The proposal also requires labelling of containers of EtO except when the EtO content is such as to make unlikely the possibility of exposure to EtO at or above the action level under the conditions of use likely to cause the highest possible exposure. The labels must state, "Danger, Contains Ethylene Oxide, Cancer and Reproductive Hazard" and must provide other appropriate warning against breathing airborne concentrations and contacting liquid EtO.

These requirements are consistent with section 6(b)(7) of the Act, which prescribes the use of labels or other appropriate forms of warning to apprise employees of the hazards to which they are exposed.

It is proposed that required labels would remain affixed to containers leaving the workplace. The purpose of this requirement is to assure that all affected employees, not only those of a particular employer, are apprised to the hazardous nature of EtO exposure where exposure could exceed the action level.

It is OSHA's view that informing employees of the hazards to which they are exposed is an important element in reducing occupational disease and injury, and one of the significant purposes of the Act. Section 6(b)(7) of the Act does not limit an employer's obligation to inform employees of hazardous conditions, to the employer's own employees. When an employer manufactures, formulates, or sells a product, the employer may create exposures not only to his or her own employees, but also to the employees of other employers involved in handling, transporting or using the product. The extent of the obligation to inform should be commensurate with the extent of the exposure. This is especially true where the manufacturer, formulator or seller will, in many cases, be the only employer capable, through his knowledge of the product, of providing the information necessary for protection of employees. A narrower reading of the statutory authority would defeat the protective purposes of the Act by effectively preventing the downstream employee from obtaining adequate information about the hazard Furthermore, the use of labels required by the standard will alert other employers who would not otherwise know of the presence of EtO in their workplace or their obligation to comply with the standard. OSHA therefore feels that this requirement is necessary and appropriate.

The proposal sets forth the specific legend to be used on the label. This language is adoted to provide uniformity with other OSHA standards and to indicate to employers precisely what is required. Requiring the label to include the statement "Cancer and Reproductive Hazard" is proposed as being appropriate in light of the available health data. These proposed requirements would be in addition to those mandated by the OSHA hazard communication standard proposed at 47 FR 12092 (March 19, 1982).

A number of EtO products which are utilized as sterilants are registered by the EPA as pesticides, in accordance with FIFRA. EPA must establish terms and conditions for the registration of such products which are sufficient to ensure that use of the products "will not generally cause unreasonable adverse effects on the environment." These terms and conditions may include restrictions and limitations on use which are specified on the label and which all users are obligated by law to comply with. For these reasons OSHA is proposing that the labeling requirements under this paragraph not apply to any EtO product registered as a pesticide, as such term is defined under FIFRA, for which labeling is required by EPA under FIFRA and regulation issued pursuant there to. OSHA feels that this provision is appropriate to mitigate any dual regulatory requirements pesticide registrants may face with regard to container labeling. It is OSHA's understanding, however, that EPA is presently developing EtO labelling requirements that will provide health warnings similar to those on the OSHA label (e.g., cancer and reproductive hazard).

The standard requires the posting of warning signs to demarcate regulated areas. These signs are intended to supplement the training which employees are required to receive under the standard. Even trained employees will need to be reminded of the locations of regulated areas and the dangers of entering these areas. In addition, other personnel, such as employees of independent maintenance contractors authorized to enter regulated areas, need to be reminded of the locations of regulated areas, the dangers of entering these areas, and the need to use protective equipment. OSHA believes that both signs and training are necessary to apprise employees adequately of the hazards associated with EtO exposure.

The standard specifies the wording of the warning signs for regulated areas to assure that the proper warning is given to employees. The word "Danger" is used to attract the attention of workers, to alert them to the fact that they are in a hazardous area (i.e., an area where the EtO airborne concentration exceeds the PEL) and to emphasize the importance of the message that follows. In addition, the use of the word "Danger" is consistent with recent OSHA health standards dealing with carcinogens. The proposed sign legend: "Respirators and Protective Clothing May Be Required to Be Worn In This Area," recognizes that there may be a difference between the EtO concentration in air, the basis used to determine when a regulated area must be established, and a particular employee's exposure. For example, there may be areas in which EtO concentrations exceed 5 pm but an employee's 8-hour TWA exposure might not exceed that level, because the employee may spend only a short time in that area.

In such instances, the employee may not be required to wear a respirator under the provisions set forth in paragraph (g). (As noted earlier, the proposal does not include any short-term exposure limit for EtO. The use of an STEL could affect many other provisions of the standard including signs and labels and the warnings to be listed thereon).

12. *Paragraph (1): Recordkeeping.* Section 8(c)(3) of the Act provides for the promulgation of regulations requiring employers to maintain accurate records of employee exposures to potentially toxic or harmful physical agents which are required to be monitored or measured.

The proposed standard requires that employers who rely on objective data to be exempted from the standard (paragraph (a)(2)) shall maintain records of such information to demonstrate that employees are not exposed to airborne EtO concentrations at or above the action level. In this respect, the objective data substitute for the initial monitoring requirements.

The proposal provides that records be kept to identify the employee monitored and to reflect the employee's exposure accurately. Specifically, records must include the following information: (a) The names and social security numbers of the employees sampled; (b) the number, duration, and results of each of the samples taken, including a description of the representative sampling procedure and equipment used to determine employee exposure where applicable; (c) a description of the operation involving exposure to EtO which is being monitored and the date on which monitoring is performed; (d) the type of respiratory protective devices, if any, worn by the employee; and (e) a description of the sampling and analytical methods used, and evidence of their accuracy.

The proposed standard also requires that the employer keep an accurate medical record for each employee subject to medical surveillance. Section 8(c) of the Act authorizes the promulgation of regulations requiring any employer to keep such records regarding the employer's activities relating to the Act as are necessary or appropriate for the enforcement of the Act or for developing information regarding the causes and prevention of occupational illnesses. OSHA believes that medical records, like exposure monitoring records, are necessary and appropriate to both the enforcement of the standard and the development of information regarding the causes and prevention of illness.

As explained above, it is necessary to relate employees' medical conditions to their exposures to develop information regarding cause and prevention. Medical records are necessary and appropriate for this purpose. In addition, medical records are necessary for the proper evaluation of the employee's health.

The proposed standard requires that all records required to be kept shall be made available upon request to the Assistant Secretary and the Director of NIOSH for examination and copying. Access to these records is necessary for the agencies to monitor compliance with the standard. These records may also contain essential information which is necessary for the agencies to carry out their other statutory responsibilities.

The proposal provides for employees, former employees, and their designated representative to have access to mandated records upon request. Section 8(c)(3) of the Act explicitly provides "employees or their representative with an opportunity to observe monitoring and to have access to the records of monitoring and exposures to toxic substances; and several other provisions of the Act contemplated that employees and their representatives are entitled to play an active role in the enforcement of the Act. Employees and their representatives need to know relevant information concerning employee exposure to toxic substances and their health consequences if they are to benefit fully from these statutory created rights. OSHA requests information as to whether details on monitoring procedures should be provided to employees who observe monitoring activities under this paragraph.

In addition, the proposal specifies that access to exposure and medical records by employees, designated representatives, and OSHA shall be in accordance with 29 CFR 1910.20. Section 1910. 20 is OSHA's recently promulgated generic standard for access to employee exposure and medical records (45 FR 35212). By its terms, it applies as to records required by specific standards, such as this EtO standard, as well as records which are voluntarily created by employers. In general, it provides for unrestricted employee and designated representative access to exposure records. Access to medical records is also provided for employees and, if the employee has given specific written consent, for the employee's designated representatives. OSHA retains unrestricted access to both kinds of records, but its access to personally identifiable records is made subject to rules of agency practice and procedure concerning OSHA access to employee medical records, which have been published at 29 CFR 1913.10. An extensive discussion of the provisions and rationale for § 1920.20 may be found at 45 FR 35312; the discussion of § 1913.10 may be found at 45 FR 35384. It is noted that revisions to the access to records standard are being developed in an ongoing rulemaking proceeding (45 FR 35212). The EtO standard may be affected by any changes which result from that rulemaking effort.

It is necessary to keep records for extended periods because of the long latency periods commonly observed for carcinogens. Cancer often cannot be detected until 20 or 30 more years after onset of exposure. The extened retention period is therefore needed for two purposes. Diagnosis of disease in employees in assisted by having present and past exposure data as well as the results of the medical exams. Retaining records for extended periods also makes it possible at some future date to review the adequacy of the standard.

The time periods proposed for retention of exposure records and medical records are thirty years, and period of employment plus thirty years, respectively. These retention periods are consistent with those in the OSHA records access standard. Comment is requested as to whether the retention periods for exposure records and medical records should be the same, and if so, what those periods should be.

The proposal requires employers to notify the Director in writing at least 3 months prior to the disposal of the records. Section 1910.20(h) also contains

requirements regarding the transfer of records. Therefore, the employer is also required to comply with any additional requirements set forth in that standard.

13. *Paragraph (m). Observation of monitoring.* Section 8(c) of the Act requires that employers provide employees and their representatives with the opportunity to observe monitoring of employee exposures to toxic subtances or harmful physical agents. In accordance with this section, the proposal contains provisions for such observation of monitoring of EtO exposures.

The observer, whether an employee or a designated representative, must be provided with, and is required to use, any personal protective equipment required to be worn by employees working in the area that is being monitored, and must comply with all other applicable safety and health procedures.

14. *Paragraph (n). Effective date*—As proposed, the final rule would become effective thirty (30) days following publication in the **Federal Register.** OSHA requests comment on whether additional time should be privided. The Agency also solicits information and supporting data on "start-up periods" and delayed implementation dates which may be necessary for various provisions of the standard.

15. *Appendices.* Four appendices have been included in this proposed standard. These appendices have been included primarily for purposes of information. None of the statements contained therein should be construed as establishing a mandatory requirement not otherwise imposed by the standards, or as detracting from an obligation which the standard does impose.

The information contained in Appendices A and B is designed to aid the employer in complying with requirements of the standard. The information in Appendix C primarily provides information needed by the physician to evaluate the results of the medical examination. It should be noted that paragraph (i) specifically requires that the information contained in Appendices A and B be provided to employees as part of their information and training program.

Appendix D gives details of the OSHA sampling method for use in monitoring employee exposures to EtO.

28. *References.* The studies and other data listed below as well as the additional material referred to in this document represent the primary sources upon which the proposal is based. A complete set of the references is available for examination and copying at the OSHA Technical Data Center, Docket Office, Room S6212, U.S. Department of Labor, Third Street and Constitution Avenue NW., Washington, D.C. 20210, between 8:30 am. and 4:30 pm, Monday through Friday, legal holidays excepted.

The materials listed below represent documents referred to in this notice (Exhibit 6) that are not referred to in the ANPR (Exhibit 2) or where not submitted to the record by interested parties (Exhibit 4) in response to the ANPR.


1. *Public Citizen Health Research Group* v. *Auchter.* D.C. Civil Action No. 81–02343. (D.C. Vir., Jan. 5, 1983).

1. Public Health Research Group v. Auchter, No. 83–1071 (D.C. Cir. March 15, 1983).

3. TLV Airborne Contaminants Committee: Documentation of the Threshold Limit Values, Third Edition. American Conference of Governmental Industrial Hygienists, Cincinnati, Ohio (1966).

4. TLV Airborne Contaminants Committee: Documentation of the Threshold Limit Values, Third Edition. American Conference of Governmental Industrial Hygienists, Cincinnati, Ohio (1971).

5. Morgan, R. W., Claxton, K. W., Divine, B. J., Kaplan, S. D., and Harris, V. B., 1981. Mortality among ethylene oxide workers. *J. Occup. Med.* 23: 767–770.

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7. Hemminki, K., Mutanen, P., Saloniemi, I., Niemi, M-L., Vaino, H., 1982. Spontaneous abortions in hospital staff engaged in sterilising instruments with chemical agents. *British Medical Journal.* 285: 1461–1463.

8. Letter dated March, 29, 1983, from Kari Hemminke, M.D., to Dr. Robert P. Beliles.

9. Jones-Price, C., Marks T. A., Ledoux, T. A., Reel, J. R., Fisher, P. W., Langhoff-Paschke, C., and Marr, M.N., December, 1982. Final Report: Teratologic Evaluation of Ethylene Oxide (Cas No. 75–21–8) in New Zealand White Rabbits, Research Triangle Institute. RTI Project No. 31U–1287 and 31U–2312

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12. Pero, W.P., Bryngelsson, T., Widegren, B., Hogstedt, B., and Welinder, H., 1982. A reduced capacity for unscheduled DNA synthesis in lymphocytes from individuals exposed to propylene oxide and ethylene oxide. *Mutation Research.* 104:193–200.

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14. Garry, V. F., Hozier, J., Jacobs, D., Wade R.L., and Gray D.G. 1979. Ethylene Oxide: Evidence of Human Chromosomal Effects. *Environmental Mutagenesis.* 1:375–382.

15. Yager, J., Hines, C., and Spear, R. 1983. Exposure to ethylene oxide at work increases sister chromatid exchanges in human peripheral lymphocytes. *SCIENCE* 219:1221–1223.

16. National Institute of Occupational Safety and Health. 1982. Chronic inhalation toxicity of ethylene oxide and propylene oxide in rats and monkeys—a prelininary report.

17. Howe, R.B. and Crump, K.S., 1982. GLOBAL 82: A computer program to extrapolate quantal animal toxicity data to low doses. Prepared under contract #41 USC 252 C3, for the Occupational Safety and Health Administration. U.S. Department of Labor.

18. OSHA Preliminary Quantitative Risk Assessment for Ethylene Oxide. Office of Carcinogen Standards. April 11, 1983.

19. Calleman, C.J., Ehrenberg, L., Jansson, B., Osterman-Golkar, Sir, Segerback, D., Svensson, K., and Wachtmeister, C.A. 1978. Monitoring and risk assessment by means of alkyl groups in hemoglobin in persons occupationally exposed to ethylene oxide. *Journal of Environmental Pathology and Toxicology.* 2:427–442.

20. Rantanen, J., Aitio, A., Hemminki, K., Jarvisalo, J., Lindstrom, K., Tossavainen, A., and Vainio, H. 1982. Exposure limits and medical surveillance in occupational health. *American Journal of Industrial Medicine.* 3:363–371.

21. The Carcinogen Assessment Group's Preliminary Risk Assessment on Ethylene Oxide. Type-One Air Program. Environmental Protection Agency. October 16, 1979.

22. Seymour, M., O'Konski, D.P., Adams, A.V., and New, C.B. 1982. Report: Economic and environmental impact study of ethylene oxide. Prepared for the Occupational Safety and Health Administration by JRB Associates. McLean, Virginia.

23. Kovar, J. and Krewski, D. 1981. Risk 81: A computer program for low dose extrapolation of quantal response toxicity data. Health and Welfare Canada.

24. Memorandum dated January 3, 1983, from Edward F. Zimowski, OSHA Health Response Team, to Dr. Robert P. Beliles, Director, Office of Carcinogen Standards, OSHA, regarding ethylene oxide sampling procedures.

25. Memorandum dated February 28, 1983 to R. Leonard Vance, Director, Health Standards Programs, from Peter Infante and Theodora A. Tsongas, Office of Carcinogen Identification and Classification, regarding the study by Hemminki et al.

26. Leidel, N.A., August 1975. Exposure Measurement Action Level and Occupational Environmental Variability. DHEW, PHS, DCD, DLCK.

27. Handwritten notes February 22, 1983 from OSHA's Office of Technical Support regarding the service life of MSA ethylene oxide canisters.

### VI. Public Participation—Notice of Hearing

Interested persons are invited to submit written data, views, and arguments with respect to this proposed standard. These comments must be postmarked on or before June 17, 1983, and submitted in quadruplicate to the Docket Officer, Docket No. H–200, Room S–6212, U.S. Department of Labor, Third Street and Constitution Avenue N.W., Washington, D.C. 20210. Written submissions must clearly identify the provisions of the proposal which are addressed and the position taken with respect to each issue.

The data, views, and arguments that are submitted will be available for public inspection and copying at the above address. All timely written submissions will be made a part of the record of the proceeding.

Pursuant to section 6(b)(3) of the Act, an opportunity to submit oral testimony concerning the issues raised by the proposed standard including economic and environmental impacts, will be provided at an informal public hearing scheduled to begin at 10:00 A.M. on July 19, 1983, in the Auditorium, Frances Perkins Building, U.S. Department of Labor, Third Street and Constitution Avenue, N.W., Washington, D.C. 20210.

### Notice of Intention To Appear

All persons desiring to participate at the hearng must file in quadruplicate a notice of intention to appear, postmarked on or before June 17, 1983, addressed to Mr. Tom Hall, OSHA Division of Consumer Affairs, Docket No. H–200, Room N–3635, U.S. Department of Labor, Third Street and Constitution Avenue NW., Washington, D.C. 20210; telephone 202–523–8024.

The notices of intention to appear, which will be available for inspection and copying at the OSHA Technical Data Center-Docket Office (Room S6212), telephone 202–523–7895, must contain the following information:

(1) The name, address, and telephone number of each person to appear;

(2) The capacity in which the person will appear;

(3) The approximate amount of time requested for the presentation;

(4) The specific issues that will be addressed;

(5) A detailed statement of the position that will be taken with respect to each issue addressed; and

(6) Whether the party intends to submit documentary evidence, and if so, a brief summary of that evidence.

### Filing of Testimony and Evidence Before Hearing

Any party requesting more than 10 minutes for a presentation at the hearing, or who will submit documentary evidence, must provide in quadruplicate the complete text of his testimony, including any documentary evidence to be presented at the hearing, to the OSHA Division of Consumer Affairs. This material must be received by July 1, 1983 and will be available for inspection and copying at the Technical Data Center-Docket Office. Each such submission will be reviewed in light of the amount of time requested in the notice of intention to appear. In those instances where the information contained in the submission does not justify the amount of time requested, a more appropriate amount of time will be allocated and the participant will be notified of that fact.

Any party who has not substantially complied with this requirement may be limited to a 10-minute presentation, and may be requested to return for questioning at a later time.

### Conduct of Hearing

The hearing will commence at 10:00 a.m. on Tuesday, July 19, 1983, with resolution of any procedural matters relating to the proceeding. The hearing will be conducted in accordance with 29 CFR Part 1911. In view of the nature of this rulemaking proceeding, the hearing will be conducted in as expedited a manner as possible with a full development of the record and the rights of the parties.

The hearing will be presided over by an Administrative Law Judge who will have all the powers necessary or appropriate to conduct a full and fair informal hearing as provided in 29 CFR Part 1911. Following the close of the hearing or of any posthearing comment period, the presiding Administrative Law Judge will certify the record to the Assistant Secretary of Labor for Occupational Safety and Health. The proposed permanent standard will be reviewed in light of all oral and written submissions received as part of the record, and a permanent standard for occupational exposure to ethylene oxide will be issued, based upon the entire record in this proceeding.

### Authority

This document was prepared under the direction of Thorne G. Auchter, Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, Third Street and Constitution Avenue N.W., Washington D.C. 20210.

Pursuant to sections 6(b) and 8 of the Occupational Safety & Health Act (29 U.S.C. 655, 657), it is hereby proposed to amend Part 1910 of 29 CFR by adding new § 1910.1047 as set forth below and delete the reference to ethylene oxide from Table Z–1 of section 1910.1000. In addition, pursuant to section 4(b)(2) of the Act, OSHA has determined that this new standard would be more effective than the corresponding standards now in Subpart B of Part 1910, and in Parts 1915, 1918, and 1926 of Title 29, Code of Federal Regulations. Therefore, these corresponding standards would be superseded by this new section 1910.1047. This determination, and the application of the new standard to the maritime and construction industries, would be implemented by adding a new paragraph (h) to § 1910.19.

### List of Subjects in 29 CFR Part 1910

Ethylene oxide, Occupational safety and health, Chemicals, Cancer, Health risk—assessment.

(Secs. 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 8–76 (41 FR 25059); 29 CFR Part 1911)

Signed at Washington, D.C., this 15th day of April 1983.

**Thorne G. Auchter,**

*Assistant Secretary of Labor.*

Part 1910 of Title 29 of the Code of Federal Regulations is therefore proposed to be amended as follows:

1. By adding a new paragraph (h) to § 1910.19 to read as follows:

**§ 1910.19 Special provisions for air contaminants.**

* * * * *

(h) *Ethylene oxide.* Section 1910.1047 shall apply to the exposure of every employee to ethylene oxide in every employment and place of employment covered by § 1910.12, § 1910.13, § 1910.14, § 1910.15, or § 1910.16, in lieu of any different standard on exposure to ethylene oxide which would otherwise be applicable by virtue of those sections.

**§ 1910.1000 [Amended]**

2. By removing the entry "Ethylene oxide . . . 50 ppm . . . 90 mg/m $^3$" from Table Z–1 of § 1910.1000.

3. By adding a new § 1910.1047 to read as follows:

**§ 1910.1047 Ethylene oxide.**

(a) *Scope and application.* (1) This section applies to all occupational exposures to ethylene oxide (EtO),

Chemical Abstracts Service Registry No. 75-21-8, except as provided in paragraph (a)(2) of this section.

(2) This section does not apply to the processing, use, and handling of products containing EtO where objective data are reasonably relied upon that demonstrates that the product is not capable of releasing EtO in excess of the action level under the expected conditions of processing, use, and handling which will cause the greatest possible release.

(3) Where products containing EtO are exempted under paragraph (a)(2) of this section, the employer shall maintain records of the objective data supporting that exemption and the basis for the employers' reliance on the data, as provided in pargraph (l)(1) of this section.

(b) *Definitions:* For the purpose of this section, the following definitions shall apply:

"*Action level*" means a concentration of airborne EtO of 0.5 ppm calculated as an eight (8)-hour time-weighted average.

"*Assistant Secretary*" means the Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, or designee.

"*Authorized person*" means any person specifically authorized by the employer whose duties require the person to enter a regulated area, or any person entering such an area as a designated representative of employees for the purpose of exercising the right to observe monitoring and measuring procedures under paragraph (m) of this section, or any other person authorized by the Act or regulations issued under the Act.

"*Director*" means the Director of the National Institute for Occupational Safety and Health, U.S. Department of Health and Human Services, or designee.

"*Emergency*" means any occurrence such as, but not limited to, equipment failure, rupture of containers, or failure of control equipment which is likely to, or does result in an unexpected massive release of EtO.

"*Employee exposure*" means exposure to airborne EtO which would occur if the employee were not using respiratory protective equipment.

"*Ethylene oxide*" or "EtO" means the three-membered ring organic compound with chemical formula $C_2H_4O$.

(c) *Permissible exposure limit (PEL).* The employer shall assure that no employee is exposed to an airborne concentration of EtO in excess of one part of EtO per million parts of air (1 ppm) as an eight (8)-hour time-weighted average (8-hour TWA).

(d) *Exposure monitoring.* (1) *General.* (i) Determinations of employee exposure shall be made from breathing zone air samples that are representative of each employee's exposure to airborne EtO over an eight (8) hour period.

(ii) Representative employee exposure shall be determined on the basis of at least one sample or consecutive samples covering the full shift for each shift for each job classification in each work area.

(iii) Where the employer can document that exposure levels are equivalent for similar operations in different work shifts, the employer shall only be required to determine representative employee exposure for that operation during one shift.

(2) *Initial monitoring.* Each employer who has a workplace or work operation covered by this standard shall perform monitoring to determine accurately the airborne concentrations of EtO to which employees may be exposed, except as provided for in paragraph (a)(2) of this section.

(3) *Monitoring frequency (periodic monitoring).* (i) If the monitoring required by paragraph (d)(2) of this section reveals employee exposure at or above the action level but at or below the PEL, the employer shall repeat such monitoring for each such employee at least every 6 months.

(ii) If the monitoring required by paragraph (d)(2) of this section reveals employee exposure above the PEL, the employer shall repeat such monitoring for each such employee at least every 3 months.

(iii) The employer may alter the monitoring schedule from quarterly to semianually for any employee for whom two consecutive measurements taken at least 7 days apart indicate that the employee exposure has decreased to the PEL or below.

(4) *Termination of monitoring.* (i) If the initial monitoring required by paragraph (d)(2) of this section reveals employee exposure to be below the action level the employer may discontinue the monitoring for that employee.

(ii) If the periodic monitoring required by paragraph (d)(3) of this section reveals that employee exposures, as indicated by at least two consecutive measurements taken at least 7 days apart, are below the action level the employer may discontinue the monitoring for that employee.A

(5) *Additional monitoring.* The employer shall institute the exposure monitoring required under paragraphs (d)(2) and (d)(3) of this section when there has been a change in the production, process, control equipment, personnel or work practices which may result in new or additional exposures to EtO or when the employer has any reason to suspect a change which may result in new or additional exposures.

(6) *Accuracy of monitoring.* Monitoring shall be accurate, to a confidence level of 95 percent, to within plus or minus 25 percent for airborne concentrations of EtO at 1 ppm and to within plus or minus 35 percent for airborne concentrations of EtO at the action level of 0.5 ppm.

(7) *Employee notification of monitoring results.* (i) The employer shall, within 10 working days after the receipt of the results of any monitoring performed under this standard, notify the affected employee of these results in writing either individually or by posting of results in an appropriate location that is accessible to affected employees.

(ii) The written notification required by paragraph(d)(7)(i) of this section shall contain the corrective action being taken by the employer to reduce employee exposure to or below the PEL, wherever the PEL is exceeded.

(3) *Regulated Areas.* (1) The employer shall establish a regulated area wherever the airborne concentration of EtO is above 1 ppm calculated as an 8-hour time-weighted average.

(2) Access to regulated areas shall be limited to authorized persons.

(3) Regulated areas shall be demarcated in any manner that minimizes the number of employees exposed to EtO within the regulated area.

(f) *Methods of compliance.* (1) *Engineering controls and work practices.* (i) The employer shall institute engineering controls and work practices to reduce and maintain employee exposure to or below the PEL, except to the extent that the employer can establish that such controls are not feasible.

(ii) Wherever the feasible engineering controls and work practices which can be instituted are not sufficient to reduce employee exposure to or below the PEL, the employer shall use them to reduce employee exposure to the lowest levels achievable by these controls and shall supplement them by the use of respiratory protection which complies with the requirements of paragraph (g) of this section.

(2) *Compliance program.* (i) The employer shall establish and implement a written program to reduce employee exposure to or below the PEL solely by means of engineering and work practice controls, as required by paragraph (f)(1) of this section. The program shall

include a schedule for periodic leak detection surveys.

(ii) Written plans for such a program shall be developed and furnished upon request for examination and copying to the Assistant Secretary, the Director, affected employees and designated employee representatives. Such plans shall be reviewed at least every 12 months to reflect the current status of the program and revised as necessary.

(g) *Respiratory protection.* (1) *General.* The employer shall provide respirators, and assure that they are used, where required by this section. Respirators shall be used in the following circumstances.

(i) During the interval necessary to install or implement feasible engineering and work practice controls;

(ii) In work operations, such as maintenance and repair activities or vessel cleaning, for which the employer establishes that engineering and work practice controls are not feasible;

(iii) In work situations where feasible engineering and work practice controls are not yet sufficient to reduce exposure to or below the PEL; and

(iv) In emergencies.

(2) *Respirator selection.* (i) Where respirators are required under this section, the employer shall select and provide, at no cost to the employee, the appropriate respirator as specified in Table 1, and shall assure that the employee uses the respirator provided.

(ii) The employer shall select respirators from among those jointly approved for protection against ethylene oxide by the Mine Safety and Health Administration (MSHA) and by the National Institute for Occupational Safety and Healath (NIOSH) under the provisions of 30 CFR Part 11. *Exception:* Air-purifying respirators shall be selected by the employer from those with joint MSHA/NIOSH approval for protection against organic vapors.

(3) *Respirator program.* (i) The employer shall institute a respiratory program in accordance with 29 CFR 1910.134(b), (d), (e), and (f).

(ii) Where air-purifying respirators are used, the air-purifying element shall be replaced prior to the expiration of their service life or at the completion of each shift, whichever occurs first. A label shall be attached to the air-purifying element to indicate the date and time at which it is first installed on the respirator.

TABLE 1.—MINIMUM REQUIREMENTS FOR RESPIRATORY PROTECTION FOR AIRBORNE ETO

| Condition of use or concentration of airborne EtO (ppm) | Minimum required respirator |
|---|---|
| Equal to or less than 50. | (a) Full facepiece respirator with organic vapor gas mask canister, front- or back-mounted. |
| Equal to or less than 2,000. | (a) Positive-pressure supplied air respirator, equipped with full facepiece, hood, or helmet, or<br>(b) Continuous-flow supplied air respirator (positive pressure) equipped with hood, helmet or suit. |
| Concentration above 2,000 or unknown concentration (such as in emergencies). | (a) Positive-presssure self-contained breathing apparatus (SCBA), equipped with full facepiece, or<br>(b) Positive-pressure full facepiece supplied air respirator equipped with an auxiliary positive-pressure selfcontained breathing apparatus. |
| Firefighting | (a) Positive pressure self-contained breathing apparatus equipped with full facepiece. |
| Escape | (a) Any respirator described above. |

(h) *Emergency situations.* (1) *Written plan.* (i) A written paln for emergency situations shall be developed for each workplace where there is a possibility of an emergency. Appropriate portions of the plan shall be implemented in the event of an emergency.

(ii) The paln shall specifically provide that employees engaged in correcting emergency conditions shall be equipped with respiratory protection as required in paragraph (g) of this section until the emergency is abated.

(2) *Alerting employees.* Where there is the possibility of employees exposure to EtO due to an emergency, means shall be developed to alert potentially affected employees of such occurrences promptly. Affected employees shall be immediately evacuated in the event that an emergency occurs.

(i) *Medical Surveillance.* (1)*General.* (i) *Employees covered.* (A) The employer shall institute a medical surveillance program for employees who are or will be exposed to EtO at or above the action level, without regard to the use of respirators, for at least 30 days in the year;

(B) Employees who have been exposed to an emergency shall be provided medical examinations as set forth in paragraph (i) (5) of this section.

(ii) *Examination by physician.* The employer shall assure that all medical examinations and procedures are performed by or under the supervision of a licensed physician, and are provided without cost to the employee, without loss of pay and at a reasonable time and place.

(2) *Initial examinations.* At the time of initial assignment to an area where the employee is likely to be exposed at or above the action level for 30 days or more in the year, and for all employees who have been exposed to an emergency by paragraph (i)(1)(i) of this section, the employer shall provide each employee an opportunity for a medical examination comprised of tests deemed appropriate by the examining physician. It is recommended that the physician consider including at least the elements suggested in Appendix C to this section in the examination:

(3) *Periodic examinations.* The employer shall provide the examinations deemed appropriate by the examining physician as specified in paragraph (i)(2) of this section at least annually for all employees specified in paragraph (i)(1)(i)(A) of this section.

(4) *Additional examination.* If the examining physician determines that any of the examinations should be provided more frequently than specified, the employer shall provide such examinations to affected employees at the frequencies recommended by the physician.

(5) *Examinations upon occurrence of an emergency.* (i) The employer shall provide appropriate medical examinations as described in paragraph (i)(2) of this section to each employee exposed to EtO due to the occurrence of an emergency.

(ii) The physician shall determine the frequency of any periodic examinations and recommend any additional examinations beyond those required by paragraph (i)(2) of this section, if deemed necessary, for each employee exposed the EtO because of an emergency.

(iii) The employer shall provide the examinations recommended by the physician at the frequencies determined necessary by the physician.

(6) *Information provided to the physician.* The employer shall provide the following information to the examining physician:

(i) A copy of this standard and Appendices A, B, and C;

(ii) A description of the affected employee's duties as they relate to the employee's exposure;

(iii) The employee's representative exposure level or anticipated exposure level;

(iv) A description of any personal protective equipment used or to be used; and

(v) Information from previous medical examinations of the affected employee which is not otherwise available to the examining physician.

(7) *Physician's written opinion.* (i) The employer shall obtain a written opinion from the examining physician which shall include:

(A) The physician's opinion as to whether the employee has any detected medical conditions which would place the employee at increased risk of material health impairment from exposure to EtO;

(B) Any recommended limitations on the employee's exposure to EtO or upon the use of personal protective equipment such as clothing or respirators; and

(C) A statement that employee has been informed by the physician of the results of the medical examination and any medical conditions resulting from EtO exposure which require further explanation or treatment.

(ii) The employer shall instruct the physician not to reveal in the written opinion given to the employer specific findings or diagnoses unrelated to occupational exposure.

(iii) The employer shall provide a copy of the physician's written opinion to the affected employee within 15 days from its receipt.

(j) *Employee information and training.* (1) *Training program.*

(i) The employer shall provide a training program for all employees exposed to EtO at or above the action level.

(ii) The training program shall be provided at the time of initial assignment, or upon institution of the training program, and at least annually thereafter. The employer shall assure that each employee is informed of the following:

(A) The information in the substance data sheets for EtO, which are contained in Appendices A and B;

(b) The nature of operations which could result in exposure to EtO above the PEL, inclulding potential emergency situations and any necessary protective steps;

(C) The purpose, proper use, and limitations of respirators the employee may be required to use;

(D) The purpose and a description of the medical surveillance program required by paragraph (i) of this section and the information contained in Appendix C;

(E) Emergency procedures required by paragraph (h) of this section;

(F) The proper use of engineering and work practice controls, including their functions and the employee's relationship to these controls; and

(G) The content of this standard.

(2) *Access to training materials.* (i) The employer shall make readily available to all affected employees and their representatives, without cost to the employee, a copy of this standard and its appendices and all materials relating to the employee information and training program.

(ii) All materials relating to the employee information and training program shall be provided upon request to the Assistant Secretary and the Director.

(k) *Precautionary labels and signs.* (1) *General.* (i) The employer may use labels or signs required by other statutes, regulations, or ordinances in addition to or in combination with signs and labels required by this paragraph.

(ii) The employer shall assure that no statement appears on or near any sign or label required by this paragraph which contradicts or detracts from the meaning of the required sign or label.

(2) *Labels.* (i) The employer shall assure that precautionary labels are affixed to all containers or EtO, whose contents are capable of causing employee exposure at or above the action level, and that the labels remain affixed when the containers of EtO leave the workplace. For the purposes of this paragraph, reaction vessels, storage tanks, and pipes or piping systems are not considered to be containers.

(ii) Precautionary labels shall bear at least the following legend and information:

(A) DANGER
CONTAINS ETHYLENE OXIDE
CANCER AND REPRODUCTIVE HAZARDS; and

(b) A warning statement against breathing airborne concentrations of EtO.

(iii) The labeling requirements under this section do not apply where EtO is used as a pesticide, as such term is defined in the Federal Insecticide, Fundicide, and Rodenticide Act (7 U.S.C. ss136 et seq.), when it is labeled pursuant to that Act and regulations issued under that Act by the Environmental Protection Agency;

(3) *Signs.* (i) The employer shall post and maintain legible signs demarcating regulated areas and entrances or accessways to regulated areas.

(ii) The sign shall bear the following legend:

DANGER
ETHYLENE OXIDE
CANCER AND REPRODUCTIVE HAZARD
AUTHORIZED PERSONNEL ONLY
RESPIRATORS AND PROTECTIVE CLOTHING MAY BE REQUIRED TO BE WORN IN THIS AREA

(l) *Recordkeeping.* (1) *Objective data for exempted operations.*

(i) Where the processing, use, and handling of products made from or containing EtO are exempted from other requirements of this section under paragraph (a)(2) of this section, the employer shall establish and maintain an accurate record of objective data reasonably relied upon in support of the exemption.

(ii) This record shall include at least the following information:

(A) The product qualifying for exemption;

(B) The source of the objective data;

(C) The testing protocol, results of testing, and/or analysis of the material for the release of EtO;

(D) A description of the operation exempted and how the data support the exemption; and

(E) Other data relevant to the operations, materials, and processing covered by the exemption.

(iii) The employer shall maintain this record for the duration of the employer's reliance upon such objective data.

(2) *Exposure measurements.* The employer shall keep an accurate record of all measurements taken to monitor employee exposure to EtO as prescribed in paragraph (d) of this section.

(i) This record shall include:

(A) The date of measurement;

(B) The operating involving exposure to EtO which is being monitored;

(C) Sampling and analytical methods used and evidence of their accuracy;

(D) Number, duration, and results of samples taken;

(E) Type of protective devices worn, if any; and

(F) Name, social security number and exposure of the employee monitored.

(ii) This record shall be maintained for at least thirty (30) years.

(3) *Medical surveillance.* (i) The employer shall establish and maintain an accurate record for each employee subject to medical suveillance under paragraph (i) of this section.

(ii) The record shall include:

(A) The name and social security number of the employee;

(B) Physican's written opinions;

(C) Any employee medical complaints related to exposure to EtO;

(D) The A copy of the information provided to the physican as required by paragraph (i)(6) of this section; and

(E) The results of the medical examination and tests performed.

(iii) The employer shall assure that this record is maintained for the duration of employment plus thirty (30) years.

(4) *Availability.*

(i) The employer shall make all records required to be maintained by this section available, upon written request, to the Assistant Secretary and the Director for examination and copying.

(ii) Exemption and exposure records required by paragraphs (1)(1) and (1)(2)

of this section shall be provided upon request, for examination and copying, to the affected employees, former employees, designated representatives and the Assistant Secretary.

(iii) Employee medical records required by paragraph (1)(3) of this section shall be provided upon request, for examination and copying, to the subject employee, anyone having the specific written consent of the subject employee, and the Assistant Secretary.

(iv) The employer shall provide the records required under this section in accordance with § 1910.20.

(5) *Transfer of records.* (i) When the employer ceases to do business, the employer shall transfer such records to the successor employer, who shall receive and retain all records required to be maintained by this section for the prescribed period.

(ii) Whenever the employer ceases to do business and there is no successor employer to receive and retain the records required to be maintained by this section for the prescribed period, these records shall be transmitted to the Director.

(iii) At the expiration of the retention period for the records required to be maintained by this section, the employer shall notify the Director in writing at least 3 months prior to the disposal of such records and shall transmit these records to the Director within that period, if so requested by the Director.

(iv) The employer shall also comply with any additional requirements concerning transfer of records set forth in 29 CFR 1910.20(h).

(m) *Observation of monitoring.* (1) *Employee observation.* The employer shall provide affected employees or their designated representatives an opportunity to observe any monitoring of employee exposure to EtO conducted in accordance with paragraph (d) of this section.

(2) *Observation procedures.* When observation of the monitoring of employee exposure to EtO requires entry into an area where the use of protective clothing or equipment is required, the observer shall be provided with and required to use such clothing and equipment and shall comply with all other applicable safety and health procedures.

(n) *Effective date.* This section shall become effective thirty (30) days following publication.

(o) *Appendices.* The information contained in the appendices is not intended by itself to create any additional obligations not otherwise imposed or to detract from any existing obligation.

## APPENDIX A—SUBSTANCE SAFETY DATA SHEET FOR ETHYLENE OXIDE

### I. Substance Identification

A. *Substance:* Ethylene oxide ($C_2H_4O$).

B. *Synonyms:* Anprolene, dihydrooxirene, dimethylene oxide, EO, 1,2-epoxyethane, EtO, ETO, oxacyeloropropane, oxane, oxidoethane, alpha/beta-oxidoethane, oxiran, oxirane.

C. Ethylene Oxide can be found as a liquid or vapor.

D. EtO is used in the manufacture of ethylene glycol, polyester fibers, bottles and films, sufacants, ethanolamines, glycol ethers, and other organic chemicals. EtO is also used as a sterilant and fumigant.

E. *Appearance and odor:* Colorless liquid below 10.4°C (50.7°F) or colorless gas with ether-like odor detected at 500 parts EtO per million parts of air (500 ppm).

F. *Permissible Exposure:* Exposure many not exceed 1 part EtO per million parts of air (1 ppm) averaged over the 8-hour work day.

### II. Health Hazard Data

A. Ethylene oxide can affect your body if you inhale the vapor (breathing), if it comes in contact with your eyes or skin, or if you swallow it.

B. *Effects of over exposure:*

1. *Short-term exposure:* Ethylene oxide in liquid form can cause eye irritation and injury to the cornea, frostbite, and severe irritation and blistering of the skin upon prolonged or confined contact. Ingestion of EtO can cause gastric irritation and liver injury. Acute effects from inhalation of EtO vapors include respiratory irritation and lung injury, headache, nausea, vomiting, diarrhea, dyspnea and cyanosis.

2. *Long-term-exposure:* EtO has been shown to cause cancer in laboratory animals and has been associated with higher incidences of cancer in humans. Adverse reproductive effects and chromosome damage may also occur from EtO exposure.

3. *Reporting signs and symptoms:* You should inform your employer if you develop any signs or symptoms and suspect that they are caused by exposure to EtO.

### III. Emergency First Aid Procedures

A. *Eye exposure:* If EtO gets into your eyes, wash your eyes immediately with large amounts of water, lifting the lower and upper lids occasionally. Get medical attention immediately. Contact lenses should not be worn when working with this chemical.

B. *Skin exposure:* If EtO gets on your skin, immediately wash the contaminated skin with water. If EtO soaks through your clothing, especially you shoes, remove the clothing immediately and wash the skin with water. If symptoms occur after washing, get medical attention immediately. Thoroughly wash the clothing before reusing. Contaminated leather shoes or other leather articles should be discarded.

C. *Inhalation:* If you or any other person breathes in large amounts of EtO, move the exposed person to fresh air at once. If breathing has stopped, perform artificial respiration. Keep the affected person warm and at rest. Get medical attention as soon as possible.

D. *Swallowing:* When EtO has been swallowed, give the person large quantities of water immediately. After the water has been swallowed, try to get the person to vomit by having him touch the back of his throat with his finger. Do not make an unconscious person vomit. Get medical attention immediately.

E. *Rescue:* Move the affected person from the hazardous exposure. If the exposed person has been overcome, notify someone else and put into effect the established emergency procedures. Do not become a casualty yourself. Understand your emergency rescue procedures and know the location of the equipment before the need arises.

F. *Special first aid procedures:* When a person is suspected of receiving an overexposure to EtO, immediately remove that person from the contaminated area using established rescue procedures. Contaminated clothing must be removed and the EtO washed from the skin immediately. Artificial respiration should be started at once if breathing has stopped. Medical aid should be obtained immediately

### IV. Respirators and Protective Clothing

A. *Respirators:* You may be required to wear a respirator for nonroutine activities, in emergencies, while your employer is in the process of reducing EtO exposures through engineering controls or where engineering controls are not feasible. If air-purifying respirators are worn, they must have a joint Mine Safety and Health Administration (MSHA or MESA) and National Institute for Occupational Safety and Health (NIOSH) label of approval for use with organic vapors. For effective protection, respirators must fit your face and head snugly. Respirators should not be loosened or removed in work situations where their use is required.

EtO does not have a detectable odor except at levels well above the permissible exposure limits. Do not depend on odor to warn you when a respirator canister is exhausted. Canisters must be labeled as to when they are first put into service and must be changed daily or before the end-of-service life, whichever comes first. Reuse of these may allow gradual penetration of EtO through the filter and cause exposures which you cannot detect by odor. If you can smell EtO while wearing a respirator, proceed immediately to fresh air. If you experience difficulty breathing while wearing a respirator, tell your employer.

B. *Protective clothing:* You may be required to wear impervious clothing, gloves, face shield, or other appropriate protective clothing to prevent skin contact with liquid EtO. Where protective clothing is required, your employer is required to provide clean garments to you as necessary to assume that the clothing protects you adequately.

Replace or repair impervious clothing that has developed leaks.

EtO should never be allowed to remain on the skin. clothing and shoes which are not impervious to EtO should not be allowed to become contaminated with EtO, and if they do, the clothing and shoes should be promptly removed and decontaminated. The

clothing should be laundered or discarded after the EtO is removed. Once EtO penetrates shoes or other leather articles, they should not be worn again.

C. *Eye protection:* You must wear splashproof safety goggles in areas where liquid EtO may contact your eyes. In addition, contact lenses should not be worn in areas where eye contact with EtO can occur.

**V. Precautions for Safe Use, Handling, and Storage**

A. EtO is a flammable liquid, and its vapors can easily form explosive mixtures in air.

B. EtO must be stored in tightly closed containers in a cool, well-ventilated area, away from heat, sparks, flames, strong oxidizers, strong bases, acetylide-forming metals such as copper, silver, mercury and their alloys, alkalines, and acids.

C. Sources of ignition such as smoking and open flames are prohibited wherever EtO is handled, used, or stored in a manner that could create a potential fire or explosion hazard.

D. You should use non-sparking tools when opening or closing metal containers of EtO, and containers must be bonded and grounded when pouring or transferring liquid EtO.

E. You should immediately remove any nonimpervious clothing that becomes wetted with EtO, and this clothing should not be reworn until the EtO is removed from the clothing.

F. Impervious clothing wet with liquid can be easily ignited. This clothing should be washed down with water before you remove it.

G. If your skin becomes wet with liquid, you should promptly and thoroughly wash or shower with soap or mild detergent to remove any EtO from your skin.

H. You should not keep food, beverages, or smoking materials, nor are you permitted to eat or smoke in regulated areas where EtO concentrations are above the permissible exposure limits.

I. Fire extinguishers and quick drenching facilities must be readily available, and you should know where they are and how to operate them.

J. Ask your supervisor where EtO is used in your area and for any additional plant safety and health rules.

**VI. Access to Information**

A. Each year, your employer is required to inform you of the information contained in this Substance Safety Data Sheet for EtO. In addition, your employer must instruct you in the proper work practices for using EtO emergency procedures, and the correct use of protective equipment.

B. Your employer is required to determine whether you are being exposed to EtO. You or your representative has the right to observe employee measurements and to record the results obtained. Your employer is required to inform you of your exposure. If your employer determines that you are being overexposed, he or she is required to inform you of the actions which are being taken to reduce your exposure to within permissible exposure limits.

C. Your employer is required to keep records of your exposures and medical examinations. These exposure records must be kept by the employer for at least thirty (30) years. Medical records must be kept for the period of your employment plus thirty (30) years.

D. Your employer is required to release your exposure and medical records to your physician upon your written request.

**APPENDIX B—SUBSTANCE TECHNICAL GUIDELINES FOR ETHYLENE OXIDE**

**I. Physical and Chemical Data**

*A. Substance identification*

1. *Synonyms:* Anprolene, dihydrooxirene, dimethylene oxide, EO, 1,2-epoxyethane, EtO, ETO oxacyclopropane, oxane, oxidoethane, alpha/beta-oxide ethane, oxiran, oxirane.
2. *Formula:* ($C_2H_4O$).
3. *Molecular weight:* 44.06

*B. Physical data*

1. Boiling point (760 mm hg): 10.4°C (50.7°F);
2. *Specific gravity (water = 1 at 4°):* 0.87 (at 20°C or 68°F);
3. *Vapor density (air = 1):* 1.49;
4. *Vapor pressure (at 20°C):* 1,095 mm Hg;
5. *Solubility in water:* complete;
6. *Appearance and odor:* Colorless liquid or gas (above 10.4°C or 50.7°F) with ether-like order above 500 ppm.

**II. Fire, Explosion, and Reactivity Hazard Data**

*A. Fire*

1. *Flash point:* less than 0°F (open cup)
2. *Stability:* decomposes violently at temperatures above 800°F;
3. *Flammable limits in air, percent by volume:* Lower: 3, Upper: 100
4. *Extinguishing media:* Carbon dioxide for small fires, polymer or alcohol foams for large fires;
5. *Special fire fighting procedures:* Dilution of ethylene oxide with 23 volumes of water renders it non-flammable;
6. *Unusual fire and explosion hazards:* Vapors of EtO will burn without the presence of air or other oxidizers. EtO vapors are heavier than air and may travel along the ground and be ignited by open flames or sparks at locations remote from the site at which EtO is being used.
7. For purposes of compliance with the requirements of 29 CFR 1910.106, EtO is classified as a flammable gas. For example, 7,500 ppm, approximately one-fourth of the lower flammable limit, would be considered to pose a potential fire and explosion hazard.
8. For purposes of compliance with 29 CFR 1910.157, EtO is classified as a Class B fire hazard.
9. For purpose of compliance with 29 CFR 1919.307, locations classified as hazardous due to the presence of EtO shall be Class I.

*B. Reactivity*

1. *Conditions contributing to instability:* EtO will polymerize violently if contaminated with aqueous alkalies, amines, mineral acids metal chlorides, or metal oxides. Violent decomposition will occur at temperatures above 800°F;
2. *Incompatibilities:* Alkalines and acids;
3. *Hazardous decomposition products:* Carbon monoxide and carbon dioxide.

**III. Spill, Leak, and Disposal Procedures**

*A. If EtO is spilled or leaked, the following steps should be taken:*

1. Removal all ignition sources.
2. The area should be evacuated at once and re-entered only after the area has been thoroughly ventilated and washed down with water.
3. If liquid EtO, collect for reclamation or wash down with water into process sewer system.

B. Persons not wearing protective equipment should be restricted from areas of spills or leaks until cleanup has been completed.

*C. Waste disposal methods*

Waste material shall be disposed of in a manner that is not hazardous to employees or to the general population. Spills of EtO and flushing of such spills shall be channeled for appropriate treatment or collection for disposal. They shall not be channeled directly into the sanitary sewer system. In selecting the method of waste disposal, applicable local, State, and Federal regulations should be consulted.

**IV. Monitoring and Measurement Procedures**

*A. Exposure above the Permissible Exposure Limit*

*1. Eight-hour exposure evaluation:* Measurements taken for the purpose of determining employee exposure under this section are best taken with consecutive samples covering the full shift. Air samples must be taken in the employee's breathing zone (air that would most nearly represent that inhaled by the employee.)

*2. Monitoring techniques:* The sampling and analysis under this section may be performed by collection of the EtO vapor on charcoal adsorption tubes or other composition adsorption tubes, with subsequent chemical analysis. Sampling and analysis may also be performed by instruments such as real-time continuous monitoring systems, portable direct reading instruments, or passive dosimeters. Analysis of resultant samples should be by gas chromatograph.

Appendix D lists the validated method of sampling and analysis which has been tested by OSHA for use with EtO. The employer has the obligation of selecting a monitoring method which meets the accuracy and precision requirements of the standard under his unique field conditions. The standard requires that the method of monitoring must be accurate, to a 95-percent confidence level, to plus or minus 25 percent for concentrations of EtO at 1 ppm, and to plus or minus 35 percent for concentrations at 0.5 ppm. In addition to the method described in Appendix D, there are numerous other methods available for monitoring for EtO in the workplace. Details on these other methods have been submitted by various companies to the rulemaking record, and are available at the OSHA Docket Office.

B. Since many of the duties relating to employee exposure are dependent on the

results of monitoring and measuring procedures, employers shall assure that the evaluation of employee exposures is performed by a competent industrial hygienist or other technically qualified person.

Employees shall be provided with, and required to wear appropriate protective clothing to prevent any possibility of skin contact with liquid EtO. Protective clothing shall include impermeable coveralls or similar full-body work clothing, gloves, head coverings, as appropriate to protect areas of the body which may come in contact with liquid EtO.

Employers should ascertain that the protective garments are impermeable to EtO. Non impermeable clothing and shoes should not be allowed to become contaminated with liquid EtO. If permeable clothing does become contaminated, it should be promptly removed, placed in a regulated area for removal of the EtO and not worn again until the EtO is removed. If leather footwear or other leather garments become wet from EtO they should be replaced and not worn again, due to the ability of leather to absorb EtO and hold it against the skin.

Any protective clothing which has developed leaks or is otherwise found to be defective should be repaired or replaced. Clean protective clothing should be provided to the employee as necessary to assure its protectiveness. Whenever impervious clothing becomes wet with liquid EtO, it should be washed down with water before being removed by the employee. Employees are also required to wear splash-proof safety goggles where there is any possibility of EtO contacting the eyes.

VI. Housekeeping and Hygiene Facilities

A. The workplace should be kept clean, orderly, and in a sanitary conditons. The employer should institute a leak and spill detection program for operations involving EtO in order to detect sources of fugitive EtO emissions.

B. Adequate washing facilities with hot and cold water are to be provided, and maintained in a sanitary condition. Suitable cleansing agents should also be provided to assure the effective removal of EtO from the skin.

VII. Miscellaneous Precautions

A. Store EtO in tightly closed containers in a cool, well-ventilated area and take all necessary precautions to avoid any explosion hazard.

B. High exposure to EtO can occur when transferring the liquid from one container to another.

C. Non sparking tools must be used to open and close metal containers. These containers must be effectively grounded and bonded prior to pouring.

D. Do not incinerate EtO cartridges, tanks or other containers.

E. Employers shall advise employees of all areas and operations where exposure to EtO could occur.

VIII. Common Operations

Common operations in which exposure to EtO is likely to occur include the following: Manufacture of EtO; synthesis of polyester fibers, bottles and films, surfactants, ethanolamines, glycol ethers, and specialty chemicals, and use as a fumigant and sterilant in the hospital, health product and spice industries.

APPENDIX C—MEDICAL SURVEILLANCE GUIDELINES FOR ETHYLENE OXIDE

I. Route of Entry

Inhalation.

II. Toxicology

Findings in humans and experimental animals exposed to airborne concentrations of EtO are indicative of damage to the genetic material (DNA). These include hemoglobin alkylation, unscheduled DNA synthesis, sister chromatid exchange, chromosomal aberration, and functional sperm abnormalities. Clinical evidence of adverse effects associated with exposure to EtO is present in the form of increased incidence of cancer in laboratory animals (leukemia, stomach), mutation in offspring in animals, and spontaneous abortions in animals and human populations.

Ethylene oxide in liquid form can cause eye irritation and injury to the cornea, frostbite, severe irritation, and blistering of the skin upon prolonged or confined contact. Ingestion of EtO can cause gastric irritation and liver injury. Acute effects from inhalation of EtO vapors include respiratory irritation and lung injury, headache, nausea, vomiting, diarrhea, dyspnea and cyanosis.

III. Signs and Symptoms of Acute Overexposure

Symptoms of overexposure include eye irritation, headache, nausea and vomiting, weakness, and diarrhea. Information is available to suggest that spontaneous abortions may be caused by exposure to high concentrations of EtO. Skin contact with liquid EtO, especially if prolonged or confined, can cause severe irritation and blistering. Irritation and injury to the eye can also occur from contact with liquid EtO.

IV. Surveillance and Preventive Considerations

A. As noted above, exposure to EtO has been linked to an increased incidence of leukemia, stomach cancer, chromosomal damage, and reproductive effects. It has been suggested that acute exposure to EtO is causally related to spontaneous abortion. The physician should be aware of the findings of these studies in evaluating the health of employees exposed to EtO.

Most reported acute effects of occupational exposure to EtO are due to contact with EtO in liquid phase. The liquid readily penetrates leather, and will produce blistering if clothing or footwear contaminated with EtO are not removed.

It is important for the physician to become familiar with the operating conditions in which exposure to EtO may occur. Those employees with skin diseases may not tolerate the wearing of whatever protective clothing may be necessary to protect them from exposure. In addition, those with chronic respiratory disease may not tolerate the wearing of negative-pressure respirators.

The employer is required to institute a medical surveillance program for all employees who are or will be exposed at or above the action level (0.5 parts EtO per million parts of air) for at least 30 days per year, without regard to the use of respirators.

The medical surveillance program must provide each covered employee with an opportunity for medical examination. All examinations and procedures must be performed by or under the supervision of a licensed physician and be provided without cost to the employee.

The examining physician is free to prescribe the specific tests to be included in the medical surveillance program. Information presently available to OSHA is insufficient for the Agency to justify the specification of the precise tests to be administered. Thus, it is believed that the examining physician is best qualified to make this judgment. Certain elements of an examination, however, are suggested as being appropriate by the health data regarding carcinogenic, mutagenic, and reproductive effects. These elements include the following:

(i) comprehensive medical and work histories with special emphasis directed to symptoms related to eyes, blood forming organs, lungs, nervous and reproductive systems, and skin.

(ii) comprehensive physical examination, with particular emphasis given to pulmonary, neurologic, reproductive, and ophthalomolgic systems, blood forming organs, and the skin.

(iii) complete blood count to include at least a white cell count, a differential count, hemoglobin, and hematocrit.

(iv) screening for chromosome damage.

The employer is required to make any prescribed tests available more often than specified if recommended by the examining physician.

The employer is required to provide physician recommended examinations to any employee exposed to emergency conditions. While little is known about the effects of high short-term exposures, it appears prudent to monitor such affected employees closely in light of existing health data.

The employer is required to provide the physician with the following information: a copy of this standard and its appendices; a description of the affected employee's duties as they relate to the employee exposure level; and information from the employee's previous medical examinations which is not readily available to the examining physician. Making this information available to the physician will aid in the evaluation of the employee's health in relation to assigned duties and fitness to wear personal protective equipment, when required.

The employer is required to obtain a written opinion from the examining physician containing the results of the medical examinations; the physician's opinion as to whether the employee has any detected medical conditions which would place the employee at increased risk of material impairment of his or her health from exposure to EtO any recommended restrictions upon the employee's exposure to EtO; or upon the use of protective clothing or equipment such as respirators; and a statement that the employee has been informed by the physician

of the results of the medical examination and of any medical conditions which require further explanation or treatment. This written opinion must not reveal specific findings or diagnoses unrelated to occupational exposure to EtO, and copy of the opinion must be provided to the affected employee.

The purpose in requiring examining physician to supply the employer with a written opinion is to provide the employer with a medical basis to aid in the determination of initial placement of employees and to assess the employee's ability to use protective clothing and equipment.

## APPENDIX D—SAMPLING AND ANALYTICAL METHODS FOR ETHYLENE OXIDE

There are a number of methods available for monitoring employee exposures to EtO. Most of these involve the use of charcoal tubes and sampling pumps, with analysis by gas chromatograph. The essential differences between the charcoal tube methods include, among others, the use of different desorbing solvents, the use of different lots of charcoal, and the use of different equipment for analysis of the samples.

Besides charcoal, methods using passive dosimeters, gas sampling bags, impingers, and detector tubes have been utilized for determination of EtO exposure. In addition, there are several portable gas analyzers and monitoring units, available on the open market.

This appendix contains details for the method which has been tested at the OSHA Analytical Laboratory in Salt Lake City. This does not indicate that this method is the only one which will be satisfactory. Copies of the descriptions of other methods available to OSHA are available in the rulemaking record, and may be obtained from the OSHA Docket Office. These include the Union Carbide, Dow Chemical, 3M, and DuPont methods, as well as NIOSH Method S–286.

Employers who note problems with sample breakthrough should try larger charcoal tubes. Tubes of larger capacity are available. In addition, lower flow rate and shorter sampling times should be beneficial in minimizing breakthrough problems.

Whatever method the employer chooses, he must assure himself of the method's accuracy and precision under the unique conditions present in his workplace.

### Ethylene Oxide

Method No.: 30.

Matrix: Air.

Target Concentration: 1.0 ppm (1.8 mg/m³).

Procedure: Samples are collected on two charcoal tubes in series and desorbed with 1% $CS_2$ in benzene. The samples are derivatized with HBr and treated with sodium carbonate. Analysis is done by gas chromatography with an electron capture detector.

Recommended Air Volume and Sampling Rate: 1 liter and 0.05 Lpm.

Detection Limit of the Overall Procedure: 13.3 ppb (0.024 mg/m³). (Based on 1.0 liter air sample.)

Reliable Quantitation Limit: 52.2 ppb (0.094 mg/m ³). (Based on 1.0 liter air sample.)

Standard Error of Estimate: 6.59% (see Backup Section 4.6).

Special Requirements: Samples must be analyzed within 15 days of sampling date.

Status of Method: The sampling and analytical method has been subjected to the established evaluation procedures of the Organic Methods Evaluation Branch.

Date: August, 1981.

Chemist: Wayne D. Potter, Organic Solvents Branch, OSHA Analytical Laboratory, Salt Lake City, Utah.

### 1. General Discussion

*1.1. Background*

1.1.1. History of Procedure—Ethylene oxide samples analyzed at the OSHA Laboratory have normally been collected on activated charcoal and desorbed with carbon disulfide. The analysis is performed with a gas chromatograph equipped with a FID (flame ionization detector) as described in NIOSH Method S286 (Ref. 5.1). This method is based on a PEL of 50 ppm and has a detection limit of about 1 ppm.

Recent studies have prompted the need for a method to analyze and detect ethylene oxide at very low concentrations (See Toxic Effects 1.1.2.).

Several attempts were made to form an ultraviolet (UV) sensitive derivative with ethylene oxide for analysis with HPLC. Among those tested that gave no detectable product were: p-anisidine, methylimidazole, aniline, and 2,3,6-trichlorobenzoic acid. Each was tested with catalysts such as triethylamine, aluminum chloride, methylene, chloride and sulfuric acid but no detectable derivative was produced.

The next derivatization attempt was to react ethylene oxide with HBr to form 2-bromoethanol. This reaction was successful. An ECD (electron capture detector) gave a very good response for 2-bromoethanol due to the presence of bromine. The use of carbon disulfide as the desorbing solvent gave too large a response and masked the 2-bromoethanol. Several other solvents were tested for both their response on the ECD and their ability to desorb ethylene oxide from the charcoal. Among those tested were toluene, xylene, ethyl benzene, hexane, cyclohexane and benzene. Benzene was the only solvent tested that gave a suitable response on the ECD and a high desorption. It was found that the desorption efficiency was improved by using 1% $CS_2$ with the benzene. The carbon disulfide did not significantly improve the recovery with the other solvents. SKC Lot 120 was used in all tests done with activated charcoal.

1.1.2 Physical Properties (Ref. 5.4.–5.6.)

Synonyms: oxirane; dimethylene oxide; 1,2-epoxy ethane; oxane; $C_2H_4O$; ETO;

Molecular Weight: 44.06

Boiling Point: 10.7° C

Melting Point: −111° C

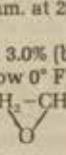
Description: Colorless, flammable gas

Vapor Pressure: 1095 mm. at 20° C

Odor: Ether-like odor

Lower Explosive Limit: 3.0% (by volume)

Flash Point (TOC): Below 0° F

Molecular Structure: 

*1.2 Limit Defining Parameters*

1.2.1. Detection Limit of the Analytical Procedure—The detection limit of the analytical procedure is 12.0 picograms of ethylene oxide per injection. This is the amount of analyte which will give a peak whose height is five times the height of the baseline noise. (See Backup Data Section 4.1 and Figure 4.1).

1.2.2 Detection Limit of the Overall Procedure—The detection limit of the overall procedure is 24.O ng of ethylene oxide per sample (13.3ppb/.024mg/m³). This is the amount of analyte spiked on the sampling device which allows recovery of an amount of analyte equivalent to the detection limit of the analytical procedure

1.2.3. Reliable Quantitation Limit—The reliable quantitation limit is 94.0 nanograms of ethylene oxide per sample (52.2 ppb/0.094 mg/m³). This is the smallest amount of analyte which can be quantitated within the requirements of 75% recovery and 95% confidence limits of ± 25%.

It must be recognized that the reliable quantitation limit and detection limits reported in the method are based upon optimization of the instrument for the smallest possible amount of analyte. When the target concentration of an analyte is exceptionally higher than these limits, they may not be attainable at the routine operating parameters. In this case, the limits reported on analyis reports will be based on the operating parameters used during the analysis of the samples.

1.2.4. Sensitivity—The sensitivity of the analytical procedure over a concentration range representing 0.5 to 2 times the target concentration based on the recommended air volume is 34105 area units per μg/mL. The sensitivity is determined by the slope of the calibration curve (See Backup Data Section 4.3). The sensitivity will vafy somewhat with the particular instrument used in the analysis.

1.2.5. Recovery—The recovery of analyte from the collection medium must be 75% or greater. The average recovery from spiked samples over the range of 0.5 to 2 times the target concentration is 88.0% (See backup Section Table 4.4.). At lower concentrations the recovery appears to be non-linear.

1.2.6. Precision (Analytical Method Only)—The pooled coefficient of variation obtained from replicate determination of analytical standards at 0.5X, 1X and 2X the target concentration is 0.036 (See Backup Data Section 4.5.).

1.2.7. Precision (Overall Procedure)—The overall procedure must provide results at the target concentration that are ±25% or better at the 95% confidence level. The precision at the 95% confidence level for the 15 day storage test is ±14.8% (See Backup Data Section 4.6.). This includes an additional ±5% for sampling error.

*1.3. Advantages*

1.3.1. The sampling procedure is convenient.

1.3.2. The analytical procedure is very sensitive and reproducible.

1.3.3. Reanalysis of samples is possible.

1.3.4. Samples are stable for at least 15 days at room temperature.

1.3.5 Interferences are reduced by the longer GC retention time of the new derivative.

*1.4. Disadvantages*

1.4.1. Two tubes in series must be used because of possible breakthrough.

1.4.2. The precision of the sampling rate may be limited by the reproducibility of the pressure drop across the tubes. The pumps are usually calibrated for one tube only.

1.4.3. The use of benzene as the desorption solvent increases the hazards of analysis because of the potential carcinogenic effects of benzene.

1.4.4. After repeated injections there can be a buildup of residue formed on the electron capture detector which decreases sensitivity.

1.4.5. Recovery from the charcoal tubes appears to be nonlinear at low concentrations.

**2. Sampling Procedure**

*2.1. Apparatus*

2.1.1. A calibrated personal sampling pump whose flow can be determined with ±5% of the recommended flow.

2.1.2. SKC Lot 120 Charcoal tubes: glass tube with both ends flame sealed, 7 cm long with a 6 mm O.D. and a 4-mm I.D., containing 2 sections of coconut shell charcoal separated by a 2-mm portion of urethane foam. The adsorbing section contains 100 mg of charcoal, the backup section 50 mg. A 3-mm portion of urethane foam is placed between the outlet end of the tube and the backup section. A plug of silylated glass wool is placed in front of the adsorbing section.

*2.2. Reagents*

2.2.1. None required.

*2.3. Sampling Technique*

2.3.1. Immediately before sampling, break the ends of the charcoal tubes. All tubes must be from the same lot.

2.3.2. Connect two tubes in series to the sampling pump with a short section of flexible tubing. A minimum amount of tubing is used to connect the two sampling tubes together. The tube closer to the pump is used as a backup. This tube should be identified as the backup tube.

2.3.3. The tubes should be placed in a vertical position during sampling to minimize channeling.

2.3.4. Air being sampled should not pass through any hose or tubing before entering the charcoal tubes.

2.3.5. Seal the charcoal tubes with plastic caps immediately after sampling. Also, seal each sample with OSHA sealing tape lengthwise.

2.3.6. With each batch of samples, submit at least one blank tube from the same lot used for samples. This tube should be subjected to exactly the same handling as the samples (break, seal, transport) except that no air is drawn through it.

2.3.7. Transport the samples (and corresponding paperwork) to the lab for analysis.

2.3.8. If bulk samples are submitted for analysis, they should be transported in glass containers with Teflon-lined caps. These samples must be mailed separately from the container used for the charcoal tubes.

*2.4. Breakthrough*

2.4.1. The breakthrough (5% breakthrough) volume for a 3.0 mg/m $^3$ ethylene oxide sample stream at approximately 85% relative humidity, 22° C and 633 mm is 2.6 liters sampled at 0.05 liters per minute. This is equivalent to 7.8 μg of ethylene oxide. Upon saturation of the tube it appeared that the water may be displacing ethylene oxide during sampling

*2.5. Desorption Efficiency*

2.5.1. The desorption efficiency, from liquid injection onto charcoal tubes, averaged 88.0% from 0.5 to 2.0 X the target concentration for a 1.0 liter air sample. At lower ranges it appears that the desorption efficiency is nonlinear (See Backup Data Section 4.2.).

2.5.2. The desorption efficiency may vary from one laboratory to another and also from one lot of charcoal to another. Thus, it is necessary to determine the desorption efficiency for a particular lot of charcoal.

*2.6. Recommended Air Volume and Sampling Rate*

2.6.1. The recommended air volume is 1.0 liter.

2.6.2. The recommended maximum sampling rate is 0.05 Lpm.

*2.7. Interferences*

2.7.1. Ethylene glycol and Freon 12 at target concentration levels did not interfere with the collection of ethylene oxide.

2.7.2. Suspected interferences should be listed on the sample data sheets.

2.7.3. The relative humidity may effect the sampling procedure.

*2.8. Safety Precautions*

2.8.1. Attach the sampling equipment to the employee so that it does not interfere with work performance.

2.8.2. Wear safety glasses when breaking the ends of the sampling tubes.

2.8.3. If possible, place the sampling tubes in a holder so the sharp end is not exposed while sampling.

**3. Analytical Method**

*3.1. Apparatus*

3.1.1. Gas chromatograph equipped with a linearized electron capture detector.

3.1.2. GC column capable of separating the derivative of ethylene oxide (2-bromoethanol) from any interferences and the 1% $CS_2$ in benzene solvent. The column used for validation studies was: 10 ft x ⅛ inch stainless steel 20% SP-2100, .1% Carbowax 1500 on 100/120 Supelcoport.

3.1.3. An electronic integrator or some other suitable method of measuring peak areas.

3.1.4. Two milliliter vials with Teflon-lined caps.

3.1.5. Gas tight syringe—500 uL or other convenient sizes for preparing standards.

3.1.6. Microliter syringes—10 uL or other convenient sizes for diluting standards and 1 uL for sample injections.

3.1.7. Pipets for dispensing the 1% $CS_2$ in benzene solvent. The Glenco 1 mL dispenser is adequate and convenient.

3.1.8. Volumetric flasks—5 mL and other convenient sizes for preparing standards.

3.1.9. Disposable Pasteur pipets.

*3.2. Reagents*

3.2.1. Benzene, reagent grade.

3.2.2. Carbon Disulfide, reagent grade.

3.2.3. Ethylene oxide, 99.7% pure.

3.2.4. Hydrobromic Acid, 48% reagent grade.

3.2.5. Sodium Carbonate, anhydrous, reagent grade.

3.2.6. Desorbing reagent, 99% Benzene/1% $CS_2$.

*3.3. Sample Preparation*

3.3.1. The front and back sections of each sample are transferred to separate 2-mL vials.

3.3.2. Each sample is desorbed with 1.0 mL of desorbing reagent.

3.3.3. The vials are sealed immediately and allowed to desorb for one hour with occasional shaking.

3.3.4. Desorbing reagent is drawn off the charcoal with a disposable pipet and put into clean 2-mL vials.

3.3.5. One drop of HBr is added to each vial. Vials are resealed and HBr is mixed well with the desorbing reagent.

3.3.6. About 0.15 gram of sodium carbonate is carefully added to each vial. Vials are again are resealed and mixed well.

*3.4. Standard Preparation*

3.4.1. Standards are prepared by injecting the pure ethylene oxide gas into the desorbing reagent.

3.4.2. A range of standards ar prepared to make a calibration curve. A concentration of 1.0 μL of ethylene oxide gas per 1 mL desorbing reagent is equivalent to 1.0 ppm air concentration (all gas volumes at 25°C and 760 mm) for the recommended 1 liter air sample. This amount is uncorrected for desorption efficiency (see Backup Data Section 4.2. for desorption efficiency corrections).

3.4.3. One drop of HBr per mL of standard is added and mixed well.

3.4.4. About 0.15 grams of sodium carbonate is carefully added for each drop of HBr. (A small reaction will occur).

*3.5. Analysis*

3.5.1. GC Conditions
Nitrogen flow rate—10 mL/min.
Injector Temperature—250°C
Detector Temperature—300°C
Column Temperature—100°C
Injection size—0.8 μL
Elution time—3.9 minutes

3.5.2. Peak areas are measured by an integrator or other suitable means.

3.5.3. The integrator results are in area units and a calibration curve is set up with concentration vs. area units.

*3.6. Interferences*

3.6.1. Any compound having the same retention time of 2-bromoethanol is a potential interference. Possible interferences should be listed on the sample data sheets.

3.6.2. GC parameters may be changed to circumvent interferences.

3.6.3. There are usually trace contaminants in benzene. These contaminants, however, posed no problem of interference.

3.6.4. Retention time data on a single column is not considered proof of chemical

identity. Samples over the 1.0 ppm target level should be confirmed by GC/Mass Spec or other suitable means.

*Calculations*

3.7.1. The concentration in ug/mL for a sample is determined by comparing the area of a particular sample to the calibration curve, which has been prepared from analytical standards.

3.7.2. The amount of analyte in each sample is corrected for desorption efficiency by use of a desorption curve.

3.7.3. Analytical results (A) from the two tubes that compose a particular air sample are added together.

3.7.5. The concentration for a sample is calculated by the following equation:

$$\text{ETO, ppm} = \frac{AXB}{C}$$

Where:
A = ug/mL
B = desportion volume in milliliters
C = air volume in liters.

3.7.6. To convert mg/m³ to parts per million (ppm) the following relationship is used:

$$\text{ETO, ppm} = \frac{\text{mg/m}^3 \times 24.45}{44.05}$$

where:
mg/m³ = results from 3.7.5.
24.45 = molar volume at 25°C and 760 mm Hg.
44.05 = molecular weight of ETO

*3.8. Safety Precautions*

3.8.1. Ethylene oxide and benzene are potential carcinogens and care must be exercised when working with these compounds.

3.8.2. All work done with the solvents (preparation of standards, desorption of samples, etc.) should be done in a hood.

3.8.3. Avoid any skin contact with all of the solvents.

3.8.4. Wear safety glasses at all times.

3.8.5. Avoid skin contact with HBr because it is highly toxic and a strong irritant to eyes and skin.

**4. Backup Data**

*4.1. Detection Limit Data*

The detection limit was determined by injecting 0.8 µL of a 0.015 µL standard of ethylene oxide into 1% $CS_2$ in benzene. The detection limit of the analytical procedure is taken to be $1.20 \times 10^{-3}$ µg per injection. This is equivalent to 8.3 ppb (0.015 mg/m³) for the recommended air volume.

*4.2. Desorption Efficiency*

Ethylene oxide was spiked onto charcoal tubes and the following recovery data was obtained.

| Amount spiked (µg) | Amount recovered (µg) | Percent recovery |
|---|---|---|
| 4.5 | 4.32 | 96.0 |
| 3.0 | 2.61 | 87.0 |
| 2.25 | 2.025 | 90.0 |
| 1.5 | 1.365 | 91.0 |
| 1.5 | 1.38 | 92.0 |
| .75 | .6525 | 87.0 |
| .375 | .315 | 84.0 |
| .375 | .312 | 83.2 |
| .1875 | .151 | 80.5 |
| .094 | .070 | 74.5 |

At lower amounts the recovery appears to be non-linear.

*4.3. Sensitivity Data*

The following data was used to determine the calibration curve.

| Injection | 0.5 × .75 µg/mL | 1 × 1.5 µg/mL | 2 × 3.0 µg/mL |
|---|---|---|---|
| 1 | 30904 | 59567 | 111778 |
| 2 | 30987 | 62914 | 106016 |
| 3 | 32555 | 58578 | 106122 |
| 4 | 32242 | 57173 | 109716 |
| X | 31672 | 59558 | 108408 |

Slope = 34,105.

*4.4. Recovery*

The recovery was determined by spiking ethylene oxide onto lot 120 charcoal tubes and desorbing with 1% $CS_2$ in benzene. Recoveries were done at 0.5, 1.0, and 2.0 × the target concentration (1 ppm) for the recommended air volume.

PERCENT RECOVERY

| Sample | 0.5 × | 1.0 × | 2.0 × |
|---|---|---|---|
| 1 | 88.7 | 95.0 | 91.7 |
| 2 | 83.8 | 95.0 | 87.3 |
| 3 | 84.2 | 91.0 | 86.0 |
| 4 | 88.0 | 91.0 | 83.0 |
| 5 | 88.0 | 86.0 | |
| | | 85.0 | |
| X | 86.5 | 90.5 | 87.0 |

Weighted average = 88.2.

*4.5. Precision of the Analytical Procedure*

The following data was used to determine the precision of the analytical method:

| | 0.5 × | 1 × | 2 × |
|---|---|---|---|
| Concentration | [1].75 | [1] 1.5 | [1] 3.0 |
| Injection | .7421 | 1.4899 | 3.1184 |
| | .7441 | 1.5826 | 3.0447 |
| | .7831 | 1.4628 | 2.9149 |
| | .7753 | 1.4244 | 2.9185 |
| Average | .7612 | 1.4899 | 2.9991 |
| Standard Deviation | .0211 | .0674 | .0998 |
| CV | 0277 | .0452 | .0333 |

[1] Microgram per milliliter.

$$\overline{CV} = \sqrt{\frac{3[.0277)^2 + 3[.0452)^2 + 3[.0333)^2}{3+3+3}}$$

$$\overline{CV} = 0.036$$

*4.6. Storage Data*

Samples were generated at 1.5 mg/m³ ethylene oxide at 85% relative humidity, 22°C and 633 mm. All samples were taken for 20 minutes at 0.05 Lpm. Six samples were analyzed as soon as possible and fifteen samples were stored at refrigerated (5°C) and fifteen samples were stored at ambient temperature (23°C). These stored samples were analyzed over a period of nineteen days.

PERCENT RECOVERY

| Day analyzed | Refrigerated | Ambient |
|---|---|---|
| 1 | 87.0 | 87.0 |
| 1 | 93.0 | 93.0 |
| 1 | 94.0 | 94.0 |
| 1 | 92.0 | 92.0 |
| 4 | 92.0 | 91.0 |
| 4 | 93.0 | 88.0 |
| 4 | 91.0 | 89.0 |
| 6 | 92.0 | |
| 6 | 92.0 | |
| 8 | | 92.0 |
| 8 | | 86.0 |
| 10 | 91.7 | |
| 10 | 95.5 | |
| 10 | 95.7 | |
| 11 | | 90.0 |
| 11 | | 82.0 |
| 13 | 78.0 | |
| 13 | 81.4 | |
| 13 | 82.4 | |
| 14 | | 78.5 |
| 14 | | 72.1 |
| 18 | 66.0 | |
| 18 | 68.0 | |
| 19 | | 64.0 |
| 19 | | 77.0 |

*4.7. Breakthrough Data*

Breakthrough studies were done at 2 ppm (3.6 mg/m³) at approximately 85% relative humidity and 22°C (ambient temperature). Two charcoal tubes were used in series. The backup tube was changed every 10 minutes and analyzed for breakthrough. The flow rate was 0.050 Lpm.

| Tube No. | Time (min.) | Percent breakthrough |
|---|---|---|
| 1 | 10 | [1] |
| 2 | 20 | [1] |
| 3 | 30 | [1] |
| 4 | 40 | 1.23 |
| 5 | 50 | 3.46 |
| 6 | 60 | 18.71 |
| 7 | 70 | 39.2 |
| 8 | 80 | 53.3 |
| 9 | 90 | 72.0 |
| 10 | 100 | 96.0 |
| 11 | 110 | 113.0 |
| 12 | 120 | 133.9 |

[1] None.

The 5% breakthrough volume was reached when 2.6 liters of test atmosphere were drawn through the charcoal tubes.

5. References

5.1. "NIOSH Manual of Analytical Methods", 2nd ed. NIOSH: Cincinnati, 1977; Method S286.

5.2. Hine, C. H., and Rowe, V. K. In "Industrial Hygiene and Toxicology", 2nd ed.; Patty, F. A., Fassett, D. W., and Irish, D. D., Eds.; Interscience Publishers: New York, 1963; Vol. II, p. 1627.

5.3. "Current Intelligence Bulletin 33: Ethylene Oxide" NIOSH, May 1981.

5.4. "IARC Monographs on the Evaluation of Carcinogenic Risk of Chemicals to Man", International Agency for Research on Cancer: Lyon, 1976; Vol. II, p. 157.

5.5. Sax., N. I. "Dangerous Properties of Industrial Materials", 4th ed.; Van Nostrand Reinhold Company, New York, 1975; p. 741

5.6. "The Condensed Chemical Dictionary", 9th ed.; Hawley, G. G., ed.; Van Nostrand Reinhold Company, New York, 1977; p. 361.

[FR Doc. 83-10553 Filed 4-18-83; 9:32 am]

BILLING CODE 4510-26-M

federal register

Thursday
April 21, 1983

Part IV

# Department of Agriculture

## Animal and Plant Health Inspection Service

## Citrus Canker; Imported From Mexico

**DEPARTMENT OF AGRICULTURE**

**Animal and Plant Health Inspection Service**

**7 CFR Part 319**

**[Docket No. 83-317]**

## Citrus Canker; Imported from Mexico

**AGENCY:** Animal and Plant Health Inspection Service, USDA.

**ACTION:** Amendment to interim rule.

**SUMMARY:** This document amends the "Citrus Canker—Mexico" interim regulations to allow any importer to import restricted articles for movement to and use in certain northern parts of Louisiana and Texas in accordance with certain conditions, and to allow restricted articles to be culled and repacked under certain conditions in restricted areas in Texas. This action is warranted in order to lessen unnecessary restrictions with respect to restricted articles.

**EFFECTIVE DATE:** April 21, 1983.

**FOR FURTHER INFORMATION CONTACT:** Frank Cooper, Staff Officer, Regulatory Services Staff, Plant Protection and Quarantine, APHIS, USDA, Room 637 Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782; 301-436-8248.

Stephen Poe, Plant Pathologist, Emergency Programs, Plant Protection and Quarantine, APHIS, USDA, Room 609 Federal Building, Hyattsville, MD 20782; 301-436-6365.

**SUPPLEMENTARY INFORMATION:**

### Background

This document amends the "Citrus Canker—Mexico" interim regulations (contained in 7 CFR 319.27 *et seq.* and referred to below as the regulations) based on a proposal published in the **Federal Register** on March 10, 1983 (48 FR 10286-10289).

The regulations were initially established on November 17, 1982, by a document published in the **Federal Register** on the same day (47 FR 51723-51729). The regulations were changed effective November 17, 1982, and this was announced in the **Federal Register** on December 2, 1982 (47 FR 54273-54275). The regulations were further changed effective January 20, 1983, by a document published in the **Federal Register** on January 5, 1983 (48 FR 387-393).

The document of March 10 proposed to amend the regulations further to allow any importer to import restricted articles for movement to and use in certain northern parts of Louisiana and Texas in accordance with certain conditions and to allow restricted articles to be culled and repacked under certain conditions in restricted areas in Texas. Based on the rationale set forth in this document and the proposal of March 10, the proposed amendments are adopted except as explained below.

The regulations were established to protect against the introduction of citrus canker disease, which is caused by the infectious bacterium *Xanthomonas campestris* pv. *citri* (Hasse 1915) Dye 1976. This was necessary because of the finding of citrus canker disease in the State of Colima and in the municipio of Coahuayana in the State of Michoacan in Mexico (these areas are referred to below as infected areas).

The regulations provide that any fruit or peel of Mexican lime *(Citrus aurantifolia)* from any area in Mexico, and any other fruit or peel of citrus or citrus relatives (fruit or peel of any genera, species, or varieties of the subfamilies Aurantioideae, Rutoideae, and Toddalioideae of the botanical family Rutaceae) from infected areas in Mexico offered for importation into the United States will be refused imporation unless imported by the U.S. Department of Agriculture for experimental or scientific purposes under certain conditions.

The regulations also designate as restricted articles fruit or peel of ethrog (*Citrus medica),* grapefruit (*Citrus paradisi),* lemon (*Citrus limon),* orange (*Citrus sinensis),* Persian lime (*Citrus latifolia),* and tangerine (*Citrus reticulata)* from uninfected areas in Mexico. Under the regulations any restricted article is allowed to be imported into the United States by the U.S. Department of Agriculture for experimental or scientific purposes under certain conditions and is allowed to be imported by any importer if imported in accordance with certain conditions.

### Movement to and Use in Louisiana and Texas

Previously, the regulations provided that a restricted article may be imported only for movement to and use in locations other than Arizona, California, Florida, Hawaii, Louisiana, Puerto Rico, Texas, or the Virgin Islands of the United States. This document amends these provisions to allow restricted articles to be moved to and used in any part of Louisiana not included in that part of Louisiana more than 15 miles south of Interstate Highway 20 and to allow restricted articles to be moved to and used in any part of Texas not included in that part of Texas more than 15 miles south of the direct route from the Louisiana border to the New Mexico border beginning on Interstate Highway 20 and continuing on Interstate Highway 10.

Previously, the regulations also required that a restricted article bear on the outer container the statement "Not to be distributed within Arizona, California, Florida, Hawaii, Louisiana, Puerto Rico, Texas, or the Virgin Islands of the United States." Therefore, in accordance with the amendment to allow restricted articles to be moved to and used in parts of Louisiana and Texas, the regulations are also amended to change the required statement to read "Not to be distributed within Arizona, California, Florida, Hawaii, any part of Louisiana more than 15 miles south of Interstate Highway 20, Puerto Rico, any part of Texas more than 15 miles south of the direct route from the Louisiana border to the New Mexico border beginning on Interstate Highway 20 and continuing on Interstate Highway 10, or the Virgin Islands of the United States."

In addition, the regulations previously provided that a restricted article may be moved from the port of entry to locations other than Arizona, California, Florida, Hawaii, Louisiana, Puerto Rico, Texas or the Virgin Islands of the United States only pursuant to a restricted destination permit issued by an inspector. Therefore, in accordance with the proposed provisions explained above, the regulations are amended to provide that a restricted destination permit also may be issued for movement to locations in the northern parts of Louisiana and Texas decribed above.

Further, the regulations are amended to allow restricted articles to be moved from the port of entry to a wholesale or chain store distributor in the specified parts of northern Louisiana and Texas only if the distributor is operating under a valid compliance agreement whereby the distributor agrees not to reship the restricted articles to areas where they would not be eligible for distribution and use, and agrees not to reship restricted articles to any other wholesale or chain store distributor in a restricted area not operating under such a compliance agreement. Also, the regulations are amended to establish due process requirements for the withdrawal of such compliance agreements for noncompliance with the

regulations or any conditions imposed pursuant thereto.

**Culling and Repacking**

Previously, the regulations only allowed restricted articles to move from the port of entry to destination and did not allow restricted articles to be culled and repacked in the restricted areas where they would not be eligible for distribution and use.

This document amends the regulations to allow culling and repacking in restricted areas in Texas only if conducted pursuant to a compliance agreement between Plant Protection and Quarantine (the unit of the animal and Plant Health Inspection Service responsible for administering the regulations) and the person conducting the culling and repacking whereby it is agreed that these activities would be conducted under the following conditions:

(1) The culling and repacking, and any related activities would be subject to monitoring by inspectors;

(2) the culling and repacking would be conducted only under conditions found by an inspector as adequate to assure that the restricted articles would not be commingled with nonrestricted articles and would remain identifiable as restricted articles during such activities (i.e., restricted articles must be separated by partition, the equipment used for culling restricted articles may not be used for processing nonrestricted articles until all restricted articles which have been culled by the equipment have been repacked for distribution or put in containers for disposal);

(3) any water used on restricted articles would contain at least 200 parts per million active chlorine;

(4) the outer containers of the repacked restricted articles would plainly and correctly bear the general nature and quantity of the contents, the country or locality of origin, the name and address of repacker, the name and address of consignee, and the statement "Not to be distributed within Arizona, California, Florida, Hawaii, any part of Louisiana more than 15 miles south of Interstate Highway 20, Puerto Rico, any part of Texas more than 15 miles south of the direct route from the Louisiana border to the New Mexico border beginning on Interstate Highway 20 and continuing on Interstate Highway 10, or the Virgin Islands of the United States"; and

(5) any restricted articles taken out of their containers and not repacked for distribution and use in areas where they are elegible for distribution and use must be disposed of daily by returning them to Mexico, or be disposed of daily by incineration or burial in a landfill (the incinerator or landfill must have equipment and use procedures that are determined by the Deputy administrator to be adequate to prevent the dissemination of citrus canker disease and be certified by the responsible State or local official as currently complying with the applicable laws for environmental protection; the incinerator or landfill must also have sufficient fencing and be managed in such a way as to effectively prevent human scavenging); any restricted articles held or moved for disposal must be held or moved in covered containers adequate to prevent spillage of the articles and marked so as to identify them as culled restricted articles; and the return of restricted articles to Mexico and any movements of restricted articles to incinerators or landfills must be made only by persons conducting culling and repacking operations under a compliance agreement.

Also, the regulations are amended to establish due process requirements for the withdrawal of such compliance agreements for noncompliance with the regulations or any specified conditions imposed pursuant thereto.

**Miscellaneous**

In order to make the regulations more easily understood, the regulations are also amended to define the areas where restricted articles are not allowed to be distributed and used as "restricted areas" and to make certain other nonsubstantive editorial changes in the regulations.

**Comments**

The document of March 10, 1983, invited the submission of written comments on or before March 30, 1983. Pursuant to requests from fruit and vegetable associations, the comment period was reopened on April 1, 1983 and extended to April 11, 1983. Also, in accordance with the document of March 10, a public hearing concerning the proposal was held in McAllen, Texas on March 24, 1983.

Many of the comments received were fully or partially in favor of the proposed provisions; however, many of the comments opposed the proposed provisions in one or more respects and are discussed below.

Commenters asserted that the boundaries separating restricted areas in Louisiana and Texas from nonrestricted areas in these States are unclear and that it could be difficult to determine precisely where the boundary line is. Further, it was asserted that the boundaries should be clearly identified and demarcated on the ground, such as State boundaries or highways. No changes are made based on these comments. The highways described above are easily identifiable, and it should not be difficult to determine whether a location is less than or more than 15 miles south from the highways. Further, it is obvious that locating the boundary 15 miles south of the highways helps make the boundary more workable in that major urban areas would not be divided by the boundary line.

Commenters asserted that the boundary line to separate restricted areas in Louisiana and Texas from nonrestricted areas in these States should be Interstate Highway 10, and that this highway which runs from Florida to California should separate the restricted areas from nonrestricted areas for all of the United States. No changes are made based on these comments. The boundary lines in Louisiana and Texas were proposed in part because they are at least one hundred fifty miles from areas in Louisiana and Texas where citrus or citrus relatives are grown in significant amounts. This was intended to provide protection against shoppers purchasing restricted articles in areas where restricted articles are allowed and taking the articles back home to restricted areas. Using Interstate Highway 10 as the boundary line in Louisiana or Texas would not provide the same degree of protection because Interstate Highway 10 in some places runs through areas in which citrus is grown and in other places runs through areas within 30 miles of commercial citrus growing areas. Further, Interstate Highway 10 runs through citrus growing areas in Arizona, California, and Florida.

Commenters asserted that the proposal would not be adequate to regulate chain store distributors from moving restricted articles from nonrestricted areas in northern Louisiana and Texas into restricted areas in these States. It was intended that business entities that are in the business of reshipping fruit from restricted areas in Louisiana and Texas should be subject to special requirements in order to keep restricted articles from being reshipped to restricted areas. In this connection, the proposal contained special requirements for wholesale distributors. It was proposed that restricted articles be allowed to be moved from the port of entry to wholesale distributors in nonrestricted areas of northern Louisiana and Texas only if the wholesale distributor is operating under

a valid compliance agreement whereby the wholesale distributor agrees not to reship the restricted articles to areas where they would not be eligible for distribution and use, and agrees not to reship restricted articles to any other wholesale distributor in a restricted area not operating under such a compliance agreement. Since chain store distributors are also in the business of reshipping fruit it has been determined that these compliance agreement requirements should also apply to chain store distributors. Therefore, the provisions are changed accordingly.

Commenters asserted that sufficient personnel and resources are not available to ensure that tourists will not carry restricted articles from nonrestricted areas to restricted areas. No changes are made based on these comments. The regulations are designed to provide protection against the movement of restricted articles into restricted areas by shoppers and commercial distributors. There may be some risk that tourists might carry restricted articles into restricted areas. However, as fully explained in the January 5 document it is extremely unlikely that these restricted articles would cause citrus canker disease to become established (48 FR 389). Further, it appears that amounts of citrus taken to restricted areas by tourists would be negligible. Because of the well known availability of commercially produced fresh citrus in the restricted areas, tourists visiting these restricted areas would likely wait until they arrive in the restricted area before purchasing citrus.

One commenter opposed allowing restricted articles to be imported into the specified northern areas of Louisiana and Texas because of the possibility that "dooryard, homeowner" citrus is grown in these areas. No changes are made based on this comment. "Dooryard, homeowner" citrus is not grown in these areas. Typical winter temperatures in these areas reach below 20° F. All citrus species are subtropical and cannot be grown where winter temperatures routinely fall below 28° F. for more than a period of several hours.

Commenters asserted that the proposal to allow culling and repacking of restricted articles in restricted areas should be withdrawn because no request was made in writing in this regard and because no Rio Grande Valley packers presented testimony at the hearing for the need to allow culling and repacking in restricted areas. Additionally an official of the Texas State Department of Agriculture requested that the Department reconsider its proposal to allow culling and repacking of restricted articles in restricted areas because no Rio Grande Valley producers presented testimony at the hearing for the need to repack. No changes are made based on these comments. Several fruit packers from the Rio Grande Valley made such requests by telephone prior to the rulemaking proceeding. Further, many written comments from fruit packers received after the hearing supported this portion of the proposal.

One commenter questioned whether city garbage services could be depended upon for timely pickup and disposal of culled articles. It was intended that only the persons conducting the culling and repacking activities under a compliance agreement would be allowed to transport the culls for disposal. This is necessary in order to assure that persons moving the culled articles understand and agree to comply with the culling and repacking requirements which require timely disposal. Accordingly, the provisions are clarified in this respect.

Commenters asserted that culled articles should not be allowed to be disposed of at landfills because of possible sources of contamination by human scavengers at the dump site, and by birds or insects. No changes are made because of birds or insects since birds and insects that would be present at such landfills are not attracted to citrus fruit. Further, as fully explained in the January 5 document it is extremely unlikely that these culled restricted articles would cause citrus canker disease to become established (48 FR 389). However, it does appear that without precautions it would be possible for human scavengers to remove culled articles from incinerators or landfills. Accordingly, the provisions are amended to specify that incinerators or landfills must have sufficient fencing and be managed in such a way as to effectively prevent human scavenging.

One commenter asserted that disposal facilities might not be able to meet the requirements for the disposal of culled articles. No changes are made based on this comment. The regulations provide for culled articles to be disposed of by incineration or burial at a facility that has equipment and procedures that are determined by the Deputy Administrator to be adequate to prevent the dissemination of citrus canker disease and certified by the responsible State or local official as currently complying with the applicable laws for environmental protection. As explained above the regulations also provide that landfills must be fenced and managed in such a way as to effectively prevent human scavenging. APHIS agrees that some facilities may not meet these requirements. However, unless a facility meets these requirements it would not be authorized to be used for disposal of culled articles.

Commenters asserted that the provisions concerning culling and repacking should contain additional provisions to require decontamination of individuals, clothing, equipment, containers, and packages involved in the culling and repacking process. No changes are made based on these comments. As a condition of importation restricted articles are required to be treated to destroy any surface contamination by citrus canker bacteria. However, there is a possibility that the articles could contain citrus canker bacteria in pores or wounds of the fruit. Any bacteria trapped in the pores or wounds would be in extremely small numbers. Further the survival time for bacteria on individuals, clothing, equipment, containers, or packages would be very short, and therefore APHIS believes that new infections would not be caused by these means. In addition, bacteria released from wounds or pores of fruit would likely result from openings in the skin of the fruit sufficient to release juice, the natural acid of which will quickly kill the bacteria.

One commenter asserted that water provides an almost ideal medium for transmitting citrus canker bacteria from fruit to fruit, and that washing fruit during the culling and repacking process could spread bacteria from restricted articles destined for distribution in citrus producing areas. As a condition of movement into the United States from the port of entry, restricted articles are required to have been thoroughly wetted with a solution containing at least 200 parts per million active chlorine for a period of at least two minutes. This treatment is adequate to destroy any surface contamination of citrus canker bacteria. However, in order to destroy any bacteria from wounds or pores that might be released during any additional washing during the culling and repacking process, it has been determined that such water must contain at least 200 parts per million active chlorine. Therefore, the interim rule is amended accordingly.

Commenters asserted that restricted articles stored in restricted areas might contaminate other articles stored nearby. No changes are made based on these comments. As a condition of importation restricted articles are required to be treated to destroy any

surface contamination by citrus canker bacteria. This is adequate to prevent the spread of bacteria during storage.

Commenters asserted that on-sight inspections during all culling and repacking operations would be necessary to prevent inadvertent or deliberate commingling of restricted articles. Commenters also asserted that APHIS should exercise close supervision over disposal operations, and that the unsupervised return of restricted articles to Mexico for disposal should be prohibited. No changes are made based on these comments. Persons conducting any of the culling and repacking operations would be required to conduct the operations under a compliance agreement. This would assure that they understand and agree to comply with the provisions designed to prevent commingling of restricted articles with nonrestricted articles, and designed to assure proper disposal of culled articles. Further, inspectors will conduct unannounced monitoring for all of these activities. APHIS believes this is adequate to assure compliance with the regulations.

Commenters asserted that there are insufficient funds and personnel to conduct the necessary monitoring activities to ensure compliance with the provisions allowing restricted articles to be moved into and used in northern parts of Louisiana and Texas, and to be culled and repacked in restricted areas in Texas. No changes are made based on these comments. These comments in part appear to assume that additional personnel would be required to accomplish effective monitoring. It is not intended that additional personnel be hired to accomplish the monitoring, but rather that trained inspectors already stationed throughout Louisiana and Texas conduct whatever monitoring is required in their own areas. Further, APHIS does not believe that it is necessary to have inspectors present at all times for any of the activities. Many of the regulated activities would be conducted under compliance agreements. Further it is intended that monitoring will include unannounced inspections. APHIS believes that this system will be adequate to ensure compliance with the regulations.

It was asserted by a representative of the Texas Department of Agriculture that the APHIS District Field Office in Austin, Texas which is scheduled to be abolished should remain and that APHIS hire additional inspection staff to conduct the necessary enforcement activities, or that APHIS should provide funding so that Texas could hire extra inspection staff for enforcement activities. APHIS is taking action to abolish the District Field Office in Austin, Texas as part of an overall field reorganization plan. However, this will not lessen the number of APHIS inspection personnel available in the Austin area. Further, APHIS believes that adequate personnel are available in the affected areas to conduct the necessary inspection activities.

Commenters questioned the validity of statements in the document of March 10 indicating that the proposal was made, in part, based on requests from State officials. Although State officials did not make the initial request that the interim rule be amended, the information in the document of March 10 is correct, since they did request that if the regulations were to be amended that they contain certain precautionary measures. These requests were made in telephone conversations with APHIS officials prior to the publication of the proposed rule, by Mr. David A. Ivie, Director, Agriculture and Environmental Sciences, Texas Department of Agriculture, and by Dr. John W. Impson, State Entomologist, Office of Agricultural and Environmental Science, Louisiana Department of Argiculture.

Under the heading "Executive Order 12291 and Regulatory Flexibility Act" the proposal, among other things, provides that:

> It is necessary to complete this rulemaking proceeding as quickly as possible in order to take any warranted action to relieve unnecessary restrictions. The emergency nature of this action makes it impracticable for the agency to follow the procedures of Executive Order 12291 with respect to this action.

Several commenters disagreed that this action was of an emergency nature. However, as discussed in the proposal APHIS believes that prompt action was warranted to relieve unnecessary restrictions.

One commenter questioned whether importers "who have no direct investment in citrus production" are allowed to petition for the type of changes specified in this rulemaking proceeding. In this connection, it should be noted that the provisions of 5 U.S.C. 553(e) provide that any interested person (regardless of whether the person has an investment in citrus production) has the right to petition for the issuance, amendment, or repeal of a rule.

One commenter asserted that instead of the imposition of restrictions the Department should take action to protect citrus growers and importers by "providing an insurance policy" to cover any losses. No changes are made based on this comment. The interim regulations are established under laws designed to prevent the introduction and spread of plant pests by the imposition of prohibitions and restrictions. These laws do not authorize insurance programs for losses because of citrus canker disease.

Many commenters asserted that the proposed amendments essentially were based on economic factors that favor a small number of importers of restricted articles. Other commenters asserted that comments in opposition to the proposal were essentially based on economic factors favoring domestic growers of fruit. Also, assertions were made that the adoption of the proposal would create a risk of introducing citrus canker disease that would be too great in comparison with the benefits that would accrue. No changes are made based on these comments. The amendments are designed to relieve unnecessary restrictions while providing adequate protection against the introduction and spread of citrus canker disease. The amendments are based upon sound biological data, not economic factors favoring either importers of restricted articles or domestic growers of fruit. It is the policy of APHIS to impose the least drastic requirements that would provide adequate protection against the introduction and spread of plant pests. It has been determined that the action taken by this document is consistent with this policy.

A number of the comments which were submitted in this rulemaking proceeding are the same as comments discussed in the document of January 5, 1983. These comments are as follows:

1. It was asserted that there is a likelihood that restricted articles would be infected with citrus canker disease (48 FR 390).

2. It was asserted that restricted articles could have bacteria trapped in the pores or wounds of the fruit (48 FR 390).

3. It was asserted that restricted articles should not be allowed to be imported into citrus producing areas in the United States (48 FR 390).

4. It was asserted that buffer zones should be established around citrus growing areas in the United States and that restricted articles should not be allowed to be shipped to areas in buffer zones (48 FR 390, 391).

5. It was asserted that not enough is known about citrus canker disease at this time to make a judgment concerning what measures should be taken to prevent its spread (48 FR 391).

6. It was asserted that Mexican limes would be prohibited from moving out of the infected areas (48 FR 391).

7. It was asserted that it is unknown what effect citrus canker disease would have on citrus or citrus relatives in the United States because of differences between temperature and rainfall levels in the areas in Mexico where citrus canker occurs and the citrus producing areas in the United States (48 FR 391).

8. It was asserted that bacteria causing this disease could mutate and attack the fruit of citrus or citrus relatives or attack additional plants of citrus or citrus relatives (48 FR 391).

9. It was asserted that the citrus canker disease in Mexico is a new strain and there has not been adequate field testing to determine what types of citrus or citrus relatives in the United States are susceptible to danger from this disease (48 FR 391).

10. It was asserted that there are no adequate control measures which could be taken if the citrus canker disease were to become established in citrus growing areas in the United States (48 FR 391).

11. It was asserted that Mexico may not have the capability and willingness to exercise controls, particularly to assure that adequate measures are taken and that the Mexican control program would be comprised by bribes (48 FR 392).

12. It was asserted that Mexico should be required to establish a feasible program to eradicate the citrus canker disease (48 FR 392).

13. It was asserted that Mexican limes should be prohibited from moving from the infected areas into the State of Veracruz, the principal Persian lime growing area in Mexico (48 FR 391).

14 It was asserted that citrus canker disease was observed in Colima on citrus other than limes (48 FR 392).

15. It was asserted that citrus canker disease could be transmitted by boxes, and equipment from Mexico (48 FR 391).

No changes are made based on these comments. The amendments made by this document will not cause a significant risk of causing the introduction of citrus canker disease. Except as otherwise explained in this document, the Department still adopts the rationale that was explained in the document of January 5, 1983, concerning these comments.

Assertions were made that restricted articles should not be allowed to be imported unless a buffer zone is established in northern Mexico into which Mexican limes and other restricted articles would not be allowed to move. No changes are made based on these comments. The issue of whether any of these articles should be allowed to move from infected areas to any noninfected areas in Mexico is fully discussed in the document of January 5, and APHIS still adopts the rationale explained in that document concerning the movement of these articles in Mexico.

Recent experiments conducted by USDA at Beltsville, Maryland, have indicated that it is possible under greenhouse conditions to artificially infect fruit of Mexican limes. This infection only occurs when the fruit is innoculated by artificial wounding and when the fruit is subsequently incubated in the greenhouse under optimum conditions. It should be noted that despite numerous surveys and inspections, infected fruit has not been found to occur in the field in Mexico. The rationale for the provisions of the interim regulations is based in part on the finding that citrus canker disease does not infect fruit in Mexico, and it still appears that citrus canker disease does not infect fruit in Mexico.

### Executive Order 12291 and Regulatory Flexibility Act

This amendment to the interim rule is issued in conformance with Executive Order 12291 and Secretary's Memorandum No. 1512–1, and has been determined to be not a "major rule." Based on information compiled by the Department, it has been determined that this would not have a significant effect on the economy; would not cause a major increase in costs or prices for consumers, individual industries, Federal, State or local government agencies, or geographic regions; and would not cause significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign based enterprises in domestic or export markets. Also, it is necessary to complete this rulemaking proceeding as quickly as possible in order to relieve unnecessary restrictions. The emergency nature of this action makes it impracticable for the agency to follow the procedure of Executive Order 12291 with respect to this action.

It appears that the restricted articles that would be allowed to be distributed and used in northern parts of Louisiana and Texas would not constitute a significant portion of these types of articles distributed and used within the United States.

Further, it has been determined that the culling and repacking of restricted articles in accordance with the provisions of this amendment in areas in Texas would not constitute a significant portion of the culling and repacking of fruits in the United States and would not constitute a significant portion of these activities involving small entities.

James O. Lee, Jr., Acting Administrator of the Animal and Plant Health Inspection Service, has determined that, under the circumstances explained above, it is anticipated that this action will not have a significant economic impact on a substantial number of small entities.

### Effective date

This rule lessens restrictions which have been found to be unnecessary. Accordingly, prompt action should be taken to delete the restrictions. Therefore, in accordance with the administrative procedure provisions of 5 U.S.C. 553, good cause is found for making this action effective less than 30 days after publication in the **Federal Register.**

### List of Subjects in 7 CFR Part 319

Agricultural commodities, Citrus Canker, Fruit, Imports, Plant diseases, Plants (agriculture), Transportation.

## PART 319—CITRUS CANKER—MEXICO

Under the circumstances referred to above, "Subpart—Citrus Canker—Mexico" in 7 CFR Part 319 is amended as follows:

1. Section 319.27–1 is amended by adding a definition of "Restricted area" in alphabetical order to read as follows:

**§ 319.27–1 Definitions.**

* * * * *

*Restricted area.* Any area listed as a restricted area in § 319.27–9.

**§ 319.27–5 [Amended]**

2. Paragraph (a)(8) of § 319.27–5 is revised to read as follows:

* * * * *

(8) The statement "Not to be distributed within Arizona, California, Florida, Hawaii, any part of Louisiana more than 15 miles south of Interstate Highway 20, Puerto Rico, any part of Texas more than 15 miles south of the direct route from the Louisiana border to the New Mexico border beginning on Interstate Highway 20 and continuing on Interstate Highway 10, or the Virgin Islands of the United States."

3. The provisions of §§ 319.27–9 and 319.27–10 are removed and new §§ 319.27–9 through 319.27–12 are added to read as follows:

**§ 319.27–9 Restricted Areas.**

The following areas are designated as restricted areas: Arizona, California,

Florida, Hawaii, any part of Louisiana more than 15 miles south of Interstate Highway 20, Puerto Rico, any part of Texas more than 15 miles south of the direct route from the Louisiana border to the New Mexico border beginning on Interstate Highway 20 and continuing on Interstate Highway 10, or the Virgin Islands of the United States.

**§ 319.27-10 Destination Requirements.**

Any restricted article may be imported only for movement to and use in an area not included as a restricted area except that restricted articles may be culled and repacked in restricted areas in Texas as provided in § 319.27-12.

**§ 319.27-11 Restricted Destination Permits.**

A restricted article may be moved from the port of entry to a location not in a restricted area only pursuant to a restricted destination permit issued by an inspector. A restricted destination permit will be issued for the movement of a restricted article only upon the presentation of evidence, such as a U.S. Customs bond, an invoice, or other shipping document indicating destination, sufficient to establish that the article would not be shipped in violation of this subpart and would be shipped to a location in the United States not in a restricted area.

**§ 319.27-12 Culling and Repacking in Texas; Movement to Areas in Northern Parts of Louisiana and Texas; Compliance Agreements.**

(a) Restricted articles may be culled and repacked in restricted areas in Texas in accordance with a valid compliance agreement between Plant Protection and Quarantine and the person conducting such activities whereby it is agreed that any culling or repacking would be conducted under the following conditions:

(1) The culling and repacking, and any related activities would be subject to monitoring by inspectors;

(2) The culling and repacking would be conducted only under conditions found by an inspector as adequate to assure that the restricted articles would not be commingled with nonrestricted articles and would remain identifiable as restricted articles during such activities (i.e., restricted articles must be separated from nonrestricted articles by being in separate rooms or by being separated by a partition, the equipment used for culling restricted articles may not be used for processing nonrestricted articles until all restricted articles which have been culled by the equipment have been repacked for distribution or put in containers for disposal);

(3) Any water used on restricted articles would contain at least 200 parts per million active chlorine;

(4) The outer containers of the repacked restricted articles would plainly and correctly bear the general nature and quantity of the contents, the country or locality of origin, the name and address of repacker, the name and address of consignee, and the statement "Not to be distributed within Arizona, California, Florida, Hawaii, any part of Louisiana more than 15 miles south of Interstate Highway 20, Puerto Rico, any part of Texas more than 15 miles south of the direct route from the Louisiana border to the New Mexico border beginning on Interstate Highway 20 and continuing on Interstate Highway 10, or the Virgin Islands of the United States"; and

(5) Any restricted articles taken out of their containers and not repacked for distribution and use in areas where they are eligible for distribution and use must be disposed of daily by returning them to Mexico, or be disposed of daily by incineration or burial in a landfill (the incinerator or landfill must have equipment and use procedures that are determined by the Deputy Administrator to be adequate to prevent the dissemination of citrus canker disease and be certified by the responsible State or local official as currently complying with the applicable laws for environmental protection; the incinerator or landfill must also have sufficient fencing and be managed in such a way as to effectively prevent human scavenging); any restricted articles held or moved for disposal must be held or moved in covered containers adequate to prevent spillage of the articles and marked so as to identify them as culled restricted articles; and the return of restricted articles to Mexico and any movements of restricted articles to incinerators or landfills must be made only by persons conducting culling and repacking operations under a compliance agreement.

(b) A restricted article may not be moved from the port of entry to any wholesale or chain store distributor of restricted articles in an area in Louisiana or Texas not designated as a restricted area, unless the distributor is operating under a valid compliance agreement between Plant Protection and Quarantine and the distributor whereby the distributor agrees not to reship restricted articles to any restricted area and agrees not to reship restricted articles to any other wholesale or chain store distributor in a restricted area not operating under such a compliance agreement.

(c) Any compliance agreement may be cancelled orally or in writing by the inspector who is supervising its enforcement whenever the inspector finds that such person has failed to comply with the provisions of this subpart or any conditions imposed pursuant thereto. If the cancellation is oral, the decision and the reasons therefor shall be confirmed in writing as promptly as circumstances permit. Any person whose compliance agreement has been cancelled may appeal the decision, in writing, to the Deputy Administrator within ten (10) days after receiving written notification of the cancellation. The appeal shall state all of the facts and reasons upon which the person relies to show that the compliance agreement was wrongfully cancelled. The Deputy Administrator shall grant or deny the appeal, in writing, stating the reasons for such decision, as promptly as circumstances allow. If there is a conflict as to any material fact, a hearing shall be held to resolve such conflict.

(Secs. 105, 106, and 107; 71 Stat. 32-34; 7 U.S.C. 150dd, 150ee, 150ff; secs. 5, 7, and 9; 37 Stat. 316-18; 7 U.S.C. 159, 160, 162; 7 CFR 2.17, 2.51, and 371.2(c).)

Done at Washington, D.C., this 20th day of April, 1983.

**William F. Helms,**

*Acting Deputy Administrator, Plant Protection and Quarantine, Animal and Plant Health Inspection Service.*

[FR Doc. 83-10812 Filed 4-20-83; 10:20 am]

BILLING CODE 3410-34-M

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