AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

5-22-84
Vol. 49 No. 100
Pages 21505-21692

federal register

Tuesday
May 22, 1984

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

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Questions and requests for specific information may be directed to the telephone numbers listed under INFORMATION AND ASSISTANCE in the READER AIDS section of this issue.

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Interstate Commerce Commission

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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 908

[Valencia Orange Reg.]

Valencia 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 Valencia oranges that may be shipped to market during the period May 25–31, 1984. Such action is needed to provide for orderly marketing of fresh Valencia oranges for this period due to the marketing situation confronting the orange industry.

EFFECTIVE DATE: May 25, 1984.

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 regulation is issued under the marketing agreement, as amended, and Order No. 908, as amended (7 CFR Part 908), regulating the handling of Valencia 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 Valencia 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 1983–84. The marketing policy was recommended by the committee following discussion at a public meeting on February 14, 1984. The committee met again publicy on May 15, 1984, to consider the current and prospective conditions of supply and demand and recommended a quantity of Valencia oranges. The committee reports the demand for Valencia oranges is very good on all sizes and grades of Valencia oranges.

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 is 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. It is necessary to effectuate the declared policy of the Act to make this regulatory provision effective as specified, and handlers have been apprised of such provisions and the effective time.

List of Subjects in 7 CFR Part 908

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

PART 908—[AMENDED]

Section 908.627 is added as follows:

§ 908.627 Valencia Orange Regulation 327.

The quantities of Valencia oranges grown in California and Arizona which may be handled during the period May 25, 1984 through May 31, 1984, are established as follows:

(a) District 1: 282,000 cartons;

(b) District 2: 318,000 cartons;

(c) District 3: Unlimited cartons.

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

Dated: May 17, 1984.

Thomas R. Clark,

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

[FR Doc. 84–13660 Filed 5–21–84; 8:45 am]
BILLING CODE 3410–02–M

DEPARTMENT OF JUSTICE

Immigration and Naturalization Service

8 CFR Part 238

Contracts With Transportation Lines; Name Change of Wardair Canada Inc.

AGENCY: Immigration and Naturalization Service, Justice.

ACTION: Final rule.

SUMMARY: This rule amends the listing of carriers which have entered into agreements with the Service to guarantee passage through the United States in immediate and continuous transit of aliens destined to foreign countries by changing the name of Wardair Canada (1975) Ltd. to Wardair Canada Inc.

EFFECTIVE DATE: May 22, 1984.

FOR FURTHER INFORMATION CONTACT: Loretta J. Shogren, Director, Policy Directives and Instructions, Immigration and Naturalization Service, 425 I Street NW., Washington, D.C. 20536, Telephone: (202) 633–3048.

SUPPLEMENTARY INFORMATION: The Commissioner of Immigration and Naturalization entered into an agreement with Wardair Canada, Ltd. on April 19, 1983 (48 FR 19157) to guarantee passage through the United States in immediate and continuous transit of aliens destined to foreign countries. On Sept. 6, 1983 (48 FR 40210), a correction was published changing the name to Wardair Canada (1975) Ltd. On October 31, 1983, Wardair Canada (1975) Ltd. officially changed its name to Wardair Canada Inc.

Compliance with 5 U.S.C. 553 as to notice of proposed rulemaking and delayed effective date is unnecessary because the amendment merely makes an editorial correction to the existing list of transportational lines.

In accordance with 5 U.S.C. 605(b), the Commissioner of Immigration and Naturalization certifies that the rule will

not have a significant impact on a substantial number of small entities.

This order constitutes a notice to the public and is not a rule within the definition of section 1(a) of E.O. 12291.

List of Subjects in 8 CFR Part 238

Airlines, Aliens, Government contracts, Travel, Travel restriction.

Accordingly, Chapter 1 of Title 8 of Code of Federal Regulations is amended as follows:

PART 238—CONTRACTS WITH TRANSPORTATION LINES

§ 238.3 [Amended]

Section 238.3(b) is amended by changing the name of "Wardair Canada (1975) Ltd." to "Wardair Canada Inc."

* * * * *

(Secs. 103, 66 Stat. 173 (8 U.S.C. 1103); 238, 66 Stat. 202 (8 U.S.C. 1228))

Dated: May 16, 1984.

Andrew J. Carmichael, Jr.,

Associate Commissioner, Examinations, Immigration and Naturalization Service.

[FR Doc. 84-13662 Filed 5-21-84; 8:45 am]

BILLING CODE 4410-10-M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 21

[Docket No. 22126; Special Conditions No. 23-ACE-8]

Special Conditions; Superchute, Ltd. Modified Cessna Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final special conditions.

SUMMARY: These Special Conditions are issued under §§ 21.16 and 21.101(b) of the Federal Aviation Regulations (FAR) to Superchute, Ltd. for the supplemental type certification of Superchute, Ltd. modifications to Cessna Models 150K, 150L, 150M and 152 airplanes and Cessna 172 and 180 series airplanes.

This modification will have novel or unusual design features associated with a parachute system for which the applicable airworthiness regulations do not contain adequate or appropriate safety standards. These special conditions contain safety standards which the Administrator finds necessary to establish a level of safety equivalent to that established in the regulations by reason of the novel or unusual features.

EFFECTIVE DATE: June 22, 1984.

FOR FURTHER INFORMATION CONTACT: William L. Olson, Aerospace Engineer, Regulations and Policy Office (ACE-110), Aircraft Certification Division, Central Region, Federal Aviation Administration, 601 East 12th Street, Kansas City, Missouri 64106; Telephone (816) 374-5688.

SUPPLEMENTARY INFORMATION:

Type Certification Basis

The certification basis for Cessna Models 150K, 150L, 150M, and 152 airplanes is Part 3 of the Civil Air Regulations (CAR), effective May 19, 1956, through Amendment 3-4, effective October 6, 1958, and in addition for the Model 152, § 23.1559 of the FAR through Amendment 23-21, effective March 1, 1978.

The certification basis for the Cessna Model 172 series airplanes is Part 3 of the CAR, effective November 1, 1949, through Amendment 3-12, effective May 18, 1954, and, in addition, for S/N 17271035 and on, § 23.1559 of the FAR through Amendment 23-21, effective March 1, 1978.

The certification basis for the Cessna 180 series airplanes is as follows:

Models 180, 180A, and 180B: Part 3 of the CAR effective November 1, 1949, through Amendment 3-8, effective June 23, 1952, except §§ 3.265 and 3.668 of Amendment 3-7 effective March 5, 1952.

Models 180C through 180H: Part 3 of the CAR, effective November 1, 1949, through Amendment 3-12 effective May 18, 1954, except § 3.265 of Amendment 3-7 effective March 5, 1952, and in addition, § 3.668 through Amendment 3-3, effective May 17, 1958.

Models 180J and 180K: Part 3 of the CAR, effective November 1, 1949. through Amendment 3-12, effective May 18, 1954, except §§ 3.265 and 3.668 and Subpart B; Subpart B of Part 3 of the CAR, effective May 15, 1956, through Amendment 3-5, effective October 1, 1959; and for S/N 18052490, 18053001, and on § 23.1559 of the FAR through Amendment 23-21, effective March 1, 1978.

Background

On January 13, 1981, Superchute, Ltd., 19 Arline Drive, Newport News, Virginia 23602, filed an application for a Supplemental Type Certificate (STC) to install Superchute systems on Cessna Model 150K, 150L and 150M airplanes. An amended application which added the Cessna Model 152, as well as the Cessna 172 and 180 series, was filed on May 22, 1981. The applicant proposes to certificate a survival means for airplane occupants in dire emergency situations. The Superchute System, which is only to be used as a last resort, is intended to prevent serious injuries to airplane occupants by parachuting the airplane to the ground.

In the Superchute system, the parachute is located in a canister on the underside of the fuselage and is tethered to the airplane with a line which is routed aft under the fuselage, up behind the horizontal stabilizer, and forward on top of the fuselage to the wing. At the wing, the line is connected to four separate lines which, in turn, are terminated at two places on the forward wing spar and at two places on the rear wing spar.

The system provides protection from inadvertent pilot operation and inadvertent jettisoning after a deliberate deployment. It also provides for jettisoning in the air and on the ground.

Discussion of Comments

Public participation in this rulemaking action was invited by Notice No. SC-81-6, which was published in the **Federal Register** (46 FR 45619; September 14, 1981) and one public comment was received. The commenter supports the proposed special conditions in principle and even advocates such systems for all airplanes. However, he does not offer any substantive comments.

List of Subjects in 14 CFR Part 21

Air transportation, Aircraft, Aviation safety, Safety.

Adoption of the Special Conditions

Accordingly, pursuant to the authority delegated to me by the Administrator, Special Conditions No. 23-ACE-8 are issued to Superchute, Ltd. for the supplemental type certification of Cessna Models 150K, 150L, 150M, and 152 airplanes in the utility category with the Superchute system and Cessna 172 and 180 series airplanes in the normal category with the Superchute system.

Special Conditions

A. Flight Conditions

1. The Superchute system must be demonstrated in flight to satisfactorily perform its intended function in the critical flight conditions within the flight envelope approved for the Superchute system.

2. It must be demonstrated in flight that inadvertent parachute deployment will have no detrimental effect on aircraft operation.

3. It must be demonstrated that the airplane can be recovered to normal flight by jettisoning the parachute during an emergency descent, and the altitude needed to recover to normal flight must be determined.

B. Airframe Conditions

1. The fuselage parachute must meet the applicable requirements of TSO-C23, or other approved equivalent, at weights at which it is to be used.

2. In addition, it must be shown that although the structure may be damaged, the

fuselage impact with the ground will result in an occupant environment such that serious injury to the occupants is improbable.

C. System and Equipment Conditions

1. It must be shown that the inadvertent jettisoning of the parachute, after it has been deliberately deployed, is extremely improbable.

2. It must be shown that arming the system, chute deployment, and chute jettisoning can only be accomplished in a sequence which would make inadvertent pilot operation extremely improbable. It must be shown that the system, after arming, may be disarmed at any time prior to chute deployment.

3. The parachute system must be shown to function reliably and to adequately perform its intended function. It must be labeled as to its identification, function, and operational limitations.

4. It must be shown that after impact the parachute can be jettisoned under various adverse weather conditions, including high winds.

D. Operating Limitation Conditions

1. Operating limitations must be prescribed to ensure proper operation within the confines of an approved flight envelope and airplane attitude.

2. An operating limitation must be prescribed that requires the parachute to be repacked at an approved interval.

(Sec. 313(a), 601, and 603, Federal Aviation Act of 1958, as amended (49 U.S.C. 1354(a), 1421, and 1423); 49 U.S.C. 106(g) (revised Pub. L. 97-449, January 12, 1983); and §§ 11.28 and 11.49(b) of the Federal Aviation Regulations (14 CFR 11.28 and 11.49(b))

Issued in Kansas City, Missouri on May 8, 1984.

Murray E. Smith,

Director, Central Region.

[FR Doc. 84-13648 Filed 5-21-84; 8:45 am]

BILLING CODE 4910-13-M

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14 CFR Part 39

[Docket No. 84-CE-3-AD; Amendment 39-4863]

Airworthiness Directives; Cessna Models 180, 182, R182, 185, A185, A188, 190, 195, 205, 206, P206, U206, TP206, TU206, 207, T207, 210 and T210 Series Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts an Airworthiness Directive (AD) applicable to certain Cessna Models 180, 182, R182, 185, A185, A188, 190, 195, 205, 206, P206, U206, TP206, TU206, 207, T207, 210 and T210 Series airplanes which requires inspection and modification of the fuel system. Incidents of engine power loss and accidents due to water contamination of the fuel system have occurred on some models of the above airplanes. The prescribed action will identify airplanes having bladder fuel cells which tend to retain water contamination, provide fuel tank drainage provisions and reduce the possibility that water may enter and be retained in the fuel tanks.

DATES: Effective Date: May 22, 1984.

Compliance: As prescribed in the body of the AD.

ADDRESSES: Cessna Service Information Letter SE79-45 dated September 10, 1979, SE82-34 dated July 23, 1982, SE84-8 dated March 16, 1984, and SE84-9 dated March 23, 1984, applicable to this AD may be obtained from Cessna Aircraft Company, P.O. Box 1521, Wichita, Kansas 67201. A copy of this information is also contained in the Rules Docket, Office of the Regional Counsel, FAA, Room 1558, 601 East 12th Street, Kansas City, Missouri 64106.

FOR FURTHER INFORMATION CONTACT: Paul O. Pendleton, Aerospace Engineer, Wichita Aircraft Certification Office, Room 238, Terminal Building 2299, Mid-Continent Airport, Wichita, Kansas 67209; Telephone number (316) 269-7010.

SUPPLEMENTARY INFORMATION: Accidents resulting from power loss attributed to fuel contamination have occurred on certain models of Cessna single-engine airplanes equipped with bladder fuel cells. Investigation of these accidents and other incidents have established the following:

1. Some airplanes are equipped with bladder fuel cells that may be wrinkled and trap water.

2. On some airplanes it may not be possible to drain all contamination in the wing bladder fuel system with the airplanes in the normal ground attitude due to tank wrinkles.

3. The absence of quick drain valves in the fuel or reservoir tanks of many airplanes makes drainage of the fuel system at these locations difficult and may contribute to neglect of proper fuel system drainage by the operators.

4. Many fuel cap installations are not being maintained to prevent entrance of water around the fuel cap seal.

The manufacturer and FAA have conducted investigations and tests to determine the behavior of water in the bladder cells and fuel system.

Based on the findings of these investigations, an inspection procedure to detect bladder cell wrinkles which may trap water has been developed. Also, the manufacturer has made available a modification to the fuel tank installation permitting relocation of the fuel tank quick drain, as necessary, to eliminate wrinkles in this area of the bladder cell, and additional quick drain valve installation kits for installation of quick drain valves in the main and reservoir tanks of airplanes not already so equipped. Service information is available that will, if followed, assure effective sealing of the fuel cap.

Since the FAA has determined that the unsafe condition described herein is likely to exist or develop on other airplanes of the same type design, an AD applicable to Cessna Models 180, 182, R182, 185, A185, A188, 190, 195, 205, 206, P206, U206, TP206, TU206, 207, T207, 210 and T210 Series airplanes is being issued. It requires: (1) Installation of quick drain valves in the fuel tank sumps and reservoir tanks, (2) inspection of the fuel bladder installation for wrinkles, (3) elimination of these wrinkles or installation of a placard prescribing special preflight inspections of those airplanes having tank wrinkles which cannot be eliminated, and (4) inspection for and correction of defects in the fuel filler cap and adapter which may prevent effective sealing of the fuel cap.

Because an emergency condition exists that requires the immediate adoption of this regulation, it is found that notice and public procedure hereon are impractical and contrary to the public interest, and good cause exists for making this amendment effective in less than 30 days.

List of Subjects in 14 CFR Part 39

Aviation safety, Aircraft.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, § 39.13 of the Federal Aviation Regulations (14 CFR 39.13) is amended by adding the following new AD.

Cessna: Applies to Models and Serial Numbers listed below having bladder fuel cells:

Model 180 Series—S/Ns 18030000 thru 18053000 (1953 thru 1978) 18053001 thru 18053203 (1979 thru 1981) (optional tanks only)

Model 182 Series—S/Ns 18233000 thru 18266590 (1956 thru 1978)

Model R182—S/Ns R18200001 thru R18200583 (1978)

Model 185 Series—S/Ns 185-0001 thru 18503683 (1961 thru 1978) 18503684 thru 18504414 (1979 thru 1983) (optional tanks only)

Model 188 Series—S/Ns 188-0446 thru 18803856 (1968 thru 1981) (wing tanks only) 18800967T thru 18803966T (1972 thru 1983)

Model T188 Series—S/Ns T18803307T thru T18803966T (1979 thru 1983)

Model 190/195 Series—S/Ns thru 16183

Model 210-5 (205) Series—S/Ns 205-0001 thru 205-0577 (1963 thru 1964)

Model 206, U206, TU206 Series—S/Ns 206-0001 thru U20604649 (1964 thru 1978)

Model P206, TP206 Series—S/Ns P206-0001 thru P20600647 (1965 thru 1970)
Model 207, T207 Series—S/Ns 20700001 thru 20700771 (1969 thru 1984)
Model 210 Series—S/Ns 21057001 thru 21058818 (1960 thru 1966)
Model T210 Series—S/Ns T210-0001 thru T210-0197 (1966)
Model A182 Series—S/Ns A182-0001 thru A182-0146 (1966 thru 1974)
Model F182 Series—S/Ns F18200001 thru F18200094 (1976 thru 1978)
Model FR182—S/Ns FR18200001 thru FR18200020 (1978)

Compliance: Required, as indicated, unless already accomplished.

To prevent power loss or engine stoppage due to water contamination of the fuel system:

(a) Within the next 50 hours time-in-service after the effective date of this AD, on all applicable airplanes, install quick drains in the fuel tank sumps and fuel tank reservoirs where applicable, in accordance with the kits specified by Cessna Service Letters SE79-45 and SE84-8, or using equivalent aircraft standard hardware.

(b) Within the next 50 hours time-in-service after the effective date of this AD, inspect the fuel tank filler area for proper sealing in accordance with the following:

(1) On all applicable airplanes:

(i) Visually inspect the wing aft of the fuel filler for indications of inflight fuel leakage.

(ii) Visually inspect the fuel cap locking mechanism and seals for cracking, distortion and any condition which might prevent sealing.

(iii) Remove the fuel filler caps and inspect the adapter sealing face for distortion, scratches, corrosion or any condition which may prevent the cap from sealing.

(2) In addition, on all applicable airplanes except models 190 and 195 airplanes:

(i) Visually check the sealing and security of the attachment of the adapter flange to the adapter plate paying particular attention to the adhesive (if present) between the parts.

(ii) Check the fuel cap seal by actuating the locking tab and noting that force is maintained between the cap, seal, and adapter when the tab is in the overcenter locked position or conduct a fuel cap seal test in accordance with Cessna Single Engine Service Information Letter SE82-34.

(3) Correct any deficiencies disclosed by the above inspections by parts replacement or adjustment, as required, before returning the airplane to service.

(c) Within the next 50 hours time-in-service after the effective date of this AD, on all applicable airplanes, except models 190 and 195, conduct an inspection for fuel tank wrinkles in accordance with the following:

(1) Drain the wing fuel tanks.

(2) Note any wrinkles which retain fluid after draining. Remove diagonal wrinkles across the inboard rear corner in the vicinity of the fuel tank drain by installation of Cessna drain kit described in Service Letter SE84-9, or by replacement of the fuel bladder. Verify that no wrinkles exist in the tank sump drain area before returning the airplane to service.

Note.—The manufacturer has identified some new bladder cells which may require installation with a special adapter to prevent the formation of the above described wrinkles and has included this part with these bladder cells. Use of this part, or the drain kit, may be necessary to eliminate these wrinkles.

(3) If wrinkles are found in the tank bottom at a location other than diagonally across the inboard rear corner, determine the amount of fluid which is trapped by these wrinkles in accordance with the following.

(i) Place the airplane in the normal ground (water) attitude.

(ii) Service tank(s) with enough fuel to completely cover bottom of tank surface. Drain tank and note any wrinkles which retain fuel.

(iii) Direct all trapped fluid to the tank drain area, using a non-absorbent squeegee or other tool compatible with the fuel bladder, and drain and measure the fluid retained in both tanks.

(iv) If this total does not exceed three ounces, no further action is required.

(v) If the total quantity drained exceeds three ounces, check the snaps and fasteners for security. If necessary, blend and smooth the tank bottom to remove wrinkles. Blending may include replacement of the protective tape on the corners or edges to maintain a tank surface which will not trap excess fluid. Caution: Excessive blending or smoothing may cause leaks to develop in the tank.

(vi) If the tanks trap fluid in excess of three ounces after compliance with paragraph (v) above, fabricate, using letters at least .10 inches in height, and install a placard in full view of the pilot which states as follows:

"Prior to flight following exposure to rain, sleet, snow, or after fueling from an unfiltered fuel source:

1. Drain and catch the contents of the fuel gascolator, wing, and (if equipped) reservoir tank sumps and check for water contamination.

2. Place the airplane on a level surface and lower the tail to within 5 inches of the ground (on nose gear airplanes).

3. Rock the wings 10 inches up and 10 inches down at least 12 times.

4. Drain and catch the contents of the fuel gascolator, wing, and (if equipped) reservoir tank sumps and check for water contamination.

5. If water is found in step 4. above, repeat steps 3. and 4. until no additional water is detected, or drain the entire airplane fuel system."

(d) Within 12 months after initial compliance with this AD, and each 12 months thereafter, reinspect the fuel filler installation of airplanes that require the placard per paragraph (c)(3)(vi) in accordance with paragraph (b) of this AD.

(e) The placard required by paragraph (c)(3)(vi) may be fabricated and installed by the airplane owner, or operator, providing that this person possesses at least a private pilot license.

(f) Airplanes may be flown in accordance with FAR 21.197 to a location where this AD may be accomplished if it is determined that no water is present in the tank from which fuel will be used.

(g) An equivalent means of compliance with this AD may be used, if approved by the Manager, Aircraft Certification Office, Federal Aviation Administration, Room 238, Terminal Building 2299, Mid-Continent Airport, Wichita, Kansas 67209; Telephone (316) 269-7000. Fuel cells and quick drain valves that are FAA approved for the applicable airplanes are approved as an equivalent means of compliance in replacement of corresponding parts required to be installed by this AD.

This amendment becomes effective May 22, 1984.

(Secs. 313(a), 601 and 603, Federal Aviation Act of 1958, as amended (49 U.S.C. 1354(a), 1421 and 1423); 49 U.S.C. 106(g) (Revised, Pub. L. 97-449, January 12, 1983); § 11.89, Federal Aviation Regulations (14 CFR 11.89))

Note.—The FAA has determined that this regulation is an emergency regulation that is not major under section 8 of Executive Order 12291. It is impracticable for the agency to follow the procedures of Order 12291 with respect to this rule since the rule must be issued immediately to correct an unsafe condition in aircraft. It has been further determined that this document involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979). If this action is subsequently determined to involve a significant regulation, a final regulatory evaluation or analysis, as appropriate, will be prepared and placed in the regulatory docket (otherwise, an evaluation is not required). A copy of it, when filed, may be obtained by contacting the Rules Docket under the caption "ADDRESSES" at the location identified.

Issued in Kansas City, Missouri, on May 4, 1984.

Murray E. Smith,

Director, Central Region.

[FR Doc. 84-13650 Filed 5-21-84; 8:45 am]

BILLING CODE 4910-13-M

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14 CFR Part 71

[Airspace Docket No. 84-AWP-7]

Alteration of Control Zone; Monterey, Calif. and Tonopah, Nev.

AGENCY: Federal Aviation Administration (FAA), Dot.

ACTION: Final rule; request for comments.

SUMMARY: This amendment alters the description of Monterey, California, and Tonopah, Nevada, Control Zones serving Monterey Peninsula and Tonopah Airports so as to reflect the part-time status of the control zone to coincide with staffing of the Monterey Airport Traffic Tower and the Tonopah Flight Service Station and weather reporting.

EFFECTIVE DATE: July 5, 1984.

Comments must be received on or before June 10, 1984.

ADDRESSES: Send comments on the rule in triplicate to: Federal Aviation Administration, Airspace and Procedures Branch, Post Office Box 92007, Worldway Postal Center, Los Angeles, California 90009–2007.

The official docket may be examined in the Western-Pacific Regional Office of Regional Counsel, 15000 Aviation Bld., Hawthorne, California, Room 6W14.

An informal docket may also be examined during normal business hours at the Western-Pacific Region, Airspace and Procedures Branch, 15000 Aviation Blvd., Hawthorne, California, Room 6E16.

FOR FURTHER INFORMATION CONTACT: Mateo M. Palenzuela, Airspace and Procedures Branch, Air Traffic Division, Federal Aviation Administration, 15000 Aviation Boulevard, Lawndale, California 90261, Telephone (213) 536–6182.

SUPPLEMENTARY INFORMATION:

Request for Comments on the Rule

Although this action is in the form of a final rule, which involves reducing the hours of the control zones to coincide with available communication and weather observations, and was not preceded by notice and public procedure, comments are invited on the rule. When the comment period ends, the FAA will use the comments submitted, together with other available information, to review the regulation. After the review, if the FAA finds that changes are appropriate, it will initiate rulemaking proceedings to amend the regulation. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in evaluating the effects of the rule and determining whether additional rulemaking is needed. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy aspects of the rule that might suggest the need to modify the rule.

The Rule

This amendment to Part 71 of the Federal Aviation Regulations amends the description of the Monterey, California, and Tonopah, Nevada, Control Zones by reducing the hours of the control zones to coincide with existing communications and weather observations. This action reduces a burden on airspace users and is so minor in nature that the FAA does not anticipate significant public interest. Therefore, I find that notice of public procedure under 5 U.S.C. 533(b) is unnecessary and that good cause exists for making this amendment effective on the next charting date.

Section 71.171 of Part 71 of the Federal Aviation Regulations was republished in Advisory Circular AC 70–3A on 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) (as republished (46 FR 455), is amended, (46 FR 455)) is further amended effective 1400 GMT, July 5, 1984, as follows:

Monterey, California

[New] Following . . . "Fort Ord, California, control zone". Add: "This control zone is effective from 0600 to 2300 hours, local time, daily or during specific dates and times established in advance by a Notice to Airmen which thereafter will be continuously published in the Airport/Facility Directory."

71.171 Tonopah, Nevada

Following . . . "southeast of the VORTAC". Add: "This control zone is effective from 0600 to 2100 hours, local time, daily or during specific dates and times established in advance by a Notice to Airmen which thereafter will be continuously published in the Airport/Facility Directory."

(Secs. 307(a) and 313(a), Federal Aviation Act of 1958 (49 U.S.C. 1348(a), 1354(a)); (49 U.S.C. 106(g) (Revised, Pub. L. 97–449, January 12, 1983)); and 14 CFR 11.69)

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 Los Angeles, California, On May 1, 1984.

H. C. McClure,

Director.

[FR Doc. 84–13647 Filed 5–21–84; 8:45 am]

BILLING CODE 4910–13–M

14 CFR Part 71

[Airspace Docket No. 84–AWP–6]

Designation of Control Zone; Los Alamitos, California (Los Alamitos AFRC)

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; comments requested.

SUMMARY: This amendment reestablishes a Control Zone for Los Alamitos Armed Forces Reserve Center (AFRC), Los Alamitos, California. This action will reassign existing controlled airspace for aircraft conducting instrument operations at Los Alamitos AAF.

DATES: Effective date: July 5, 1984.

Comments must be received on or before June 10, 1984.

ADDRESSES: Send comments on the rule in triplicate to: Federal Aviation Administration, Airspace and Procedures Branch, AWP–530, Post Office Box 92007, Worldway Postal Center, Los Angeles, California 90009–2007.

The official docket may be examined in the Western-Pacific Regional Office of Regional Counsel, 15000 Aviation Blvd., Hawthorne, California, Room 6W14.

An informal docket may also be examined during normal business hours at the Western-Pacific Region, Airspace and Procedures Branch, 15000 Aviation Blvd., Hawthorne, California Room 6E16.

FOR FURTHER INFORMATION CONTACT: Mateo M. Palenzuela, Airspace and Procedures Branch, Air Traffic Division, Federal Aviation Administration, 15000 Aviation Boulevard, Lawndale, California 90261, Telephone (213) 536–6182.

SUPPLEMENTARY INFORMATION:

Request for Comments on the Rule

Athough this action is in the form of a final rule, which involves the redesignation of existing controlled airspace for aircraft conducting instrument operations at Los Alamitos AAF, and was not preceded by notice and public procedure, comments are invited on the rule. When the comment period ends, the FAA will use the comments submitted, together with other available information, to review the regulation. After the review, if the FAA finds that changes are appropriate, it will initiate rulemaking proceedings to amend the regulation. Comments that provide the factual basis supporting the views and suggestions presented are

particularly helpful in evaluating the effects of the rule and determining whether additional rulemaking is needed. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy aspects of the rule that might suggest the need to modify the rule.

The Rule

The purpose of this amendment to § 71.171 of Part 71 of the Federal Aviation Regulations (14 CFR Part 71) is to reestablish the Los Alamitos Armed Forces Reserve Center, Los Alamitos, California, Control Zone to provide Los Alamitos with a separate Control Zone during the times the Los Alamitos AFRC Control Tower is in operation. With separate Control Zone, each airport can operate according to actual weather conditions at that airport. The rule will provide air traffic service to all users, and would further enhance safety without increasing the size of the existing Control Zone. This action reduces a burden on airspace users and is so minor in nature that the FAA does not anticipate significant public interest. Therefore, I find that notice or public procedure under 5 U.S.C. 553(b) is unnecessary and that good cause exists for making this amendment effective in less than 30 days after its publication in the Federal Register.

Section 71.171 of Part 71 of the Federal Aviation Regulations was republished in Advisory Circular AC 70-3A on January 3, 1983.

List of Subjects in 14 CFR Part 71

Aviation safety, Control zones.

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 republished (46 FR 455)), is amended, effective 1500 GMT, July 5, 1984, as follows:

§ 71.171 Los Alamitos, California. (Revised)

(Los Alamitos AAF) within a 5 mile radius of Los Alamitos Armed Forces Reserve Center (latitude 33°47'30" N., longitude 118°02'50" W.) at a point beginning with latitude 33°51'40" N., longitude 118°04'50" W. to a 5 mile semicircle to the east to latitude 33°45'00" N., longitude 118°07'10" W., straightline to point of beginning, excluding the portion within a 1 mile radius of Meadowlark Airport (latitude 33°43'08" N., longitude 118°02'13" W.). This control zone is effective from 0700 to 2200 hours, local time daily, or during specific dates and times established in advance by a Notice of Airmen which will be continuously published in the Airport/Facility Directory. However, at other times, the control zone is under control jurisdiction of Long Beach.

(Secs. 307(a) and 313(a), Federal Aviation Act of 1958 (49 U.S.C. 1348(a), 1354(a)); (49 U.S.C. 106(g) (Revised, Pub. L. 97-449, January 12, 1983)); and 14 CFR 11.69)

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 Los Angeles, California, on May 1, 1984.

H. C. McClure,

Director.

[FR Doc. 84-13646 Filed 5-21-84; 8:45 am]

BILLING CODE 4910-13-M

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14 CFR Part 75

[Airspace Docket No. 84-AWA-9]

Alteration of Jet Route J-105, Dallas-Fort Worth, TX

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: This rule realigns Jet Route J-105 between Dallas/Fort Worth, TX (DFW) and Razorback, AR (RZC). A new parallel runway has opened at DFW which requires flow changes to DFW Airport. This action will enhance the traffic flow within the Fort Worth Air Route Traffic Control Center (ARTCC) area.

DATES: Effective date—July 5, 1984.

Comments must be received on or before June 25, 1984.

ADDRESSES: Send comments on the rule in triplicate to: Director, FAA, Southwest Region, Attention: Manager Air Traffic Division, Docket No. 84-AWA-9, Federal Aviation Administration, P.O. Box 1689, Fort Worth, TX 76101.

The official docket may be examined in the Rules Docket, weekdays, except Federal holidays, between 8:30 a.m. and 5:00 p.m. The FAA Rules Docket is located in the Office of the Chief Counsel, Room 916, 800 Independence Avenue, SW., Washington, D.C.

An informal docket may also be examined during normal business hours at the office of the Regional Air Traffic Division.

FOR FURTHER INFORMATION CONTACT: Boyd V. Archer, Airspace and Air Traffic Rules Branch (AAT-230), Airspace-Rules and Aeronautical Information Division, Air Traffic Service, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, D.C. 20591; telephone: (202) 426-8783.

SUPPLEMENTARY INFORMATION:

Request for comments on the rule

Although this action is in the form of a final rule, which involves realigning J-105 between DFW, TX, and RZC, AR, VORTAC's to enhance traffic flows within the Fort Worth ARTCC area, and, thus, was not preceded by notice and public procedure, comments are invited on the rule. When the comment period ends, the FAA will use the comments submitted, together with other available information, to review the regulation. After the review, if the FAA finds that changes are appropriate, it will initiate rulemaking proceedings to amend the regulation. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in evaluating the effects of the rule and determining whether additional rulemaking is needed. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy aspects of the rule that might suggest the need to modify the rule.

The Rule

The purpose of this amendment to § 75.100 of Part 75 of the Federal Aviation Regulations (14 CFR Part 75) is to realign J-105 between DFW and RZC VORTAC's. A new parallel runway has opened at DFW which requires flow changes to DFW Airport. This action will permit the Fort Worth ARTCC to realign sector boundaries and equalize sector workload between the four sectors north of the DFW terminal area extending to the northern boundary of

the Fort Worth ARTCC. This action will enhance safety by the rerouting of arrival and departure aircraft in the DFW terminal area by balancing the volume of aircraft that will traverse the four sectors. Section 75.100 of Part 75 of the Federal Aviation Regulations was republished in FAA Handbook 7400.6 dated January 3, 1984.

Under the circumstances presented, the FAA concludes that there is an immediate need for a regulation to realign J-105 between DFW and RZC to increase safety. Therefore, I find that notice and public procedure under 5 U.S.C. 553(b) is impracticable and that good cause exists for making this amendment effective on July 5, 1984.

List of subjects in 14 CFR Part 75

Jet routes, Aviation safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, § 75.100 of Part 75 of the Federal Aviation Regulations (14 CFR Part 75), is amended, effective 0901 GMT, July 5, 1984, as follows:

J-105 [Amended]

By deleting the words ", via Razorback, AR" and substituting the words ": via INT Dallas-Fort Worth 027° and Razorback, AR, 225° radials; Razorback".

(Secs. 307(a) and 313(a), Federal Aviation Act of 1958 (49 U.S.C. 1348(a) and 1354(a)); (49 U.S.C. 106(g) (Revised, Pub. L. 97-449, January 12, 1983)); and 14 CFR 11.69)

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 Washington, D.C., on May 3, 1984.

B. Keith Potts,

Manager, Airspace-Rules and Aeronautical Information Division.

[FR Doc. 84-13649 Filed 5-21-84; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 271

[Docket No. RM79-76-130 (Colorado—28); Order No. 377]

High-Cost Gas Produced From Tight Formations; Colorado

Issued May 18, 1984.

AGENCY: Federal Energy Regulatory Commission, DOE.

ACTION: Final rule.

SUMMARY: Under section 107(c)(5) of the Natural Gas Policy Act of 1978, the Federal Energy Regulatory Commission (Commission) may designate certain types of natural gas as high-cost gas. High-cost gas is produced under conditions which present extraordinary risks or costs and once designated may receive an incentive price. The Commission issued a rule under section 107(c)(5) designating natural gas produced from tight formations as high-cost gas. 18 CFR 271.703. Jurisdictional agencies may submit recommendations of areas for designation as tight formations. Here the Commission adopts the recommendation of the State of Colorado Oil and Gas Commission that portions of the Dakota and Morrison Formations in Garfield, Mesa, and Rio Blanco Counties, Colorado, each be designated as a tight formation under § 271.703.

EFFECTIVE DATE: This rule is effective June 18, 1984.

FOR FURTHER INFORMATION CONTACT: Peter J. Roidakis, (202) 357-8307 or Victor H. Zabel, (202) 357-8616.

SUPPLEMENTARY INFORMATION:

Before Commissioners: Raymond J. O'Connor, Chairman; Georgiana Sheldon, J. David Hughes, A. G. Sousa and Oliver G. Richard III.

The Commission hereby amends 271.703(d) of its regulations (18 CFR 271.703(d) (1983)) to include portions of the Dakota and Morrison Formations as designated tight formations eligible for incentive pricing under § 271.703. The amendment was proposed in a Notice of Proposed Rulemaking by the Director, Office of Pipeline and Producer Regulation, issued November 14, 1983 (48 FR 52592 (1983)),[1] based on a recommendation by the State of Colorado Oil and Gas Conservation Commission (Colorado) under § 271.703, that portions of the Dakota and Morrison Formations in Garfield, Mesa, and Rio Blanco Counties, Colorado, each be designated as a tight formation.

Evidence submitted by Colorado supports the assertion that the portions of the Dakota and Morrison Formations set forth in the revised recommendation meet the guidelines contained in § 271.703(c)(2). The Commission adopts that recommendation.

This amendment shall become effective June 18, 1984.

List of Subjects in 18 CFR Part 271

Natural gas, Incentive price, Tight formations.

(Department of Energy Organization Act, 42 U.S.C. 7101 *et seq.*; Natural Gas Policy Act of 1978, 15 U.S.C 3301-3432; Administrative Procedure Act, 5 U.S.C. 553.)

In consideration of the foregoing, Part 271 of Subchapter H, Chapter I, *Code of Federal Regulations*, is amended as set forth below.

By the Commission.

Kenneth F. Plumb,

Secretary.

PART 271—[AMENDED]

Section 271.703 is amended by adding paragraphs (d) (163) and (164) to read as follows:

[1] This was the second notice of proposed rulemaking in these proceedings and four comments were received. The first notice of proposed rulemaking was issued August 31, 1982 (47 FR 38906 (1982)). The Commission received twenty-two comments to the first notice, including objections and a request for public hearing from Southwest Gas Corporation (Southwest) on September 16, 1982. On February 18, 1983, the Commission staff notified Colorado by letter that several comments had raised questions about Colorado's proposal, particularly about well test data and the degree of development in parts of the recommended area. The letter requested additional information about well drilling and testing and about the exclusion of certain data from consideration in the recommendation. Colorado submitted a revised recommendation to the Commission on October 3, 1983, based on hearings held in Denver, Colorado on April 18, and May 16, 1983. Colorado submitted a correction to the revised recommendation on October 24, 1983. The revised recommendation (Colorado Order Nos. NG32-2 and NG33-2 (corrected)) excludes areas which had been included in the first recommendation. The revised recommendation was noticed in the second notice of proposed rulemaking on November 14, 1983. Southwest stated in its comments to the November 14, 1983 notice that, in light of the revisions made by Colorado, it was withdrawing its request for a public hearing. It further stated that its previous comments should not be construed to apply to Colorado's revised recommendation. Other commenters, Northwest Pipeline Corporation and Beartooth Oil and Gas Company, both supported the revised recommendation, while only one commenter, Tenneco Oil Company, contended that the deletion of the portion of the acreage which Colorado removed from its initial recommendation was in error. The Department of the Interior's Bureau of Land Management concurred with Colorado's second, revised recommendation. (About 94 percent of the recommended area consists of Federal and Indian acreage.)

§ 271.703 Tight formations.

* * * * *

(d) *Designated tight formations.*

* * * * *

(163) *Dakota Formation in Colorado.* RM79–130 (Colorado—28).

(i) *Delineation of formation.* The Dakota Formation is located in Garfield, Mesa, and Rio Blanco Counties, Colorado, in all or parts of Townships 1 North, 1 South, 2 South, 3 South, Ranges 100 through 104 West, 6th P.M., Townships 4 and 5 South, Ranges 102 through 104 West, 6th P.M., Townships 6 through 8 South, Ranges 103 through 105 West, 6th P.M., Townships 9 and 10 South, Ranges 103 and 104 West, 6th P.M., and Townships 1 and 2 North, Ranges 2 and 3 West, Ute P.M.

(ii) *Depth.* The Dakota Formation is overlain by the Dakota Silt and is underlain by the Morrison Formation. The average thickness is about 150 feet. The average depth to the top of the Dakota Formation is 5,450 feet.

(164) *Morrison Formation in Colorado.* RM79–76–130 (Colorado—28).

(i) *Delineation of formation.* The Morrison Formation is located in Garfield, Mesa, and Rio Blanco Counties, Colorado, in all or parts of Townships 1 North, 1 South, 2 South, and 3 South, Ranges 100 through 104 West, 6th P.M., Townships 4 and 5 South, Ranges 102 through 104 West, 6th P.M., Townships 9 and 10 South, Ranges 103 and 104 West, 6th P.M., and Townships, 1 and 2 North, Ranges 2 and 3 West, Ute P.M.

(ii) *Depth.* The Morrison Formation is overlain by the Dakota Formation and is underlain by the Entrada Formation. The thickness ranges from about 300 to more than 600 feet. The average depth to the top of the Morrison Formation is 5,590 feet.

[FR Doc. 84–13710 Filed 5–21–84; 8:45 am]
BILLING CODE 6717–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Social Security Administration

20 CFR Part 404

Old-Age, Disability, Dependents' and Survivors' Insurance Benefits; Period of Disability; Time at Which Surviving Child's Relationship Requirement Must Be Met

AGENCY: Social Security Administration, HHS.

ACTION: Final rule.

SUMMARY: In this regulation, we are amending our rule for determining whether a claimant is the child of a deceased insured worker. The revised rule specifies that the determination is made by looking to the inheritance laws that were in effect at the time the insured worker died in the State where the insured had his or her permanent home. With this revision, it should be unmistakably clear that the relationship determination is not based on changes in State law which occurred since the death of the insured.

EFFECTIVE DATE: This regulation is effective May 22, 1984.

FOR FURTHER INFORMATION CONTACT: Jack Schanberger, Room 3–B–4 Operations Building, 6401 Security Boulevard, Baltimore, Maryland 21235, (301) 594–6785.

SUPPLEMENTARY INFORMATION: Section 216(h)(2)(A) of the Social Security Act (the Act) states in part that in determining whether an applicant is the child of a deceased insured individual, the Secretary shall apply such law as would be applied in determining the devolution of intestate personal property by the courts of the State in which the insured individual was domiciled at the time of his or her death. When determining an applicant's relationship to the insured under section 216(h)(2)(A), we have always looked to the law that was in effect in the insured's State of domicile at the time he or she died. Some Federal courts have also interpreted the provision this way. See *Ramon v. Califano,* 493 F. Supp. 158 (W.D. Tex. 1980); *Allen v. Califano,* 452 F. Supp. 205 (D. Md. 1978).

However, in a recent circuit court decision, *Owens* v. *Schweiker,* 692 F. 2d 80 (9th Cir. 1982), the court, focusing on the ambiguous language and grammatical construction of section 216(h)(2)(A), interpreted the provision differently than we have (and differently than other Federal courts have) and concluded that the Act should be read to require the use of the State law of domicile that was in effect at the time of the Secretary's determination on the child's claim.

We believe that our longstanding interpretation of section 216(h)(2)(A) is consistent with the intent of Congress and is a realistic application of Social Security program purposes and principles. A purpose of the program is to replace in part the wages of an individual who is no longer able to work because of retirement, disability, or death, and to provide monthly benefits to the individual's survivors who were dependent on him or her when he or she died. Realistically that dependency no longer exists months or years after the individual's death, and therefore the child's relationship status beginning some time after the individual's death would seem, in terms of economic dependency, to be irrelevant. That conclusion accords with section 216(h)(3)(C) of the Act, under which an applicant qualifies as a surviving child of the worker only if documentary proof of paternity was made during the worker's lifetime, or the worker was living with or contributing to the support of the child at the time of death.

The Act provides that the relationship between an insured and a child is to be determined under section 216(h)(3)(C) when an applicant does not qualify under section 216(h)(2). However, the *Owens* decision would permit a reversal of that sequence of tests, so that an applicant who does not meet the required relationship at the crucial time under section 216(h)(3)(C) could qualify at a later point in time under section 216(h)(2)(A).

Moreover, section 202(d)(1)(C) specifically requires that a surviving child must have been dependent upon the insured worker when he died. This is another clear indication that Congress intended that a surviving child beneficiary have the required status at the time of the insured's death.

For the above reasons, and to avoid conflicting interpretations of section 216(h)(2)(A) in the future, we are amending 20 CFR 404.354(b) to clearly state that we look to the inheritance law which was in effect in the State of the insured individual's domicile when he or she died.

Comments

On July 26, 1983, this revised rule was published as a Notice of Proposed Rulemaking (48 FR 33910). We received comments from only one source. Our response to those comments follows.

While the commenting group voiced several comments regarding the amendment, their overall concern is that, by amending this regulation, SSA is deliberately denying Social Security benefits to illegitimate children who would otherwise be eligible under State intestacy laws in existence after the worker's death. It is important to state at the outset that the purpose of this amendment is to establish a consistent point in time for determining relationship status under section 216(h)(2)(A) of the Act, so that all applications will be treated the same. By applying the State intestacy law in effect at the time the worker died rather than any change in State law which occurred since the worker's death, the rule works indiscriminately in favor of or against a particular applicant,

depending on where the worker died and what the State law was at the time. Further, we would also note that all State laws which have been changed are not necessarily more liberal than those which existed previously. For example, the State of Arkansas had a general rule of clear and convincing evidence of paternity, but changed its intestacy statute in 1979 to require meeting at least one of six specific conditions. Thus, although some States have liberalized their intestacy laws, others have not, and this amendment, rather than serving to deny benefits to children in most cases, merely serves to apply a consistent rule in every case.

One comment is that the proposed rule violates the plain language of section 216(h)(2)(A) of the Act. We believe that the proposed rule accords with the statutory provision requiring application of the law of the State in which the insured person was domiciled "at the time of his death." The commenter's contrary interpretation of that language indicates, as we stated in the NPRM, that the language of the statute is ambiguous.

Another comment is that the two Federal court cases cited in the NPRM as interpreting section 216(h)(2)(A) consistently with our longstanding view of the law—*Ramon* v. *Califano,* 493 F. Supp. 158 (W. D. Tex. 1980) and *Allen* v. *Califano,* 452 F. Supp. 205 (D. Md. 1978)—actually did not analyze the issue, but merely conclude that the law in existence at the time of the insured's death is the applicable law. This overlooks the fact that in *Allen,* plaintiffs specifically argued that the current State law should be applied in their case, but the court, after analyzing section 216(h)(2)(A) and the applicable regulation, concluded that the appropriate law to be applied is the law in effect at the time the worker died.

The group that commented was further concerned that this amendment would require that children who qualify for benefits under section 216(h)(2)(A) would also have to prove actual dependency. However, this amendment does not alter the fact that children who qualify under section 216(h)(2)(A) are deemed dependent. Rather, this amendment only clarifies the point in time for qualifying under State intestacy statutes in order to meet the relationship requirement. Once a child qualifies under the applicable State intestacy law, that child is deemed dependent.

The comments also state that applying the State intestacy law in existence at the worker's death will cause administrative inconvenience, for, whenever an applicant does not meet the section 216(h)(2)(A) test, we are forced to apply the alternative section 216(h)(3) test. However, by analyzing a relationship claim under alternative sections, we are simply applying the statute as written and not adding extra steps.

In addition, the comments inappropriately rely on other cases which deal with illegitimate children as support for their position that it is the current intestacy law rather than the law in existence at the time of the worker's death, which controls in section 216(h)(2)(A) cases. For example, the commenters infer that this was the reason for the Supreme Court vacating the Fourth Circuit's decision in *Jones* v. *Heckler,* 51 U.S.L.W. 3756 (April 18, 1983) and remanding the case in light of a change in Mississippi's intestacy law. However, the *Jones* case does not involve the issue at hand, but rather concerns a State statute which appears to be unconstitutional in light of *Trimble* v. *Gordon,* 430 U.S. 762 (1977), but has not been resolved by the Mississippi State courts.

Finally, the commenting group is concerned that, by applying the intestacy laws in effect on the date of the worker's death, we would, in some cases be applying laws which have later been declared unconstitutional. This is not correct. We believe we have properly followed a procedure which takes into account the date of death of the insured. For example, if an insured died prior to the enactment of a new legitimation or inheritance statute, the law in effect at the time of the insured's death is applied, absent an indication in the State statute or by the State courts that the newly enacted provision has some retroactive effect. However, when a State court (or the Supreme Court) declares that the statute in effect prior to the enactment of a new statute is unconstitutional, our view is that the courts of the State will not invoke the unconstitutional statute when making current (as opposed to past) distributions of interstate personal property. Therefore, while our starting point is always the State law that was in effect when the worker died, we will also look to see if that law was later declared unconstitutional by the State court. If it has been, then, in those limited situations, we will apply the State's later interpretation of what that date-of-death law should have been.

Regulatory Procedures

Executive Order 12291—This regulation has been reviewed under Executive Order 12291. It will have no effect on any costs or prices in any part of the economy. There will be no program or administrative costs resulting from this regulation. Therefore, it does not meet any of the criteria for a major regulation, and a Regulatory Impact Analysis is not required.

Paperwork Reduction Act—This regulation imposes no reporting/recordkeeping requirements requiring OMB clearance.

Regulatory Flexibility Act—We certify that this regulation will not have a significant economic impact on a substantial number of small entities because it affects only the entitlement of individuals to monthly benefits. Therefore, a Regulatory Flexibility Analysis as provided in Pub. L. 96–354, the Regulatory Flexibility Act, is not required.

List of Subjects in 20 CFR Part 404

Administrative practice and procedure, Death benefits, Disabled, Old-Age, Survivors, and Disability Insurance.

(Catalog of Federal Domestic Assistance Programs No. 13.805, Social Security—Survivors Insurance)

Dated: February 21, 1984.

Martha A. McSteen,

Acting Commissioner of Social Security.

Approved: May 1, 1984.

Margaret M. Heckler,

Secretary of Health and Human Services.

PART 404—[AMENDED]

Subpart D of Part 404 of Chapter III of Title 20 of the CFR is amended as follows:

1. The authority citation for Subpart D reads as follows:

Authority: Secs. 202, 205, 216, 223, 228, 1102 of the Social Security Act, 49 Stat. 623, 53 Stat. 1368, 64 Stat. 492, 70 Stat. 815, 94 Stat. 449, 80 Stat. 67, 49 Stat. 647; Sec. 5, Reorganization Plan No. 1 of 1953, 67 Stat. 631; 42 U.S.C. 402, 405, 416, 423, 425, 428, and 1302; and 5 U.S.C. Appendix.

2. Section 404. 354 is amended by revising paragraph (b) to read as follows:

§ 404.354 Your relationship to the insured.

* * * * *

(b) *Use of State laws.* To decide your relationship to the insured, we look to the laws that are in effect in the State where the insured has his or her permanent home when you apply for benefits. If the insured is deceased, we look to the laws that were in effect at the time the insured worker died in the State where the insured had his or her permanent home. If the insured's permanent home is not or was not in one of the 50 States, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, or

American Samoa, we will look at the laws of the District of Columbia. For a definition of permanent home, see § 404.303. The State laws we use are the ones the courts would use to decide whether you could inherit a child's share of the insured's personal property if he or she were to die without leaving a will. If these laws would not permit you to inherit the insured's personal property as his or her child, you may still be eligible for child's benefits if you are related to the insured in one of the other ways described in §§ 404.355–404.359.

[FR Doc. 84–13722 Filed 5–21–84; 8:45 am]
BILLING CODE 4190–11–M

Food and Drug Administration

21 CFR Part 109

[Docket No.77N–0080]

Polychlorinated Biphenyls (PCBs) in Fish and Shellfish; Reduction of Tolerances; Final Decision

AGENCY: Food and Drug Administration.

ACTION: Final rule; final decision following a formal evidentiary public hearing.

SUMMARY: The Commissioner of Food and Drugs is issuing a Final Decision following a formal evidentiary hearing to consider objections to the agency's final rule concerning a tolerance for polychlorinated biphenyls ("PCBs") in fish and shellfish. The Commissioner concludes that the appropriate tolerance, after taking into account public health and human food loss considerations, is 2 parts per million ("ppm"), as provided for in the final rule.

EFFECTIVE DATE: August 20, 1984.

ADDRESS: The testimony and evidence submitted, the initial decision, and all other documents cited in this decision may be seen in the Dockets Management Branch (HFA–305), Rm. 4–62, 5600 Fishers Lane, Rockville, Md., 20857, from 9 a.m. to 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Allen Heim, Ph. D., Office of Science Coordination, HF–8, Food and Drug Administration, Department of Health and Human Services, 5600 Fishers Lane, Rockville, Md., 20857, 301–443–1587.

SUPPLEMENTARY INFORMATION:

I. Background

This rulemaking proceeding involves the tolerance for unavoidable residues of PCBs in fish and shellfish, 21 CFR 109.30(a)(7). In 1977 the Food and Drug Administration ("FDA") proposed to lower the tolerance for PCBs in several classes of food. In relevant part, FDA proposed to lower the tolerance in fish and shellfish from 5 ppm to 2 ppm. 43 FR 17487 (April 1, 1977). In 1979 the agency promulgated a final rule based on the proposal, including lowering the tolerance in fish and shellfish to 2 ppm. 44 FR 38330 (June 29, 1979).

Section 406 of the Federal Food, Drug, and Cosmetic Act ("the act"), 21 U.S.C. 346, authorizes the establishment of tolerances for poisonous or deleterious substances added to food that cannot be avoided by good manufacturing practice. PCBs are such a substance. Although the agency's paramount concern is protection of the public health, under section 406 the agency must consider, in establishing a tolerance, the extent to which a contaminant is unavoidable. In essence, the agency is permitted to find where the proper balance lies between adequately protecting the public health and avoiding excessive losses of food to American consumers. 44 FR 38330–31. Pursuant to that mandate, the agency examined the amount of commercial fish that would be lost as human food as a result of lowering the tolerance.

As required by section 701(e) of the act, 21 U.S.C. 371(e), which applies to regulations promulgated under the authority of section 406, FDA provided persons who would be affected adversely by the final rule an opportunity to object and request a formal evidentiary hearing. Over 20 persons objected to provisions of the final rule concerning fish and shellfish, but only the National Fisheries Institute, Inc. ("NFI") requested a hearing. 44 FR 57389 (October 5, 1979). As provided by section 701(e)(2) of the act, that objection and request for hearing automatically stayed the effective date of the final rule, pending resolution of the issues raised in NFI's objection. In the **Federal Register** of May 1, 1981, FDA announced a formal evidentiary hearing on NFI's objection, on the issue of the "magnitude of the human food loss" from reducing the tolerance to 2 ppm. 46 FR 24551. NFI and FDA's Bureau of Foods [1] ("Bureau") were parties at the hearing. In addition to the parties, the National Marine Fisheries Service ("NMFS") of the U.S. Department of Commerce and the Environmental Defense Fund ("EDF") filed notices of participation. EDF subsequently withdrew from participation.

Administrative Law judge ("ALJ") Daniel J. Davidson issued his initial Decision on February 8, 1982. FDA announced the availability of the Initial Decision in the **Federal Register** of March 9, 1982. 46 FR 10079. NFI and the Bureau filed exceptions to Judge Davidson's Initial Decision under 21 CFR 12.125.

I am issuing this Final Decision under section 406 of the act and 21 CFR 12.130. In taking this action, I have all the powers I would have had in making the Initial Decision. 21 CFR 12.130(a). Section II of my Final Decision discusses Judge Davidson's Initial Decision, evidence and testimony introduced during the hearing, the exceptions filed by the Bureau and NFI, and my resolution of the hearing issue.

Although the hearing was limited to the issue of the magnitude of human food loss, the agency invited interested persons to submit other relevant materials for possible inclusion in the rulemaking record. Participants could argue in briefs to the Commissioner that a different tolerance should be set. 46 FR 24553. NFI, the Bureau, NMFS, EDF, the Chemical Manufacturers Association ("CMA"), the General Electric Company ("GE"), the State of Michigan, and others submitted additional information, briefs, or both.

Section III of my Final Decision discusses the scientific issues raised in these submissions and briefs. Section IV deals with several miscellaneous issues. In Section V, I balance the magnitude of the human food loss that would result from lowering the tolerance to 2 ppm and the public health risks from PCBs. My ultimate conclusion is that a tolerance of 2 ppm for PCBs in fish and shellfish adequately protect the public health, while not causing excessive loss of food to American consumers.

II. The Evidentiary Hearing Issues

A. The Initial Decision

Judge Davidson made detailed findings about the human food loss resulting from lowering the tolerances from 5 ppm to 2 ppm:

Imports	0
Unviable fisheries	0
Related species	0
Domestic harvest in violation:	
Alewives	$843,900
Buffalofish	128,000
Carp	223,000
Catfish	3,884,000
Trout	80,000
Whitefish and chubs	1,161,000
Bluefish	68,000
Lobster	4,061,600
Striped bass	2,984,000
Total	13,453,500
Times multiplier of six	80,721,000
Elasticity effect	6,000,000
Grand total	86,721,000

Initial Decision, Appendix 2 (footnotes omitted).

[1] The Bureau of Foods is now named the Center for Food Safety and Applied Nutrition.

Judge Davidson's figures are in 1980 dollars.[2] The loss figures for the individual species are dockside values; except for alewives, they are not now in dispute. Judge Davidson determined the human food loss at 2 ppm by subtracting the loss at 5 ppm from the loss at 2 ppm so as to represent the net loss from reducing the tolerance. He concluded that retail value is the appropriate measure of human food loss and applied a "multiplier" of six to derive retail value from dockside value.

B. Exceptions to the Initial Decision

NFI excepts to Judge Davidson's figures for imports and unviable fisheries; the Bureau excepts to the figures for alewives and the elasticity effect. Both parties except to the "multiplier" and the grand total. These exceptions, and my resolution of each, are discussed below.

1. Imports

Judge Davidson concluded that no human food loss from imports could be found. Initial Decision at 5. He reasoned that the record contains only unsupported claims of loss due to imports.

NFI excepts to that finding, and argues that the Judge should have found a human food loss of $31,410,000. NFI Exceptions at 5. NFI's figure was derived by assuming that the same percentage of imported fish as domestic fish would exceed a 2 ppm tolerance. Applying those percentages to the value at time of entry into the United States and amount of imported whitefish, freshwater trout, and lobster,[3] NFI derived a loss of about $15.7 million, or $31.2 million after the application of a "conservative" multiplier of 2. NFI Exceptions at 6; N–21 at 12. Of the $15.7 million loss, about $400,000 is due to freshwater trout and $500,000 is due to whitefish. The remainder, almost $15 million, is attributed to lobster. *See* N–21 at 3, 11.

I conclude that no food loss can be attributed to imports. Although neither Judge Davidson nor NFI considered different imported species separately, I believe that it is useful to do so. First, there was specific testimony concerning imported lobsters. Bureau witness Dr. Talhelm testified that no imported lobsters were reported to be violative. G–8 at 16. Dr. Gates testified for the Bureau that imported lobster samples were found to contain no significant levels of PCBs. G–9 at 3, 9. NFI did not rebut any of that testimony. Consequently, I conclude that no food loss can be attributed to imported lobster.

I agree with Judge Davidson's reasoning as applied to freshwater trout and whitefish. Except for lobster, there was no testimony concerning PCB levels in imported fish. NFI's food loss argument is based on the fact that "[t]he PCB sample data were, in many instances, drawn from the marketplace." NFI Exceptions at 6. NFI contends that "[t]here is no evidence that imports contain measurably different PCB levels [than domestic landings]." NFI Exceptions at 6. But that contention is based only on the testimony of Dr. Strand, that the "samples of the FDA survey *may*, in fact, have included imported products." N–21 at 9 (Emphasis added.) As authority, Dr. Strand cited only G–5, a 1979 Bureau of Foods memorandum, which stated "[t]he [NFI] comment assumes that imported species are contaminated to the same extent as corresponding domestic species. It is quite possible they are not, however, . . . " G–5 at 1–2. I acknowledge that FDA samples may have included imports. On the basis of the evidence, however, I conclude that any finding concerning a specific human food loss due to imported fish would be speculative. It would not be based on substantial evidence, as required by section 701(e)(3) of the act.

2. Unviable Fisheries

It is not disputed that, as the percentage of fish that exceed the tolerance level may increase due to the tolerance reduction to 2 ppm, some persons engaged in fishing may cease to operate. Some segments of the fishing industry could possibly cease operations completely. 44 FR 38335, col. 1. What is in dispute is whether a loss due to "unviable" fisheries can be quantified.

NFI asserted during the hearing that there would be a $51.6 million loss due to unviable fisheries. Judge Davidson declined to include a figure for unviable fisheries in his calculation of the total loss, on the basis that NFI did not adequately substantiate its loss figure. Initial Decision at 6. NFI excepts to that conclusion. NFI states that the total loss due to unviable fisheries should be $361.2 million ($51.6 million times a multiplier of 7). NFI Exceptions at 5.

I conclude that Judge Davidson was correct. NFI's expert witness Dr. Strand derived the $51.6 million figure by assuming that a fishery would become unviable if the percentage of the catch exceeding a 2 ppm tolerance goes above 25%. N–21 at 8–9. Dr. Strand based his calculation on the following statement in a "position paper" by the executive director of the Midwest Federated Fisheries Council: [4]

> It should be pointed out that the commercial fisheries of the Great Lakes are already operating at less than 50 percent of the potential annual harvest . . . *A 25% reduction in the present level of production* (implied by the change from 5 ppm to 2 ppm) would put the fishermen, who are barely making it, out of business completely.
>
> N–21 at 8, quoting from N–18 at 4. (Emphasis added.)

The position paper (N–18) does not state the basis for its contention or how the 25% figure was derived. There is nothing in the record concerning the qualifications of the position paper's author, so there is no basis on which I can conclude that he is a qualified expert on the subject. Moreover, Bureau expert Dr. Talhelm testified that Dr. Strand's use of 25% was arbitrary, and that 10% or 30% could have been used just as well. G–8 at 10. Consequently, I conclude that NFI has not substantiated its claimed loss due to unviable fisheries.

Even if I were to conclude that the evidence supported the use of a 25% trigger level for unviable fisheries, I would derive a much smaller loss attributed to unviable fisheries.[5] I base this result on two factors. First, the statement quoted above addressed only the Great Lakes fisheries. There is nothing in the record concerning a trigger level for other fisheries. Because Dr. Strand's calculation included two marine species, striped bass and lobster, which are not found in the Great Lakes, *see* N–2, no loss attributed to these marine species could be included.

Second, NFI states in its exceptions that:

> in applying the unviable fishery "trigger," the entire loss to be expected, not the

[2] Unless stated otherwise, all dollar figures in my Final Decision are in 1980 dollars. Conversion from 1974 dollars to 1980 dollars is based on use of the factors in the Initial Decision at page 3, note 3.

[3] NFI witness Dr. Strand apparently based his calculations on the assumption that 28.6% of all lobsters would violate a 2 ppm tolerance. *See* N–21 at 3. However, Judge Davidson found only 10% of lobster would violate a 2 ppm tolerance. Initial Decision at 7. Although NFI did not except to that finding, it continues to use, without explanation, the 28.6% figure in its exception concerning imports.

[4] Although NFI contends that Dr. Strand relied only "in part" on this statement, NFI Exceptions at 3, Dr. Strand's testimony does not indicate any other source for his assumptions. *See* N–21 at 8.

[5] Dr. Strand did not indicate how he arrived at the $51.6 million figure, other than to state that it is based on catfish, freshwater trout, striped bass, and lobster. N–21 at 9. Apparently his calculation was based on the total landed value of these species, N–21 at 4, Table 2, reduced by the percent loss for each of those species at 2 ppm, N–21 at 6, Table 3. The reduction is necessary to avoid any double counting, as the value of the violative fish has already been taken into account.

increment between 5 ppm and 2 ppm, must be considered. Judge Davidson's method brings the loss for catfish below the "trigger," whereas it is actually above. Compare Doc. N–21, p. 3 with [Initial Decision at] 10.

NFI Exceptions at 5, n. 4. Specifically, the data for catfish indicate a 26.0% loss at a tolerance of 2 ppm, and a 4.7% loss at 5 ppm. N–21 at 3, Table 1. Judge Davidson based his calculations on the incremental loss in reducing the tolerance from 5 ppm to 2 ppm (*i.e.*, for catfish, on a net loss of 21.3%, obtained by subtracting 4.7% from 26.0%. Initial Decision at Appendix 1). No one excepted to that method of calculation. The statement by the executive director of the Midwest Federated Fisheries Council quoted above, on which NFI relies, clearly discusses a "*reduction* in the *present* level of production (implied by the change from 5 ppm to 2 ppm)." (Emphasis added.) Applying that statement, the reduction in the level of catfish production is 21.3%. Because the amount lost is below the 25% trigger level, no loss can be attributed to an unviable catfish fishery.

Consequently, after elimination of the two marine species and catfish, a loss for unviable fisheries can be calculated only with respect to trout. Even if I were to include any loss due to unviable fisheries, it would only be $179,000.[6]

3. Alewives

Judge Davidson found that reducing the tolerance from 5 ppm to 2 ppm would result in the annual loss of alewives with a dockside value of $843,900. He arrived at this figure based on testimony that 70% of all alewives caught nationally were taken from the Great Lakes, and that Great Lakes alewives are not used as human food. Therefore, he assumed that the human food loss would, at a maximum, be 30% of the domestic catch (30% of the annual catch of $2,813,000 (N–21 at 4, Table 2) equals $843,900).[7] Initial Decision at 7.

The Bureau excepts to that figure, and asserts that no loss should be attributed to alewives. The Bureau's argument is that the record does not support Judge Davidson's assumption that 30% of the alewife harvest is used for food. Bureau Exceptions at 4.

I do not agree with the Bureau. Bureau expert Dr. Talhelm testified that "[a]lewives on the east coast of the United States, I believe, are used for human food consumption." G–8 at 5. I conclude that his statement is sufficient support for the finding that 30% of the alewife catch is used for human food.[8]

4. Multiplier

In the proposal, FDA stated that the processed value of fish is about seven times its landed or dockside value; "processing" includes "cleaning, canning, distributing, retailing, etc." 42 FR 17492, col. 2. The preamble to the final rule discussed only landed value.

During the hearing, the Bureau argued that the most appropriate measure of human food loss is the dockside value. Bureau Brief to ALJ at 9–10. In the alternative, the Bureau argued that a "multiplier" of two or three should be used to calculate retail value from dockside value, and in essence disavowed use of the multiplier of seven. *Id.* at 14. NFI's position was that the agency had developed the multiplier of seven and the Bureau was bound by that figure. NFI Brief to ALJ at 3–4.

Against this background Judge Davidson decided that retail value represents human food loss, and found that the appropriate multiplier is six. Initial Decision at 5. Both the Bureau and NFI except to that finding. The Bureau states that the multiplier should be one or three. Bureau Exceptions at 5. NFI takes the position that the multiplier should be seven. NFI Exceptions at 7.

I conclude that it is appropriate to measure human food loss in dockside value, rather than value after processing or retail value. Although the preamble to the proposal and the economic analyses prepared for the proposed and final rules (G–1 and G–2) all discuss both landed and processed value, the preamble to the final rule does not. Thus, that preamble reveals that the agency's decision to lower the tolerance to 2 ppm was based, in the final analysis, on the assumption that the resulting human food loss would have a landed value of $9.6 million ($5.7 million in 1974 dollars). I believe it is appropriate that my decision on the hearing issue provide an answer that can be directly compared with that $9.6 million figure. Having reached this conclusion, I need not decide whether Judge Davidson's use of a "multiplier" of six to derive retail value from dockside value was correct.

Moreover, based on economic principles, I believe that landed value is the most appropriate measure for human food loss. In the short-run fishermen must bear the brunt of loss due to reducing the tolerance. In the short run, fishermen use their resources to catch fish without knowing whether the fish will violate the PCB tolerance. If the fish cannot be sold, the fisherman loses what he would have received for the fish but for the tolerance—the landed or dockside value. Persons in the marketing chain such as processors and retailers, and consumers, are not as fixed in the short run. For example, a processor typically has many suppliers of fish. If the processor cannot buy from one source, it probably can make up the difference from alternate sources. Similarly, consumers can react easily by shifting consumption patterns to other species of fish or other foods. Because of this ability to turn to different sources of supply, a lower tolerance level will not have a direct effect on these sectors of the economy and the value that would have been added by processing, distributing, and retailing to the landed value of fish that violate the lower tolerance should not be considered.

5. Elasticity Effect

Based on the testimony of Bureau witness Dr. Talhelm, Judge Davidson found that there would be a $6 million annual cost due to the "elasticity effect." He reasoned that lowering the tolerance would increase the value of the fish remaining on the market by no more than that amount. Initial Decision at 7.

The Bureau points out that the Judge misread Dr. Talhelm's testimony. Bureau Exceptions at 3. The Bureau is correct. What Dr. Talhelm actually stated was "I am positive that, even under these additional assumptions [the price elasticity of fish], the estimated *landed* value of the losses would *still* be less than $6 million per year." G–8 at 18 (Emphasis added.) Because Dr. Talhelm did not provide any estimate of the loss due to the elasticity effect, I conclude that a specific dollar loss cannot be attributed to the elasticity effect.

NFI attempts to bolster Judge Davidson's finding by arguing that it represents (after taking into account a multiplier effect of six) a dockside loss of $1 million, "which is an entirely reasonable estimate." NFI Reply to Exceptions at 2. I conclude that this argument is without merit, as it is nothing more than an attempted *post hoc* rationalization without evidentiary support. Moreover, it is based on a total misreading of the testimony. Since Dr. Talhelm testified about "landed" value, the reduction of his estimate by the "multiplier" to derive dockside value is

[6] The incremental loss of trout from reducing the tolerance from 5 ppm to 2 ppm is 30.7% (Initial Decision, Appendix 1), which exceeds the 25% trigger level. The $179,000 figure is based on annual landings of trout worth $259,000 (Table 2, N–21 at 4), reduced by $80,000, the value of violative trout at a 2 ppm tolerance that have already been taken into account (Initial Decision, Appendix 2).

[7] Judge Davidson implicitly assumed that all alewives would violate a 2 ppm tolerance. *See* N–21 at 2, 3. That assumption is not in dispute.

[8] Approximately 70% of the U.S. alewife catch comes from the Great Lakes; the remaining 30% comes from the east coast. G–7 at 14–15; *see* G–2 at 51.

obviously incorrect, as the terms landed and dockside are synonymous.

C. Conclusion

I have concluded that Judge Davidson correctly found that there would be no quantifiable human food loss due to imports or unviable fisheries, and that he correctly calculated the potential loss due to alewives. I have also concluded that human food loss should be stated in terms of dockside or landed value, and that no specific loss can be attributed to the elasticity effect. Therefore, I find that the human food loss in 1980 dollars, from reducing the tolerance from 5 ppm, is $13,453,500 landed value.[9]

Although Judge Davidson also calculated the human food loss for tolerances from 2.5 ppm to 4.5 ppm, those calculations are incomplete due to the lack of date concerning lobster and alewife losses at these intermediate tolerances. *See* Initial Decision, Appendix 2, note * *. Because these 2 species account for over one-third of the dollar loss at 2 ppm, I conclude that any calculation of the human food loss at intermediate tolerances would be based on speculation rather than substantial evidence. Consequently, I am not making any findings about the human food loss at tolerances between 2 ppm and 5 ppm.

I further conclude that Judge Davidson correctly decided all issues not addressed above.

III. Scientific Issues

In announcing the hearing concerning the magnitude of the human food loss, the agency stated that information not reasonably available during the notice and comment aspect of this rulemaking relating to other aspects of the tolerance, including the toxicity of PCBs, could be submitted for consideration by the Commissioner if the Commissioner finds good cause for their late inclusion in the rulemaking record. 46 FR 24552, col. 2. Hearing participants and other interested persons submitted over 100 scientific articles and reports for consideration by the Commissioner. Some of these articles and reports were discussed in the agency's risk assessment ("Risk Assessment") supporting the final rule (44 FR 38340, reference 45), some were available at that time but were not discussed, and some were written after the date of this risk assessment.

In view of the changing nature of scientific knowledge and the public health importance of a tolerance for PCBs in fish and shellfish, it is important that the agency's decision be based on all currently known relevant information. Therefore, I conclude that there is good cause for including in the rulemaking record all newly submitted reports and studies that are not presently part of the record. This includes those newly submitted studies that were reasonably available at the time of the notice and comment part of this rulemaking, but that were not then submitted for whatever reason.

I am aware that none of the additional submissions answer many of the uncertainties that FDA acknowledged in the preamble to the proposal (*e.g.*, studies involved commercial grade PCB mixtures, rather than the PCB isomers in fish, *see* 42 FR 17488), cols. 2 and 3). Nevertheless, the submissions are relevant to the toxicity of PCBs and a final decision on the tolerance, so I reject NMFS's suggestion that the Bureau's submissions not be included in the rulemaking record. NMFS Reply Brief at 5.

The Office of Science Coordination has reviewed all submitted papers. The results of that review are summarized in a report that is available from the Dockets Management Branch. ("Report"). I agree with the results of that review, and adopt the Report as part of my Final Decision. That review concluded that the newly submitted data support the conclusions of the Risk Assessment upon which the final rule is based.

In their briefs, NFI and GE generally take the position that FDA's concerns about the potential health risks associated with PCBs are overstated. I do not agree with that position. My responses to their specific arguments follow.

NFI argues that FDA's concerns are unfounded because PCBs are only a cancer promoter, not an initiator. NFI Brief at 5. Presently, there is no consensus in the scientific community regarding the mechanisms of initiation and promotion. However, regardless of whether PCBs are promoters or initiators, I believe the data indicate that PCBs present a significant potential risk to our population. In the preamble to the final rule, FDA stated that "[a]lthough the data do not fully resolve such important questions as the carcinogenicity of PCB's they lead to the conclusion that neither 'no-effect' nor 'allowable daily intake' levels for PCB's can be established with any confidence and that, from a toxicological point of view, human exposure to PCB's should be reduced." 44 FR 38331, col. 2. I conclude that that statement continues to be valid today.

NFI and GE contend that PCB levels in fish pose no health problems. NFI Brief at 5; GE Brief at 9–10. I do not agree. NFI and GE cite a study that investigated potential adverse health effects from human consumption of Lake Michigan fish contaminated with PCB residues. The study was considered in the Risk Assessment and discussed in the preamble to the proposal, 42 FR 17492–93 (Reference 40). Although no adverse health effects or groups of symptoms that were clearly related to PCB exposure could be identified in the exposed group, the investigators reported a highly significant correlation between the quantity of Lake Michigan fish consumed and the concentration of PCBs in the blood of study participants. It is significant that abstinence from Lake Michigan fish consumption for a period of 90 days did not significantly change PCB blood levels. Moreover, the study's authors cautioned that the absence of any adverse health effects similar to those effects observed in workers exposed to PCBs does not exclude the possibility that long term effects will occur.

NFI states that occupational exposure to PCBs at levels very much higher than would be experienced by those ingesting contaminated fish "leads to some health problems but not cancer or chronic health problems." NFI Brief at 5–6. FDA has identified a potential risk of PCB-induced hepatocellular carcinoma and adenoma by use of data from rodent carcinogenesis bioassays. Report at 4. This risk is supported by data in non-human primates and man indicating that the liver is a target of PCBs. Report at 5–6. There are also reports that an increased incidence of cancer has been observed in workers exposed to PCBs (Brown and Jones (1981)).[10] Although the incidence is low and a cause-and-effect relationship has not been established, these data—coupled with the fact that cancer has a long latent period—support the conclusion that chronic exposure to PCBs through the diet poses a potential risk.

GE argues that, because extrapolation of animal data to human experience is difficult and often misleading, priority should be given to valid human data. GE Brief at 3. I agree. The agency would prefer to base its risk assessment completely on valid human data. 42 FR 17487–88. However, there are rarely enough adequate human data to assess actual human risk without using data

[9] This is the same figure calculated by Judge Davidson, before application of the multiplier and addition of loss due to the elasticity effect. *See* page 6, *supra*.

[10] Citations are to references in Appendix I of the Report.

from non-human studies. There is general consensus among scientists that properly conducted animal studies are useful in the assessment of human health risks. Here, the results of human and animal data show a significant similarity of PCB-related effects between animals and human beings. For example, a review of the available carcinogenesis data in 1978 compared the responses of man, monkey, and rat to PCBs and concluded that hepatic hypertrophy was one of the responses common to all species (IARC (1978); see Table 9, p. 70). Liver has been found to be the predominant target organ in rodents and abnormal liver function has been observed in human beings exposed to PCBs in the workplace. Report at 5–6. Also, an abnormal incidence of liver cancer was reported in a population of PCB exposed workers (Brown and Jones (1981)).

I recognize that remaining unanswered questions about the human response to PCBs probably will be resolved only by valid human data. Nevertheless, submitted data not available at the time of the Risk Assessment underscore the agency's concerns about PCBs and support the hypothesis that the human liver is a target of PCBs and may be adversely affected by exposure to PCBs. Under section 406 of the act, FDA must make a qualitative judgment on the basis of available data—however incomplete—to insure the proper balance between adequate public health protection and excessive loss of food. Therefore, I conclude that the extrapolation of the animal data is both necessary and proper.

GE suggests that, because PCB-induced morphological changes in the gastric mucosa of monkeys are not reported in rodents or other species, and because there are no clinical findings suggesting increased occurrences of stomach cancer in man, extrapolation from animal models to man is not appropriate. GE Brief at 4. I believe GE's suggestion misses the point, as the human liver, not the stomach, is the principal source of concern.

GE contends that animal studies do not clearly indicate that PCBs induce cancer. GE Brief at 6. Although the question of whether PCBs are carcinogenic still has not been fully resolved, results of studies completed since the Risk Assessment support its conclusion that the liver is a target organ for PCBs in the rodent and that hepatocellular carcinoma or adenoma can result from PCB ingestion. Eleven of twelve rodent studies submitted in this proceeding reported significant PCB-associated incidences of hepatoma, hepatocellular carcinoma or adenoma, or hepatic neoplastic nodules. Report at 4. These endpoint histopathologies are generally recognized as indicative of carcinogenic or precarcinogenic responses. In addition, Shimada and Sato (1980) reported the finding of a PCB-moiety that was apparently covalently bound to rat hepatic macromolecules. This finding corroborates the animal studies, since it is generally accepted that the finding of intracellular, covalently bound agents is an important step in the mechanism of carcinogenesis. Two general statements can be made. First, there is agreement among scientists that induction of hepatocellular carcinomas early in the course of a bioassay is indicative of carcinogenicity under bioassay conditions. Nagasaki *et al.* (1972) observed hepatocellular carcinoma at 32 weeks in mice that were fed PCBs. Second, the occurrence of hepatocellular tumors in more than one species and/or more than one sex gives added weight to a finding of carcinogenicity. Here, increases in hepatocellular tumors were observed in both mice and rats fed PCBs.

Although GE correctly points out that the results of clinical studies with exposed workers have not proved conclusively that PCBs cause adverse liver abnormalities in human beings, GE Brief at 6–7, that point is hardly controlling. What is important is that the results of the studies do raise concerns about the response of the human liver to PCBs and indicate that the human liver is a target of PCBs. FDA is concerned about the induction of PCB-associated liver abnormalities in human beings as a result of long term, low level exposure to PCBs.

GE contends that PCBs pose no serious risk of teratogenesis to human beings because animal studies showed negative results or highly questionable positive results. GE Brief at 5–6. The concerns raised in the Risk Assessment about the potential of PCBs to cause reproductive and fetotoxic effects were based on the results of a study in Rhesus monkeys (Barsotti *et al.* (1976)). Those concerns continue because a subsequent report of behavioral tests with the infant Rhesus monkeys who survived that study indicated increased errors in five of nine learning tasks at ages eight and 24 months, even though they were no longer nursing. During that period, tissue concentrations of PCBs in those infant monkeys decreased linearly with time (Bowman *et al.* (1978)). This suggests that PCBs may cause irreversible neurobehavioral abnormalities. Additional support for this concern is provided by the results of a study in minks in which PCBs at 2 ppm in the diet caused complete reproductive failure (Bleavins *et al.* (1980)).

GE contends that "no serious effects on reproduction or infant mortality were found among 100 nursing mothers in Michigan." GE Brief at 5. GE's contention is based on a study that was conducted to measure the levels of PCBs in human milk collected in the state of Michigan (Wickizer *et al.* (1981)). That study does not support GE's contention, because it did not purport to collect data concerning adverse health consequences to any of the donors. The study is important, however, because it demonstrates that PCBs have been found in human milk at levels (1.5 ± 0.8 ppm) almost the same as those levels found in the milk of Rhesus monkeys whose infants displayed significant signs of toxicity.

GE discusses the observation that "in the process of metabolizing PCBs, excess amounts of proteins (enzymes) known as mixed function oxydases (sic) (MFOs) are produced in occupationally exposed individuals, principally in the liver." GE Brief at 10. Contrary to GE's assertion, I do not believe that these data, together with the results of other toxicological experiments, support the conclusion that the observed increase in enzyme activity is of no consequence to health over the individual's lifetime. The fact that an increase in enzyme activity in the human liver was observed supports the conclusion that the liver is a target organ of PCBs in human beings and more generally underscores FDA's concerns about the safety of PCB's to human health.

GE discusses "Yusho disease." GE Brief at 7. The Yusho tragedy helped alert the public and this agency to the dangers of PCB contamination. It is discussed in the preamble to the proposal, 42 FR 17488, col. 1, and in the Risk Assessment. However, the Yusho incident involved short-term exposure to high levels of PCBs, while the focus of this proceeding is the long-term ingestion of low levels of PCBs. Gaffy (1981), in a paper submitted by CMA, stated that "it is doubtful whether any generalization can be made from the [Yusho] incident to lower level environmental or occupational exposures to PCBs." Therefore, I will not respond to GE's specific contentions concerning Yusho disease. Similarly, dermatological ailments, *see* GE Brief at 9, are not the focus of FDA's concerns.

I have considered the scientific arguments of EDF and the Bureau in making my final decision. Because their

arguments support the final rule, I will not address them specifically.

IV. Miscellaneous Isssue

Several miscellaneous issues were raised in the briefs to the Commissioner and other pleadings. They are addressed in this section of my decision.

NFI argues that the agency unlawfully interpreted NFI's objection to the final rule in an overly narrow way, thereby denying it the right to a hearing on some issues. NFI Brief at 8–11. But that contention is not borne out by an examination of NFI's objection. NFI objected "on the grounds that the loss of food which would be caused by the proposed reduction of the tolerance is grossly understated by the agency . . ." N–1 at 1. That is precisely the issue on which FDA granted a hearing—"the magnitude of the human food loss (in terms of dollars, poundage, percentage of catch, etc.) that would result from lowering the tolerance of PCB's in fish from 5 ppm to 2 ppm." 46 Fed. Reg. 24552, col. 2.

NMFS argues in its brief to the Commissioner that FDA should perform a new risk analysis that specifically takes lobster into account. NMFS Brief at 6. At the time of the Risk Assessment, no data concerning PCB levels in lobster were available.

In response to that argument, a Bureau scientist recalculated the risk estimates, taking residue PCB levels in lobster into account. Those calculations show that the overall risk estimates would increase by 1.5% at most. The Bureau scientist's report is attached to the Bureau's reply brief to the Commissioner. Because the Bureau's calculations establish that the Risk Assessment results are still valid, no purpose would be served by further delaying the effective date of the 2 ppm tolerance while a new risk assessment is performed.

NFI filed a motion to strike that recalculation of the Risk Assessment, on the basis that the evidentiary record had closed and that NFI would be prejudiced because it would not have a chance to rebut the Bureau's recalculations. I am denying NFI's motion to strike and conclude that it is without merit. In its response to the motion to strike, the Bureau stated that it would not oppose the submission of any rebuttal information by NFI. Because NFI did not even attempt to rebut the Bureau's recalculation, it is obvious that NFI has not been prejudiced. Moreover, the recalculation was submitted for consideration by the Commissioner. It had nothing to do with the hearing issue and was not affected by the closing of the hearing evidentiary record.

NMFS also argues in its reply brief that FDA should undertake a new risk assessment that takes into account tolerance levels between 2 ppm and 5 ppm. NMFS stated that it would work with FDA in supporting such an endeavor. NMFS Reply Brief at 14.

As the agency previously stated, it must act on the basis of existing information, even if incomplete. 44 FR 38331, col. 1. FDA would not be fulfilling its obligation to protect the public health by further delaying the effective date of the reduced tolerance. I acknowledge NMFS's offer of assistance, and will consider it in connection with FDA's on-going monitoring of PCBs and, if necessary, future revisions of the tolerance.

NFI argues that FDA failed to comply with the requirements of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, and Executive Order 12291, 46 FR 13192 (February 19, 1981). NFI Brief at 12. That argument is answered by the plain language of that Act and Order. Section (1)(a)(1) of the Executive Order states that it does not apply to administrative actions governed by 5 U.S.C. 556 and 557, which apply to rulemakings pursuant to section 701(e) of the act. The Regulatory Flexibility Act does not apply to rulemaking initiated before its effective date, January 1, 1981. Pub. L. 96–354, section 4.

NFI contends that FDA should conduct a much broader inquiry into the economic costs of the reduced tolerance on the nation. NFI Brief at 11. On the other hand, EDF argues that economic considerations cannot play a significant part in this rulemaking. EDF Brief at 4–10. As discussed in the preamble to the final rule, 44 FR 38330, col. 3, the agency's paramount consideration in establishing a tolerance is protection of the public health. FDA is authorized by section 406 of the act to consider the unavoidability of substances such as PCBs. It is in connection with the unavoidability of PCBs that human foods loss, and thus the limited issue of the value of the food loss, are relevent.

V. Conclusion

In promulgating the final rule, the agency concluded that a 2 ppm tolerance would strike a proper balance between protecting consumers from the risks associated with exposure to PCBs, and the loss of food due to the lowered tolerance. That balancing was based on an estimated annual food loss, in terms of landed value, of $9.6 million ($5.7 million in 1974 dollars). For the reasons discussed in the preamble and supporting economic analysis (G–2), that estimate was based on a number of assumptions and inherently subject to considerable uncertainty.

I have concluded above that the annual dockside human food loss is $13.5 million, rather than the $9.6 million estimate stated in the preamble to the final rule. I have further concluded that the Risk Assessment supporting the final rule continues to be valid in light of newly submitted scientific information. The only question that remains is whether a balancing of the unchanged public health considerations and the increased human food loss yields a tolerance greater than 2 ppm. I conclude that the answer is no. I conclude that, even with an estimated human food loss of $13.5 million rather than $9.6 million, 2 ppm is nevertheless the proper balance between public health protection and loss of food.

I believe that we should keep in mind the fact that total annual domestic landings of fish are almost $1.6 billion.[11] Thus, the total human food loss is less than 1% of all domestic landings.

NMF argues that, based on a balancing of risks to human health and human food loss considerations, the tolerance should be 3.5 ppm. NMFS Brief at 4. Although the risk assessment supporting the final rule included calculations of risk only at 5 ppm, 2 ppm, and 1 ppm, NMFS submitted the results of risk calculations at various levels between 5 ppm and 2 ppm.[12] F–32 and F–33.

I do not agree with NMFS's reasoning. The risk calculations for tolerances between 5 ppm and 2 ppm do not show any sudden decrease in the number of expected cancers below the 3.5 ppm level. Rather, the expected cancer rate drops quickly between 2 ppm and 1 ppm. Those calculations show that the expected cancer rate is basically an arithmetic progression at levels between 5 ppm and 2 ppm and are consistent with my final decision that 2 ppm is the appropriate tolreance. Moreover, NMFS's argument is based on a comparison of Judge Davidson's total human food loss findings at 2 ppm and 3.5 ppm. As I have already stated, Judge Davidson's human food loss figures for intermediate tolerances are seriously

[11] According to the economic analysis for the final rule, domestic landings in 1974 were $932 million. G–2 at 3. Expressed in 1980 dollars, that figure becomes $1.56 billion.

[12] Judge Davidson granted the motions of the Bureau and EDF to strike these submissions because they were beyond the scope of the hearing. Order, dated October 16, 1981. Judge Davidson's decision on the motions was correct. For the reasons already stated, however, page 20 *supra*, the submissions are part of the overall rulemaking record and can be considered by the Commissioner in making a final agency decision.

incomplete, such that no meaningful comparisons between 2 ppm and higher tolerances are possible.

NFI and GE argue that a balancing of economic costs and public health benefits leads to the result that the tolerance should be 5 ppm. NFI Brief at 14; GE Brief at 11. I have already discussed and rejected the arguments that the agency's public health concerns about PCBs are overstated, and that FDA has not considered the full economic impact of reducing the tolerance. Consequently, I reject the suggestion that the tolerance not be lowered.

In rejecting the balancing results urged by NMFS, NFI, and GE, I believe it is important to keep in mind that a decision to set the tolerance at 2 ppm, rather than at some other higher or lower level, is inherently, judgmental in character. As stated in the preamble to the final rule, section 406 of the act does not provide a formula for weighing public health concerns against loss of food. 44 FR 38336, col. 1. In the final analysis, as Commissioner of the agency charged by Congress with protecting the public health in this area, I must make an informed judgment in light of the statutory criteria. My judgment is that 2 ppm is the appropriate tolerance.

The foregoing decision in its entirety constitutes my findings of fact and conclusions of law.

List of Subjects in 21 CFR Part 109

Contaminants, Polychlorinated Biphenyls (PCB's).

VI. Final Order

Therefore, on the basis of the foregoing findings of fact and conclusions of law and the record in the above proceeding and under the Federal Food, Drug, and Cosmetic Act (secs. 306, 402(a), 406, 701 (a) and (e), 52 Stat. 1045–1046 as amended, 1055, 70 Stat. 919 as amended (21 U.S.C. 336, 342(a), 346, 371 (a) and (e))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10): It is ordered that the stay of 21 CFR 109.30(a)(7), as ordered in the Federal Register of October 5, 1979 (44 FR 57389), be terminated effective August 20, 1984.

Dated: May 14, 1984.

Mark Novitch;

Acting Commissioner of Food and Drugs.

[FR Doc. 84-13656 Filed 5-17-84; 10:30 am]

BILLING CODE 4160-01-M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of Assistant Secretary for Housing—Federal Housing Commissioner

24 CFR Parts 201, 203, and 234

[Docket No. N-84-1379; FR-1981]

Mortgage Insurance; Changes to Maximum Mortgage Limits for Single Family Residences and Manufactured Homes and Lots

AGENCY: Office of Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Notice of revisions to FHA maximum mortgage limits for high-cost areas.

SUMMARY: This Notice revises the listing of areas eligible for "high-cost" mortgage limits under certain of HUD's insuring authorities under the National Housing Act. Mortgage limits are adjusted in an area when the Secretary determines that middle- and moderate-income persons have limited housing opportunities because of high prevailing housing sales prices.

EFFECTIVE DATE: May 22, 1984.

FOR FURTHER INFORMATION CONTACT: For single family: John J. Coonts, Director, Single Family Development Division, Room 9270, Telephone (202) 755–8720. For manufactured homes: William L. Halpern, Acting Director, Office of Title I Insured Loans, Room 9160, Telephone (202) 755–6680; 451 Seventh Street, SW., Washington, D.C. 20410. [Telephones are not toll-free numbers.]

SUPPLEMENTARY INFORMATION: .

Background

The National Housing Act (NHA) (12 U.S.C. 1701–1749) authorizes HUD to insure mortgages for single family residences (from one- to four-family structures), condominiums, manufactured homes, manufactured home lots, and combination manufactured homes and lots. The NHA, as amended by the Housing and Community Development Act of 1980 and the Housing and Community Development Amendments of 1981, permits HUD to increase the maximum mortgage limits under most of these programs to reflect regional differences in the cost of housing. In addition, sections 2(b) and 214 of the NHA provide for special high-cost limits for insured mortgages in Alaska, Guam and Hawaii.

The Housing and Urban-Rural Recovery Act of 1983 (Pub. L. 98–181, November 30, 1983) (the 1983 Act further amended HUD's insuring authority. Of particular interest here are (1) the authorization to insure condominiums in high-cost areas at the same levels as the high-cost limits for one-family residences insured under section 203(b) of the National Housing Act; and (2) the authorization to increase maximum loan limits under the Title I loan insurance program for combination manufactured home and lot loans and for individual lot loans in high-cost areas, so long as the percentage increase in the maximum loan limit does not exceed the percentage increase made to a one-family residence in the area authorized under section 203(b) of the NHA.

The Department implemented these provisions of the 1983 Act in related documents published in the Federal Register on April 11, 1984 (see 49 FR 14332, 14335, 14336), effective May 22, 1984. These documents amended the Department's rules to codify the procedure of announcing high-cost mortgage limits for single family residences, condominiums, combination manufactured homes and lots and manufactured home lots by notice in the Federal Register (see the April 11, 1984 documents, amending 24 CFR 201.1504, 203.18b, 203.29, 234.27, and 234.49). In addition, the documents codified the procedure whereby a party may request an alternative mortgage limit (see the same sections cited above).

This Document

In this document, the Department publishes its entire list of high-cost areas with applicable mortgage limits. The listing is different in several ways from the last complete listing, which was published on December 6, 1983 (48 FR 54703).

First, there is no longer a separate listing for condominium units, since these limits are now the same as those for other one-family residences.

Second, the listing includes instructions on how to compute the high-cost limits for combination manufactured homes and lots and individual lots, and specifies the special high-cost amounts for manufactured homes, combination manufactured homes and lots and individual lots insured in Alaska, Guam and Hawaii.

Third, it adds the following new high-cost areas, with applicable limits: Lowell, MA–NH PMSA; Lawrence-Haverhill, MA–NH PMSA; Hartford, CT PMSA; Nashua, NH PMSA; Charlotte-Gastonia-Rock Hill, NC–SC MSA; Raleigh-Durham, NC MSA; Jacksonville,

FL MSA; Orlando, FL MSA; Madison, WI MSA; Ann Arbor, MI PMSA; Des Moines, IA MSA; Omaha, NB–IA MSA; Albany, Saratoga, Schenectady, Dutchess, Ulster and Onondaga Counties, NY; Caguas, PR PMSA; Mayaguez, PR MSA; Ponce, PR MSA; Colorado Springs, CO MSA; and the State of Oregon.

Fourth, it further increases the limits for the following existing high-cost areas: Boston, MA PMSA; Salem-Gloucester, MA PMSA; Bridgeport-Milford, CT PMSA; Howard and Anne Arundel Counties, MD; Norfolk-Virginia Beach-Newport News, VA MSA; Atlanta, GA MSA; Memphis, TN–AR–MS MSA; Milwaukee, WI PMSA; Chicago, IL PMSA; Lake County, IL PMSA; Joliet, IL PMSA; Aurora-Elgin, IL PMSA; Dallas, TX PMSA; Ft. Worth, TX PMSA; Houston, TX PMSA; Austin, TX PMSA; San Antonio, TX MSA; Oklahoma City, OK MSA; Denver, CO PMSA; Boulder-Longmont, CO PMSA; Fresno, CA—all areas; Sacramento, CA—all areas; Tucson, AZ MSA; Seattle, WA PMSA; Tacoma, WA PMSA; Portland, OR PMSA; and Vancouver, WA PMSA.

And, fifth, it makes changes to the list based on a new definition of "metropolitan area." The jurisdictions of Abington Town, Plymouth County, MA; Boxford Town, Essex County, MA; Currituck County, NC; Hood and Wise Counties, TX; Sandoval County, NM; Mayes County, OK; Gilpin County, CO; and Tooele County, UT were identified in the December 6, 1983 **Federal Register** document as ineligible to continue as high-cost areas because they were removed from the metropolitan area receiving high-cost designation. These removals were the result of the redefinition of metropolitan areas by the Office of Management and Budget in June, 1983 and adopted by the Department for this program in the December, 1983 document. Because of the potential harm to applications for mortgage insurance in process, the Department agreed to retain these areas on the list temporarily and allowed persons the opportunity to submit data until April 6, 1984, which demonstrated the need to retain the high-cost designation. No one from these jurisdictions submitted data which warrants a finding by the Department that there are limited housing opportunities because of high housing sales prices. Except as noted below, these areas no longer appear on the high-cost listing and their limits will revert to the statutory limit of $67,500 on the effective date of this Notice, May 22, 1984.

One jurisdiction, Boxford Town, Essex County, MA, was transferred from the Boston, MA PMSA to the Lawrence-Haverhill, MA–NH PMSA. Lawrence-Haverhill, MA–NH PMSA is being added to the list of high-cost areas in today's document. Therefore, Boxford Town does not lose its status as a high-cost area. And Gilpin County, CO, loses its designation as a high-cost area, but does not revert to the statutory limit of $67,500, because the entire State of Colorado has a current limit of $71,800. Therefore, Gilpin County, CO will revert to the limit of $71,800 on the effective date of this Notice.

These high-cost limits are effective May 22, 1984 and supersede other published amounts in effect, to the extent they are inconsistent with figures appearing in this document.

The listing of high-cost areas appears in two parts. Part I explains high-cost limits for mortgages insured under Title I of the National Housing Act. Part II lists each high-cost area, with applicable limits for single family residences insured under sections 203(b), 234(c) and 214 of the National Housing Act.

List of Subjects

24 CFR Part 201

Fire prevention, Health facilities, Historic preservation, Home improvement, Loan programs—housing and community development, Manufactured homes, Reporting and recordkeeping requirements.

24 CFR Part 203

Home improvement, Loan programs—housing and community development, Mortgage insurance, Reporting and recordkeeping requirements, Solar energy.

24 CFR Part 234

Mortgage insurance, Reporting and recordkeeping requirements.

Accordingly, the Commissioner hereby publishes the revised dollar limitations as follows:

NATIONAL HOUSING ACT HIGH-COST MORTGAGE LIMITS

I. Title I: Method of Computing Limits

A. *Section 2(b)(1)(D). Combination manufactured home and lot (excluding Alaska, Guam and Hawaii):*

To determine the high-cost limit for a combination manufactured home and lot loan, multiply the dollar amount in the "one-family" column of Part II of this list by .80. For example, the first entry, Bristol County, MA, has a one-family limit of $81,200. The combination home and lot loan limit for Bristol County is $81,200×.80, or $64,960.

B. *Section 2(b)(1)(E). Lot only (excluding Alaska, Guam and Hawaii):*

To determine the high-cost limit for a lot loan, multiply the dollar amount in the "one-family" column of Part II of this list by .20. For example, the first entry, Bristol County, MA, has a one-family limit of $81,200. The lot only loan limit for Bristol County is $81,200×.20, or $16,240.

C. *Section 2(b)(2). Alaska, Guam and Hawaii limits:*

The maximum dollar limits for Alaska, Guam and Hawaii may be 140% of the statutory loan limits set out in section 2(b)(1).

Accordingly, the dollar limits for Alaska, Guam and Hawaii are as follows:

1. For manufactured homes: $56,700. ($40,500×140%).

2. for combination manufactured homes and lots: $75,600. ($54,000×140%).

3. For lots only: $18,900. ($13,500×140%).

II. Title II: Updating of FHA Sections 203(b), 234(c) and 214 Areawide Mortgage Limits

Market area designation and local jurisdictions	Mortgage limits			
	1-family and condominium unit	2-family	3-family	4-family
Region I				
HUD Field Office: Boston Office				
Boston, MA PMSA				
Briston County, MA (part)	$81,200	$91,450	$111,150	$128,250
Mansfield town				
Norton town				
Raynham town				
Essex County, MA (part):				
Lynn city				
Lynnfield town				
Nahant town				
Saugus town				
Middlesex County, MA (part):				
Acton town				
Arlington town				
Ashland town				
Ayer town				
Bedford town				
Belmont town				
Boxborough town				
Burlingtown town				
Cambridge city				
Carlisle town				
Concord town				
Everett city				
Framingham town				
Groton town				
Holliston town				
Hopkinton town				
Hudson town				
Lexington town				
Lincoln tosn				
Littleton town				
Malden city				
Marlborough city				
Maynard town				
Medford city				
Melrose city				

II. TITLE II: UPDATING OF FHA SECTIONS 203(b), 234(c) AND 214 AREAWIDE MORTGAGE LIMITS—Continued

Market area designation and local jurisdictions	Mortgage limits			
	1-family and condominium unit	2-family	3-family	4-family
Natick town				
Newton city				
North Reading town				
Reading town				
Sherborn town				
Shirley town	$81,200	$91,450	$111,150	$128,250
Somerville city				
Stoneham town				
Stow town				
Sudbury town				
Townsend town				
Wakefield town				
Waltham city				
Watertown town				
Wayland town				
Weston town				
Wilmington town				
Winchester town				
Woburn city				
Norfolk County, MA (part):				
Bellingham town				
Braintree town				
Brookline town				
Canton town				
Cohasset town				
Dedham town				
Dover town				
Foxborough town				
Franklin town				
Holbrook town				
Medfield town				
Medway town				
Millis town				
Milton town				
Needham town				
Norfolk town				
Norwood town				
Quincy city				
Randolph town				
Sharon town				
Stoughton town				
Walpole town				
Wellesley town				
Westwood town				
Weymouth town				
Wrentham town				
Plymouth County, MA (part):				
Carver town				
Duxbury town				
Hanover town				
Hanson town				
Hingham town				
Hull town				
Kingston town				
Lakeville town	$81,200	$91,450	$111,150	$128,250
Marshfield town				
Middleborough town				
Norwell town				
Pembroke town				
Plymouth town				
Plympton town				
Rockland town				
Scituate town				

II. TITLE II: UPDATING OF FHA SECTIONS 203(b), 234(c) AND 214 AREAWIDE MORTGAGE LIMITS—Continued

Market area designation and local jurisdictions	Mortgage limits			
	1-family and condominium unit	2-family	3-family	4-family
Suffolk County, MA:				
Boston city				
Chelsea city				
Revere city				
Winthrop town				
Worcester County, MA (part):				
Berlin town				
Bolton town				
Harvard town				
Hopedale town				
Lancaster town				
Mendon town				
Milford town				
Southborough town				
Upton town				
Salem-Gloucester, MA PMSA				
Essex County, MA (part)	$81,200	$91,450	$111,150	$128,250
Beverly city				
Danvers town				
Essex town				
Gloucester city				
Hamilton town				
Ipswich town				
Manchester town				
Marblehead town				
Middleton town				
Peabody city				
Rockport town				
Rowley town				
Salem city				
Swampscott town				
Topsfield town				
Wenham town				
Lowell, MA–NH PMSA				
Middlesex County, MA (part)	$70,800	$79,700	$96,850	$111,750
Billerica town				
Chelmsford town				
Dracut town				
Dunstable town				
Lowell city				
Pepperell town				
Tewksbury town				
Tyngsborough town				
Westford town				
Lawrence-Haverhill, MA–NH PMSA (part)				
Essex County, MA (part)	$70,800	$79,700	$96,850	$111,750
Amesbury town				
Andover town				
Boxford town				
Georgetown town				
Groveland town				
Haverhill city				
Lawrence city				
Merrimac town				
Methuen town				
Newbury town				

II. TITLE II: UPDATING OF FHA SECTIONS 203(b), 234(c) AND 214 AREAWIDE MORTGAGE LIMITS—Continued

Market area designation and local jurisdictions	Mortgage limits			
	1-family and condominium unit	2-family	3-family	4-family
Newburyport city				
North Andover town				
Salisbury town				
West Newbury town				
HUD FIELD OFFICE: HARTFORD OFFICE				
Bridgeport-Milford, CT PMSA				
Fairfield County (part)	$82,750	$93,250	$113,250	$130,700
Bridgeport city				
Easton town				
Fairfield town				
Monroe town				
Shelton city				
Stratford town				
Trumbull town				
New Haven County CT (part):				
Ansonia city				
Beacon Falls town				
Derby city				
Milford city				
Oxford town				
Seymour town				
Danbury, CT PMSA				
Fairfield County (part)	$90,000	$101,300	$122,650	$142,650
Bethel town				
Brookfield town				
Danbury city				
New Fairfield town				
Newtown town	$90,000	$101,300	$122,650	$142,650
Redding town				
Ridgefield town				
Sherman town				
Litchfield County, CT (part):				
Bridgewater town				
New Milford town				
Norwalk, CT PMSA				
Fairfield County (part)	$90,000	$101,300	$122,650	$142,650
Norwalk city				
Weston town				
Westport town				
Wilton town				
Stamford, CT PMSA				
Fairfield County (part)	$90,000	$101,300	$122,650	$142,650
Stamford city				
Darien town				
Greenwich town				
New Canaan town				
Hartford, CT PMSA				
Hartford County (part)	$79,800	$89,850	$109,200	$126,000
Avon town				
Bloomfield town				

II. TITLE II: UPDATING OF FHA SECTIONS 203(b), 234(c) AND 214 AREAWIDE MORTGAGE LIMITS—Continued

Market area designation and local jurisdictions	Mortgage limits			
	1-family and condominium unit	2-family	3-family	4-family
Canton town				
East Granby town				
East Hartford town				
East Windsor town				
Enfield town				
Farmington town				
Glastonbury town				
Granby town				
Hartford city				
Manchester town				
Marlborough town				
Newington town				
Rocky Hill town				
Simsbury town				
South Windsor town				
Suffield town				
West Hartford town				
Wethersfield town				
Windsor town				
Windsor Locks town				
Litchfield County (part)	$79,800	$89,850	$109,200	$126,000
Barkhamsted town				
New Hartford town				
Middlesex County (part):				
East Haddam town				
New London County (part):				
Colchester town				
Tolland County (part):				
Andover town				
Bolton town				
Columbia town				
Coventry town				
Ellington town				
Hebron town				
Somers town				
Stafford town				
Tolland town				
Vernon town				
Willington town				
State of Connecticut—All Other Metro and Non-Metro Areas	$71,800	$80,900	$98,300	$113,400
HUD FIELD OFFICE: MANCHESTER OFFICE				
Nashua, NH PMSA				
Hillsborough County, NH (part)	$70,800	$79,700	$96,850	$111,750
Amherst town				
Brookline town				
Hollis town				
Hudson town				
Litchfield town				
Merrimack town				
Milford town				
Mont Vernon town				
Nashua city				
Wilton town				
Rockingham County, NH (part):				
Londonderry town				
Lowell, MA–NH PMSA				
Hillsborough County, NH (part)	$70,800	$79,700	$96,850	$111,750
Pelham town				
Lawrence-Haverhill, MA–NH PMSA				
Rockingham County, NH (part)	$70,800	$79,700	$96,850	$111,750
Atkinson town				
Brentwood town				
Danville town				
Derry town				
East Kingston town				
Hampstead town				
Kingston town				
Newton town	$70,800	$79,700	$96,850	$111,750
Plaistow town				
Salem town				
Sandown town				
Seabrook town				
Windham town				
Region II				
HUD FIELD OFFICE: CARIBBEAN OFFICE				
San Juan, PR PMSA				
Barceloneta Municipio	$79,400	$89,450	$108,700	$125,400
Bayamon Municipio				
Canovanas Municipio				
Carolina Municipio				
Catano Municipio				
Corozal Municipio				
Dorado Municipio				
Fajardo Municipio				
Florida Municipio				
Guaynabo Municipio				
Humacao Municipio				
Juncos Municipio				
Las Piedras Municipio				
Loiza Municipio				
Luquillo Municipio				
Manati Municipio				
Naranjito Municipio				
Rio Grande Municipio				
San Juan Municipio				
Toa Alta Municipio				
Toa Baja Municipio				
Trujillo Alto Municipio				
Vega Alta Municipio				
Vega Baja Municipio				
Caguas, PR PMSA				
Aguas Buenas Municipio	$79,400	$89,450	$108,700	$125,400
Caguas Municipio				
Cayey Municipio				
Cidra Municipio				
Gurabo Municipio				
San Lorenzo Municipio				
Mayaguez, PR MSA				
Anasco Municipio	$79,650	$89,700	$109,000	$125,800
Cabo Rojo Municipio				
Hormigueros Municipio				
Mayaguez Municipio				
San German Municipio				
Ponce, PR MSA				
Juana Diaz Municipio	$81,700	$92,000	$111,800	$129,000
Ponce Municipio				
HUD FIELD OFFICE: NEW YORK OFFICE				
New York, NY PMSA				
Bronx County	$90,000	$101,300	$122,650	$142,650
Kings County				
New York County				
Putnam County				
Queens County				
Richmond County				
Rockland County				
Westchester County				
Nassau-Suffolk, NY PMSA				
Nassau County	$90,000	$101,300	$122,600	$142,650
Suffolk County				
HUD FIELD OFFICE: ALBANY OFFICE				
Albany County	$85,500	$96,300	$117,000	$135,000
Saratoga County				
Schenectady County				
Dutchess County	$90,000	$101,300	$122,650	$142,650
Ulster County				
Onondaga County	$84,350	$95,000	$115,400	$133,200
HUD FIELD OFFICE: NEWARK OFFICE				
Bergen-Passaic, NJ PMSA				
Bergen County	$90,000	$101,300	$122,650	$142,650
Passaic County				
Jersey City, NJ PMSA				
Hudson County	$90,000	$101,300	$122,650	$142,650
Middlesex-Somerset-Hunterdon, NJ PMSA				
Hunterdon County	$90,000	$101,300	$122,650	$142,650
Middlesex County				
Somerset County				
Monmouth-Ocean, NJ PMSA				
Monmouth County	$90,000	$101,300	$122,650	$142,650
Newark, NJ PMSA				
Essex County	$90,000	$101,300	$122,650	$142,650
Morris County				
Sussex County				
Union County				
HUD FIELD OFFICE: CAMDEN OFFICE				
Atlantic City, NJ MSA				
Atlantic County	$89,000	$100,000	$121,000	$141,000
Cape May County				
Monmouth-Ocean, NJ PMSA				
Ocean County	$90,000	$101,300	$122,650	$142,650
Trenton, NY MSA				
Mercer County	$68,500	$77,000	$93,500	$108,000
Wilmington, DE–NJ–MD PMSA				
Salem County, NJ	$70,200	$79,100	$96,100	$110,900
Region III				
HUD FIELD OFFICE: PHILADELPHIA OFFICE				
Wilmington, DE–NJ–MD PMSA				
New Castle County, DE	$70,200	$79,100	$96,100	$110,900
HUD FIELD OFFICE: WASHINGTON, DC OFFICE				
Washington, DC–MD–VA MSA				
District of Columbia	$90,000	$101,300	$122,650	$142,650

II. TITLE II: UPDATING OF FHA SECTIONS 203(b), 234(c) AND 214 AREAWIDE MORTGAGE LIMITS—Continued

Market area designation and local jurisdictions	Mortgage limits			
	1-family and condominium unit	2-family	3-family	4-family
Montgomery County, MD				
Prince Georges County, MD				
Alexandria, city, VA				
Fairfax County, VA				
Falls Church city, VA				
Manassas city, VA				
Manassas Park city, VA				
Arlington County, VA				
Loudon County, VA				
Prince William County, VA				
HUD FIELD OFFICE: BALTIMORE OFFICE				
Washington DC–MD–VA MSA				
Charles County, MD	$90,000	$101,300	$122,650	$142,650
Calvert County, MD				
Frederick County, MD				
Baltimore, MD MSA (part)				
Howard County	$90,000	$101,300	$122,650	$142,650
Anne Arundel County				
Baltimore, MD MSA (part)				
Baltimore city	$74,700	$84,200	$102,300	$118,000
Baltimore County				
Carroll County				
Harford County				
Queen Anne's County				
Wilmington, DE–NJ–MD PMSA				
Cecil County, MD	$70,200	$79,100	$96,100	$110,900
HUD FIELD OFFICE: RICHMOND OFFICE				
Washington, DC–MD–VA MSA (part)				
Stafford County, VA	$90,000	$101,300	$122,650	$142,650
Richmond City	$68,300	$76,900	$93,500	$107,900
Charles City County				
Chesterfield County				
Dinwiddie County				
Goochland County				
Hanover County				
Henrico County				
New Kent County				
Powhatan County				
Prince George County				
Colonial Heights city				
Hopewell city				
Petersburg city				
Norfolk-VA Beach-Newport News, VA MSA				
Chesapeake city	$78,500	$88,450	$107,450	$124,000
Hampton city				
Newport News city				
Norfolk city				
Poquoson city				
Portsmouth city				
Suffolk city				
Virginia Beach city				
Williamsburg city				
Gloucester County				
James City County				
York County				
Region IV				
HUD FIELD OFFICE: COLUMBIA OFFICE				
Charleston-North Charleston, SC MSA				
Berkeley County	$80,500	$90,500	$110,000	$127,500
Charleston County				
Dorchester County				
Greenville-Spartanburg, SC MSA				
Greenville County	$72,900	$82,100	$99,700	$115,100
Pickens County				
Spartanburg County				
Charlotte-Gastonia-Rock Hill, NC–SC MSA (part)				
York County, SC	$76,000	$85,500	$104,000	$120,500
HUD FIELD OFFICE: GREENSBORO OFFICE				
Raleigh-Durham, NC MSA				
Durham County	$75,800	$85,350	$103,700	$119,700
Franklin County				
Orange County				
Wake County				
Charlotte-Gastonia-Rock Hill, NC–SC MSA				
Cabarrus County	$76,000	$85,500	$104,000	$120,500
Gaston County				
Lincoln County				
Mecklenburg County				
Rowan County				
Union County				
HUD FIELD OFFICE: ATLANTA OFFICE				
Atlanta, GA MSA				
Butts County	$85,250	$96,000	$116,650	$134,600
Barrow County				
Cherokee County				
Clayton County				
Cobb County				
Coweta County				
Dekalb County				
Douglas County				
Fayette County				
Forsyth County				
Fulton County				
Gwinnett County				
Henry County				
Newton County				
Paulding County				
Rockdale County				
Spalding County				
Walton County				
HUD FIELD OFFICE: BIRMINGHAM OFFICE				
Mobile, AL MSA				
Baldwin County	$75,000	$84,000	$102,500	$118,000
Mobile County				
Montgomery, AL MSA				
Autauga County				
Elmore County				
Montgomery County				
HUD FIELD OFFICE: LOUISVILLE OFFICE				
Cincinnati, OH–KY–IN PMSA (part)				
Boone County, KY	$80,750	$90,950	$110,500	$127,500
Campbell County, KY				
Kenton County, KY				
HUD FIELD OFFICE: MEMPHIS OFFICE				
Memphis, TN–AR–MS MSA				
Shelby County, TN	$87,750	$98,850	$120,100	$138,600
Tipton County, TN				
HUD FIELD OFFICE: NASHVILLE OFFICE				
Nashville, TN MSA				
Cheatham County	$75,000	$84,000	$102,500	$118,000
Davidson County				
Dickson County				
Robertson County				
Rutherford County				
Sumner County				
Williamson County				
Wilson County				
HUD FIELD OFFICE: JACKSON OFFICE				
Jackson, MS MSA				
Hinds County	$76,000	$85,600	$104,000	$120,000
Madison County				
Rankin County				
Memphis, TN–AR–MS MSA				
Desoto County, MS	$87,750	$98,850	$120,100	$138,600
HUD FIELD OFFICE: CORAL GABLES OFFICE				
Ft. Lauderdale-Hollywood-Pampano Beach, FL PMSA				
Broward County	$78,700	$88,700	$107,700	$124,300
Miami-Hialeah, FL PMSA				
Dade County	$81,800	$92,100	$111,900	$129,100
West Palm Beach-Boca Raton-Delray Beach, FL MSA				
Palm Beach County	$79,700	$89,800	$109,100	$125,900
Non-Metro Areas:				
Collier County	$76,000	$85,500	$103,500	$120,500
HUD FIELD OFFICE: TAMPA OFFICE				
Sarasota, FL MSA				
Sarasota County	$76,100	$85,700	$104,100	$120,000
Tampa-St. Petersburg-Clearwater, FL MSA				
Hernando County	$71,500	$80,500	$97,900	$112,900

II. TITLE II: UPDATING OF FHA SECTIONS 203(b), 234(c) AND 214 AREAWIDE MORTGAGE LIMITS—Continued

Market area designation and local jurisdictions	Mortgage limits			
	1-family and condominium unit	2-family	3-family	4-family
Hillsborough County				
Pasco County				
Pinellas County				
HUD FIELD OFFICE: JACKSONVILLE OFFICE				
Jacksonville, FL MSA				
Clay County	$72,800	$82,000	$99,600	$114,950
Duval County				
Nassau County				
St. Johns County				
HUD FIELD OFFICE: ORLANDO OFFICE				
Orlando, FL MSA				
Orange County	$72,800	$82,000	$99,600	$114,950
Osceola County				
Seminole County				
Region V				
HUD FIELD OFFICE: MINNEAPOLIS-ST. PAUL OFFICE				
Minneapolis-St. Paul, MN MSA				
Anoka County	$90,000	$101,300	$122,650	$142,650
Carver County				
Chisago County				
Dakota County				
Hennepin County				
Isanti County				
Ramsey County				
Scott County				
Washington County				
Wright County				
St. Cloud, MN MSA				
Benton County	$68,500	$77,000	$93,500	$108,500
Sherburne County				
Stearns County				
HUD FIELD OFFICE: MILWAUKEE OFFICE				
Minneapolis-St. Paul, MN MSA				
St. Croix County, WI	$90,000	$101,300	$122,650	$142,650
Milwaukee, WI PMSA				
Milwaukee County	$77,800	$87,600	$106,450	$122,850
Ozaukee County				
Washington County				
Waukesha County				
Madison, WI				
Dane County	$70,800	$79,750	$96,900	$111,800
HUD FIELD OFFICE: CHICAGO OFFICE				
Chicago, IL PMSA				
Cook County	$87,250	$98,300	$119,400	$137,800
DuPage County				
McHenry County				
Lake County, IL PMSA				
Lake County	$87,250	$98,300	$119,400	$137,800
Joliet, IL PMSA				
Grundy County	$87,250	$98,300	$119,400	$137,800
Will County				
Aurora-Elgin, IL PMSA				
Kane County	$87,250	$98,300	$119,400	$137,800
Kendall County				
St. Louis, MO-IL PMSA				
Monroe County, IL	$85,500	$96,300	$117,000	$135,000
East St. Louis-Belleville, IL PMSA				
Clinton County, IL	$85,500	$96,300	$117,000	$135,000
St. Clair County, IL				
HUD FIELD OFFICE: DETROIT OFFICE				
Detroit, MI PMSA				
Lapeer County	$75,300	$84,800	$103,000	$118,900
Livingston County				
Macomb County				
Monroe County				
Oakland County				
St. Clair County				
Wayne County				
Ann Arbor, MI PMSA				
Washtenaw County	$76,800	$86,500	$105,100	$121,250
HUD FIELD OFFICE: CLEVELAND OFFICE				
Cleveland, OH PMSA				
Cuyahoga County	$75,400	$84,900	$103,100	$119,000
Geauga County				
Lake County				
Medina County				
HUD FIELD OFFICE: COLUMBUS OFFICE				
Columbus, OH MSA				
Delaware County	$81,100	$91,400	$111,000	$128,100
Fairfield County				
Franklin County				
Licking County				
Madison County				
Pickaway County				
Union County				
HUD FIELD OFFICE: CINCINNATI OFFICE				
Cincinnati, OH-KY-IN PMSA (part)				
Clermont County, OH	$80,750	$90,950	$110,500	$127,500
Hamilton County, OH				
Warren County, OH				
Hamilton-Middleton, OH PMSA				
Butler County	$80,750	$90,950	$110,500	$127,500
HUD FIELD OFFICE: INDIANAPOLIS OFFICE				
Cincinnati, OH-KY-IN PMSA (part)				
Dearborn County, IN	$80,750	$90,950	$110,500	$127,500
Region VI				
HUD FIELD OFFICE: DALLAS OFFICE				
Dallas, TX PMSA				
Collin County	$90,000	$101,300	$122,650	$142,650
Dallas County				
Denton County				
Ellis County				
Kaufman County				
Rockwall County				
Sherman-Denison TX MSA				
Grayson County	$78,000	$88,000	$106,500	$124,000
HUD FIELD OFFICE: FORT WORTH OFFICE				
Ft. Worth-Arlington, TX PMSA				
Johnson County	$90,000	$101,300	$122,650	$142,650
Parker County				
Tarrant County				
HUD FIELD OFFICE: HOUSTON OFFICE				
Houston, TX PMSA				
Brazoria County	$90,000	$101,300	$122,650	$142,650
Fort Bend County				
Harris County				
Liberty County				
Montgomery County				
Waller County				
HUD FIELD OFFICE: LUBBOCK OFFICE				
Amarillo, TX MSA				
Potter County	$68,500	$77,000	$93,500	$108,500
Randall County				
Lubbock, TX MSA				
Lubbock County	$70,000	$78,500	$95,500	$110,500
Midland, TX MSA				
Midland County	$70,000	$78,500	$95,500	$110,500
HUD FIELD OFFICE: SAN ANTONIO OFFICE				
Austin, TX MSA				
Hays County	$90,000	$101,300	$122,650	$142,650
Travis County				
Williamson County				
San Antonio, TX MSA				
Bexar County	$82,750	$93,250	$113,250	$130,700
Comal County				
Guadalupe County				
Corpus Christi, TX MSA				
Nueces County	$70,000	$78,500	$95,500	$110,500
San Patricio County				
HUD FIELD OFFICE: LITTLE ROCK OFFICE				
Memphis, TN-AR-MS MSA				
Crittenden County, AR	$87,750	$96,850	$120,100	$138,600
HUD FIELD OFFICE: OKLAHOMA CITY OFFICE				
Oklahoma City, OK MSA				
Canadian County	$72,800	$82,000	$99,600	$114,950
Cleveland County				
Logan County				
McClain County				
Oklahoma County				
Pottawatomie County				
HUD FIELD OFFICE: NEW ORLEANS OFFICE				
Baton Rouge, LA MSA				
Ascension Parish	$76,000	$85,500	$103,500	$120,500
East Baton Rouge Parish				
Livingston Parish				
West Baton Rouge Parish				
New Orleans, LA MSA				
Jefferson Parish	$76,000	$85,500	$103,500	$120,500

II. TITLE II: UPDATING OF FHA SECTIONS 203(b), 234(c) AND 214 AREAWIDE MORTGAGE LIMITS—Continued

Market area designation and local jurisdictions	Mortgage limits			
	1-family and condominium unit	2-family	3-family	4-family
Orleans Parish				
St. Bernard Parish				
St. Charles Parish				
St. John the Baptist Parish				
St. Tammany Parish				
HUD FIELD OFFICE: SHREVEPORT OFFICE				
Shreveport, LA MSA				
Bossier Parish	$75,500	$85,000	$103,300	$119,200
Caddo Parish				
HUD FIELD OFFICE: ALBUQUERQUE OFFICE				
Albuquerque, NM MSA				
Bernalillo County	$76,500	$86,000	$104,000	$121,000
HUD FIELD OFFICE: TULSA OFFICE				
Tulsa, OK MSA				
Creek County	$82,500	$92,900	$112,900	$130,300
Osage County				
Rogers County				
Tulsa County				
Wagoner County				
Region VII				
HUD FIELD OFFICE: KANSAS CITY OFFICE				
Kansas City, MO PMSA				
Cass County, MO	$81,600	$91,900	$111,700	$128,900
Clay County, MO				
Jackson County, MO				
Lafayette County, MO				
Platt County, MO				
Ray County, MO				
Kansas City, KS PMSA				
Johnson County, KS	$81,600	$91,900	$111,700	$128,900
Leavenworth County, KS				
Miami County, KS				
Wyandotte County, KS				
HUD FIELD OFFICE: ST. LOUIS OFFICE				
St. Louis, MO–IL PMSA				
St. Louis City	$85,500	$96,300	$117,000	$135,000
Franklin County				
Jefferson County				
St. Charles County				
St. Louis County				
HUD FIELD OFFICE: DES MOINES OFFICE				
Des Moines, IA MSA				
Dallas County	$69,300	$78,000	$94,850	$109,450
Polk County				
Warren County				
Omaha, NB–IA MSA (part)				
Pottawattamie County, IA	$78,800	$88,750	$107,800	$124,400
HUD FIELD OFFICE: OMAHA OFFICE				
Omaha, NB–IA MSA (part)				
Douglas County, NE	$78,800	$88,750	$107,800	$124,400
Sarpy County, NE				
Washington County, NE				
Region VIII				
HUD FIELD OFFICE: DENVER OFFICE				
Denver, CO PMSA				
Adams County	$90,000	$101,300	$122,650	$142,650
Arapahoe County				
Denver County				
Douglas County				
Jefferson County				
Boulder-Longmont, CO PMSA				
Boulder County, CO	$90,000	$101,300	$122,650	$142,650
Colorado Springs, CO MSA				
El Paso County	$80,750	$90,950	$110,500	$127,500
State of Colorado: All Other Areas	$71,800	$80,900	$98,300	$113,400
State of Wyoming	$75,000	$84,000	$102,500	$118,000
HUD FIELD OFFICE: HELENA OFFICE				
State of Montana	$75,500	$84,000	$102,500	$118,000
HUD FIELD OFFICE: SALT LAKE CITY OFFICE				
Salt Lake City-Ogden, UT MSA				
Davis County	$75,000	$84,000	$102,500	$118,000
Salt Lake County				
Weber County				
Region IX				
HUD FIELD OFFICE: LOS ANGELES OFFICE				
Los Angeles Office Metro and Non-Metro Areas				
Los Angeles County	$90,000	$101,300	$122,650	$142,650
San Luis Obispo County				
Santa Barbara County				
Ventura County				
HUD FIELD OFFICE: SAN FRANCISCO OFFICE				
San Francisco Office Metro and Non-Metro Areas				
Alameda County	$90,000	$101,300	$122,650	$142,650
Contra Costa County				
Del Norte County				
Humboldt County				
Lake County				
Marin County				
Mendocino County	$90,000	$101,300	$122,650	$142,650
Monterey County				
Napa County				
San Benito County				
San Francisco County				
San Mateo County				
Santa Clara County				
Santa Cruz County				
Solano County				
Sonoma County				
HUD FIELD OFFICE: FRESNO OFFICE				
Fresno Office Metro and Non-Metro Areas				
Fresno County	$90,000	$101,300	$122,650	$142,650
Kern County				
Kings County				
Madera County				
Mariposa County				
Merced County				
Stanislaus County				
Tulare County				
HUD FIELD OFFICE: SACRAMENTO OFFICE				
Sacramento Office Metro and Non-Metro Areas				
Alpine County	$90,000	$101,300	$122,650	$142,650
Amador County				
Butte County				
Calaveras County				
Colusa County				
El Dorado County				
Glenn County				
Lassen County				
Modoc County				
Nevada County				
Placer County				
Plumas County				
Sacramento County				
San Joaquin County				
Shasta County				
Sierra County				
Siskiyou County				
Sutter County				
Tehama County				
Trinity County				
Tuolumne County				
Yolo County				
Yuba County				
HUD FIELD OFFICE: SAN DIEGO OFFICE				
San Diego Office Metro and Non-Metro Areas				
Imperial County	$90,000	$101,300	$122,650	$142,650
San Diego County				
HUD FIELD OFFICE: SANTA ANA OFFICE				
Santa Ana Office Metro Areas	$90,000	$101,300	$122,650	$142,650
Orange County				
Riverside County				
San Bernardino County				
Non-Metro Areas	$75,000	$84,000	$102,500	$118,000
Inyo County				
Mono County				
HUD FIELD OFFICE: LAS VEGAS OFFICE				
Las Vegas, NV MSA				
Clark County	$90,000	$101,300	$122,650	$142,650
State of Nevada				
Non-Metro Areas: Lincoln County	$75,000	$84,000	$102,500	$118,000
Nye County (part)				
HUD FIELD OFFICE: RENO OFFICE				
Reno, NV MSA				
Washoe County	$89,500	$101,000	$122,000	$142,000
State of Nevada				
Non-Metro Areas: Carson City County	$75,000	$84,000	$102,500	$118,000

II. TITLE II: UPDATING OF FHA SECTIONS 203(b), 234(c) AND 214 AREAWIDE MORTGAGE LIMITS—Continued

Market area designation and local jurisdictions	Mortgage limits			
	1-family and condominium unit	2-family	3-family	4-family
Churchill County Douglas County Elko County Esmeralda County Eureka County Humboldt County Lander County Lyon County Mineral County Nye County (Part) Pershing County Storey County White Pine County				
HUD FIELD OFFICE: PHOENIX OFFICE				
Phoenix, AZ MSA Maricopa County	$87,100	$98,100	$119,200	$137,600
HUD FIELD OFFICE: TUCSON OFFICE				
Tucson, AZ MSA Pima County	$90,000	$101,300	$122,650	$142,650
HUD FIELD OFFICE: HONOLULU OFFICE				
State of Hawaii				
Metro and Non-Metro Areas	$135,000	$151,950	$183,950	$213,950
Territory of Guam	$101,250	$114,000	$138,000	$160,500
Region X				
HUD FIELD OFFICE: SEATTLE OFFICE				
Seattle, WA PMSA King County Snohomish County	$87,750	$98,850	$120,100	$138,600
Tacoma, WA PMSA Pierce County	$75,300	$84,800	$103,050	$118,900
Yakima, WA MSA Yakima, County	$72,000	$81,500	$99,000	$114,000
Bremerton, WA MSA Kitsap County	$80,200	$90,350	$109,750	$126,650
HUD FIELD OFFICE: PORTLAND OFFICE				
Portland, OR PMSA Clackamas County Multnomah County Washington County Yamhill County	$86,450	$97,350	$118,300	$136,500
Vancouver, WA PMSA Clark County, WA	$86,450	$97,350	$118,300	$136,500
State of Oregon All other areas	$85,200	$95,950	$116,600	$134,550
HUD FIELD OFFICE: ANCHORAGE OFFICE				
State of Alaska All Areas	$135,000	$151,950	$183,950	$213,950
HUD FIELD OFFICE: SPOKANE OFFICE				
Richland-Kennewick-Pasco, WA MSA Benton County Franklin County	$72,000	$81,500	$99,000	$114,000
Spokane, WA MSA Spokane County	$72,000	$81,500	$99,000	$114,000
HUD FIELD OFFICE: BOISE OFFICE				
Boise City, ID MSA Ada County	$75,000	$84,000	$102,500	$118,000

Dated: May 16, 1984.

Maurice L. Barksdale,

Assistant Secretary for Housing—Federal Housing Commissioner.

[FR Doc. 84-13572 Filed 5-21-84; 8:45 am]

BILLING CODE 4210-27-M

DEPARTMENT OF DEFENSE

Department of the Air Force

32 CFR Part 812

User Charges

AGENCY: Department of the Air Force, DOD.

ACTION: Final rule.

SUMMARY: The Department of the Air Force is revising its rule which prescribes policy and procedures for developing an equitable and uniform system of charges for special services and for selling or leasing property to persons or organizations outside Department of Defense (DOD) and outside the Federal Government. It is being revised to incorporate changes in Air Force procedures due to the revision of a DOD Instruction, which this rule implements. The intended effect is to provide current information on Air force policy and procedures.

EFFECTIVE DATE: June 1, 1983.

FOR FURTHER INFORMATION CONTACT: Mr. Williamson, HQ Air Force Accounting and Finance Center, AFAFC/XSG, Denver, Colorado 80279, telephone (303) 370-7471.

SUPPLEMENTARY INFORMATION: This revision changes degree of risk assumed by lessee. It states Air Force policy on specialized or technical services provided to state and local government. It implements DODI 7230.7, August 15, 1978, and DODI 7730.53, December 23, 1982. Because this part implements a higher directive, it was not published as proposed for public comment. It is published as a final rule for information purposes. The Department of the Air Force has determined that this part is not a major rule as defined by Executive Order 12291; is not subject to the relevant provisions of the Regulatory Flexibility Act of 1980 (Pub. L. 96-354); and does not contain reporting or recordkeeping requirements under the criteria of the Paperwork Reduction Act of 1980 (Pub. L. 96-511).

List of Subjects in 32 CFR Part 812

Federal buildings and facilities, Surplus Government property, Intergovernmental Relations.

Accordingly, 32 CFR Part 812, is revised as follows:

PART 812—USER CHARGES

Subpart A—General Information

Sec.

812.0 Purpose.
812.1 Policy.
812.2 Responsibilities assigned.
812.3 Non-User charge transactions.
812.4 Waived or reduced charges.
812.5 User charge exclusions.
812.6 Charges for special services.
812.7 Charges for lease or sale of property.
812.8 Processing collections.
812.9 Accounting and control.
812.10 Conflicts or recommendations.

Subpart B—Specialized or Technical Services Provided to State and Local Government

812.11 Air Force policy.
812.12 Explanation of terms.
812.13 Background.
812.14 Types of services.
812.15 Conditions under which services may be provided.
812.16 Processing payments.
812.17 Questionable services.

Authority: Sec. 8012, 70A Stat. 488; 10 U.S.C. 8012.

Note.—This part is derived from Air Force Regulation 117-8, 1 June 1983.

Note.—Part 806 of this chapter states the basic policies and instructions governing the disclosure of records and tells members of the public what they must do to inspect or obtain copies of the material referenced herein.

Subpart A—General Information

§ 812.0 Purpose.

This part prescribes general policy for developing an equitable and uniform system of charges for special services and for selling or leasing property to persons or organizations outside DOD and outside the Federal Government; states the scope of user charges activities; furnishes guidelines and requirements for determining amounts of user charges, disposing of receipts, and accounting control of revenue from such charges. It implements DOD Instruction 7230.7, 15 August 1978, and DOD Instruction 7730.53, 23 December 1982. This part applies to all Air Force activities providing special benefits to non-DOD and non-Government recipients.

§ 812.1 Policy.

Air Force activities should not compete with available commercial facilities in providing special benefits or in selling or leasing property to recipients outside DOD or outside the Federal Government. However, impose

a reasonable charge when authorized special benefits are provided that:

(a) Enable the recipient to obtain more immediate or substantial gain or values (which may or may not be measurable in monetary terms) than those accruing to the general public, or

(b) Are performed at the request of the recipient and are above and beyond the services regularly received by or available without charge to the general public.

§ 812.2 Responsibilities assigned.

Responsibility for initiating and developing schedules of charges and fees consistent with the policies in this part rests with:

(a) HQ USAF for common types of assistance furnished on a department-wide basis (these schedules are in Air Force functional area directives).

(b) Major commands for types of assistance peculiar to their respective commands.

(c) Each activity concern for items or types of assistance furnished for which standard fees are not prescribed by higher authority. Each activity:

(1) Identifies the benefits or services covered by this part.

(2) Determines the extent of the special benefits provided.

(3) Determines cost or fair market value.

(4) Establishes the charges.

§ 812.3 Non-User charge transactions.

The provisions of this part do not cover or apply to the areas listed below. This does not necessarily mean charges are not made in these areas but, if made, they are determined under the provisions of other Air Force directives and are not considered user charges. Charges for services furnished non-Government audiovisual media, for example, are made under AFR 190–16. Similarily, charges for Armed Forces participation in public events are governed by AFR 190–5, Field Press Censorship. Additional non-user charge areas include:

(a) Morale, welfare, and recreation services to military personnel and civilian employees.

(b) Sale or disposal of surplus property under approved programs.

(c) Services furnished the general public relating to or furthering the Air Force recruiting program.

(d) Any services furnished representatives of public information media or the general public in the interest of public understanding of the Air Force.

(e) Any records made available to the public under the Freedom of Information Act.

(f) Any requests for release of Air Force-developed computer programs to non-Government customers.

(g) Foreign military sales of materiel and services.

§ 812.4 Waived or reduced charges.

In general, charges may be waived or reduced when:

(a) Payment of the full cost or fee by a State or local government or by a nonprofit group would not be in the interest of the program. See Subpart B for types of services and conditions under which services may be provided.

(b) Furnishing the service without charge is an appropriate courtesy to a foreign country or international organization, or comparable fees are set on a reciprocal basis with a foreign country.

(c) The incremental cost of collecting the fees would be an unduly large part of the receipts from the activity.

§ 812.5 User charge exclusions.

Although of a user charge nature, the following are considered exempt from the requirement to assess a charge. The list is not all-inclusive. Refer recommendations for additional exclusions to the office of primary responsibility (OPR) for this directive.

(a) Any services requested by members of the armed forces when the document or information requested is required by such personnel in their capacity as members of the armed forces of the United States.

(b) Any services requested by members of the armed forces who are in a casualty status, or by their next-of-kin or legal representative, and requests for information from any source relating to a casualty.

(c) The address of record of an active duty member or former member of the armed forces, when it can be furnished informally through local directory (locator) reference, when requested by a member of the armed forces, a relative, or legal representative of a member of the armed forces, or the address of record requested by any source, when the address is required for the purpose of paying monies or forwarding property to a member or former member of the armed forces.

(d) Any services requested by or on behalf of a member or former member of the armed forces or, if deceased, their next of kin or legal representative pertaining to requests for:

(1) Information required to obtain financial benefits regardless of the terms of separation from the service;

(2) Document showing membership and military record in the armed forces if discharged or release was under honorable conditions except as provided in § 812.5(d)(1) and (4);

(3) Information relating to a decoration or award or information required for memorialization purposes;

(4) Review or change in type of discharge or correction of records;

(5) Personal documents, for example, birth certificates, when such documents were required to be furnished by the individual.

(e) Services which are furnished free in accordance with statutes or executive orders.

(f) Information from or copies of medical and dental records and/or X-ray films of patients or former patients of military medical or dental facilities, when such information is required and requests for such data are submitted by an accredited medical facility, physician or dentist, or requested by the patient, next of kind, or legal representative.

(g) Any services involving confirmation of employment, disciplinary or other records, salaries of active or separated civilian or military personnel when requested by prospective employers, or recognized sources of inquiry for credit or financial purposes.

(h) Any services requested by and furnished to a member of Congress for official use.

(i) Any services requested by State, territorial, county, or municipal government, or an agency thereof, which is carrying on a function related to or furthering an objective of DOD.

(j) Any services requested by a court when the furnishing of such will serve as a substitute for personal court appearance of a military or civilian employee of DOD.

(k) Any services requested by a nonprofit orgnization which is carrying on a function related to or furthering an objective of the Federal Government or in the interest of public health and welfare.

(l) Any services requested by an individual or corporation which is carrying on a function related to or furthering an objective of the Federal Government, when the cost of such services would be charageable directly to a Federal Government contract or grant held by the individual or corporation.

(m) Any services requested by donors with respect to their gifts.

(n) Requests for services which are occasional and incidental (including any request from a resident of a foreign country), of a type that is not requested often, if it is administratively determined that a fee would be inappopriate in such an occasional case.

(o) Any request from Federal employees for completion of forms applicable to claims for reimbursement in connection with the Federal Employees Health Benefit Act of 1959.

(p) Administrative services normally provided in reference or reading rooms for public inspection of records, except for copies of records or documents furnished.

(q) Any request for military locator service by a financial institution located on a DOD installation.

(r) Any request for military locator service from financial organizations, engaged in the composite check program, that are not located on a DOD Installation. Each request for an address of record must include:

(1) A statement that the organization is listed as a composite check recipient in the current U.S. Treasury Bureau of Accounts, Financial Organizations Directory.

(2) A statement that the individual whose address is requested has his or her pay forwarded as a direct deposit by DOD disbursing officer;

(3) The financial organization's account number for the individual.

(s) Any services rendered in response to requests for classification review of DOD classified records, submitted under Executive Order 11652, as implemented by DOD Regulation 5200.1–R, which consist of the work performed in conducting the classification review, or in granting and carrying to completion an appeal from a denial of declassification after such review.

(t) Any services of a humanitarian nature performed in certain emergency situations such as: life-saving transportation for non-US Armed Forces patients, search and rescue operations, and airlift of personnel and supplies to a site of disaster. This does not mean inter- and intra-Governmental agreements to recover all or part of costs should not be negotiated. Rather, it means the recipient or beneficiary is not assessed a user charge.

§ 812.6 Charges for special services.

(a) *Establishing Fees.* Establish user charge fees for special services on the basis of total costs or fair market value, whichever is higher, and not by the value of the services to the recipient. When applicable, determine fair market value in accordance with commercial rates in the local geographical area by referring to public pricing information, trade association information, market surveys, and other available information; do not conduct surveys solely for this purpose. Whenever feasible, establish and publish rates and fees in advance to facilitate uniformity of charges. Review rate and fee schedules annually or whenever significant changes in costs occur. Primary user charge rate and fee schedules are contained in 32 CFR Part 813, Schedule of Fees for Copying, Certifying and Searching Records and Other Documentary Material, and 32 CFR Part 811, Sale or Release of Audiovisual Documentation.

(b) *Determining Costs.* Determine or estimate costs from the best available records in the activity. Use existing cost systems; however, do not establish cost accounting systems solely to determine user charges. The following direct and indirect costs are included within the definition and determination of total costs:

(1) Civilian salaries or wages and associated Air Force share of fringe expenses. Use predetermined rates in AFR 173–10, paragraph 2–33, as the basis for assessing charges.

(2) Military personnel costs and associated Air Force share of fringe expenses. The rates to be charged and the basis for charging DOD, non-DOD Federal, and non-Federal agencies are in AFR 177–101, General Accounting and Financial System at Base Level, chapter 33.

(3) Costa for materials, supplies, travel, communications, utilities, equipment and property rental, and maintenance of property and equipment.

(4) An asset use charge at 4 percent of direct costs to cover depreciation and interest on investment in DOD owned fixed assets.

(5) Costs of research, and of establishing standards and regulations when directly associated with the service performed.

(6) An administrative surcharge at 3 percent of total costs § 812.6(b)(1) through (5) to cover general and administrative costs.

§ 812.7 Charges for lease or sale of property.

When Federally owned property or resources are leased or sold, assess a rental cost or sales price based on a determination of fair market value. Determine fair market value by applying sound business management principles in accordance with comparable commercial practices. Charges need not be limited to recovery of costs; they may produce net revenues to the Government.

(a) *Sale of Material.* In the absence of a known market value, determine the fair value for sale of material on the basis of an aggregate of the:

(1) Standard price of the item carried in inventory (or at a reduced price when so authorized for sale within DOD).

(2) Accessorial and administrative costs provide in AFR 172–5, Reimbursement for Accessorial and Administrative Costs.

(b) *Lease or Rental of Property.* Fair market value for lease or rental of property is normally determined according to commercial rates for similar property in the local geographical area.

(1) In cases involving lease or rental of military equipment, where there is no commercial counterpart, base fair market value on a computation of an annual rent made up of the sum of annual depreciation and interest on investment. Determine amount of interest on investment by applying a 10 percent interest factor to the net book value (acquisition cost plus additions less depreciation) of the asset. Add the cost of support, including general and administrative expenses, if support is furnished.

(2) In determining the fair market value of property to be leased, consider the degree lessee assumes risk of loss or damage to the property and holds the Government harmless against claims or liability by the lessee or third parties.

§ 812.8 Processing collections.

(a) Dispose of receipts per existing instructions.

(b) Normally, collect charges and fees in advance or at the time service is rendered. However, when multiple requests for services are received on a continuing basis from reliable requesters, services may be performed on an account receivable basis (that is, recording an account receivable when the service is provided, with subsequent billing of the organization requesting the service).

(c) Normally, deposit fees and charges collected to the appropriate receipt account. However, when authorized by law or Air Force directives, deposit fees and charges collected to the credit of the appropriation or fund responsible for the principle financial support of the services. Deposit collections in excess of recovery of full costs to the appropriate receipt account. Deposit collections for utilities and services in connection with the lease of property to the appropriation or fund responsible for financing the operations of the equipment and facility.

§ 812.9 Accounting and control.

(a) Activities providing special benefits or leasing and selling property must make sure user charges imposed are in accordance with this directive. Request revisions, through appropriate OPR channels, when rate and fee

schedules included in functional area regulations do not appear adequate in view of current experience. When charges are determined locally, give special attention to ensure compliance with this part.

(b) Activities generating user charge transactions furnish the accounting and finance office (AFO) all pertinent information necessary to voucher, collect, and otherwise account for each user charge being imposed. AFOs or their designees verify the accuracy and completeness of documentation supporting each user charge transaction. AFOs or designees also periodically review records, documentation, and procedures to ensure compliance with this part. An effective working relationship must be maintained between the AFO and activities generating user charge transactions.

§ 812.10 Conflicts or recommendations.

If this part conflicts with other parts or law, or otherwise appears to require modification, submit recommendations to AFAFC/XSGB, Denver CO 80279.

Subpart B—Specialized or Technical Services Provided to State and Local Government.

§ 812.11 Air Force policy.

Air Force activities should cooperate fully with State and local units of government to provide any specialized or technical services authorized. Such services generally supplement but do not take the place of existing services. The Air Force will consider providing the services which are not reasonably and readily available through ordinary business channels.

§ 812.12 Explanation of terms.

For purposes of this part, DOD has provided these explanations:

(a) "State" means any State in the United States, the District of Columbia, the Commonwealth of Puerto Rico, any territory or possession of the United States, or any agency or instrumentality of a State, but not the governments of the political subdivisions of a State.

(b) The terms "political subdivision" or "local government" means a local unit of government, including specifically a county, municipality, city, town, township, or a school or other special district created by or under State law, or combinations of any of these.

(c) "Specialized or technical services" means statistical and other studies and compilations, development projects, technical test and evaluations, technical information, training activities, surveys, reports, documents, and any other similar service functions which the Air Force is especially equipped and authorized by law to perform.

§ 812.13 Background.

Title III of the Intergovernmental Cooperation Act of 1968:

(a) Encourages intergovernmental cooperation in providing specialized or technical services to State and local governmental activities.

(b) Enables State and local governments to avoid unnecessary duplication of special service functions.

(c) Authorizes the Air Force to provide reimbursable specialized and technical services described in § 812.4 under conditions detailed in § 812.5 of this part.

§ 812.14 Types of services.

(a) Air Force activities may provide the following specialized or technical services and related facilities:

(1) Specialized Services Required by Air Force. Any existing statistical or other studies and compilations, results of technical tests and evaluations, technical information, surveys, reports, and documents, and any such materials which may be developed or prepared in the future to meet the needs of the Air Force or to carry out its normal program responsibilities. Examples: The testing of high octane gas, and studies involving sound repression made by the Air Force.

(2) Specialized Services Similar to Those Required by Air Force. Preparation of statistical or other studies and compilations, technical tests and evaluations, technical information, surveys, reports, and documents, and assistance in the conduct of such activities and in the preparation of such materials, provided they are of a type similar to those which the Air Force is authorized by law to conduct or prepare. Example: Studies on airport construction, or technical information relating to testing of compounds used in runways.

(3) Training. Training of the type which the Air Force is authorized by law to conduct for its personnel and others or which is similar to such training. Example: Conducting special training for State and local government in areas such as aerial photography.

(4) Technical Aid (Grant-in-Aid and Other). Technical aid in the preparation of proposals for development and other projects for which the Air Force provides grants-in-aid or other assistance, provided such aid primarily strengthens the ability of the recipient to develop its own capacity to prepare proposals. This type of service is not applicable to Air Force at this time.

(5) Technical Information Normally Available. Technical information, data processing, communications and personnel management systems services, and technical advice on improving logistical and management services which the Air Force normally provides for itself or others. Example: Sale of a data processing program used by Air Force for blanket checks.

(b) Any of the above specialized or technical services provided to the States and their political subdivisions under existing authorities will also be provided under Title III of the Intergovernmental Cooperation Act of 1968 and the terms of this part.

§ 812.15 Conditions under which services may be provided.

(a) Commanders of major commands or separate operating agencies of the Air Force are authorized to provide specialized or technical services only under the following conditions:

(1) If such services are provided either to State or local governments.

(2) Upon the written request of a State or local government. The chief executive of such entity normally should address the request to the Air Force commander involved.

(3) If the Air Force activity provides similar services for its own use. In addition, the requesting entity must certify that it cannot reasonably and expeditiously procure such services through ordinary business channels.

(4) If the Air Force will not incur additional expenses, including civilian and military personnel costs, solely for the purposes of providing such services, unless such costs are charged to the user.

(5) If the unit of government making the request fully reimburses or arranges to fully reimburse the Air Force for services, including payment of civilian/military salaries and all other identifiable direct and indirect costs involved.

(b) If a commander denies a request, he or she should state the reasons for the denial in writing to the entity making the request.

(c) Technical information provided under this instruction may not be further disseminated to third party governmental agencies, unless expressly authorized by the originating Air Force agency.

§ 812.16 Processing payments.

Deposit all monies received for specialized and technical services provided to the credit of the principal appropriation which has borne or will bear the cost of such services; for example, deposit to 57*3500 when

military pay and allowances is the reimbursable element of cost.

§ 812.17 Questionable services.

(a) These services fall within two categories:

(1) Specialized or technical services not covered in § 812.14(a)

(2) Specialized or technical services requested when there is a doubt as to whether the service is covered by § 812.14(a).

(b) If a commander receives a request for a service described in § 812.17(a), and his activity has a special competence to provide it, he should forward the request to AFAFC/XSGB, Denver CO 80279.

(c) The request will be reviewed and evaluated by AFAFC/XSGB before forwarding it through OASD (Comptroller), Wash DC 20301, to the Office of Management and Budget for action. Appropriate contact with applicable Air Staff offices will be made by AZFAFC/XSGB during evaluation of each request.

Winnibel F. Holmes,

Air Force Federal Register Liaison Officer.

[FR Doc. 84-13678 Filed 5-21-84; 8:45 am]

BILLING CODE 3910-01-M

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32 CFR Part 842

Administrative Claims: Personal Injury and Property Damage

AGENCY: Department of the Air Force, Defense.

ACTION: Final rule.

SUMMARY: The Air Force is amending its regulations which govern the processing of administrative claims for personal injury and property damage both on behalf of and against the government. The passage of legislative amendments to federal claims statutes, and changes of Air Force claims policy make necessary this amendment. The purpose of this notice is to inform the public of these changes.

EFFECTIVE DATE: March 20, 1984.

FOR FURTHER INFORMATION CONTACT: R. R. Semeta, Colonel, USAF, Chief, Claims and Tort Litigation Staff, Office of The Judge Advocate General, Department of the Air Force, Washington, D.C. 20324, telephone (202) 693-0350.

SUPPLEMENTARY INFORMATION: The Department of the Air Force in the future will process claims for privately owned vehicles belonging to its military personnel and civilian employees damaged or lost through government negligence under the Federal Tort Claims Act or the Military Claims Act instead of under the Military Personnel and Civilian Employees' Claims Act. Local Air Force bases may now pay appraisal fees of $100 or less under the Military Personnel and Civilian Employees' Claims Act, without seeking Headquarters U.S. Air Force approval. The Air Force is expanding its definition of an "Air Force directed mission" by the Civil Air Patrol to include training as well as operational missions. An amendment to federal statutes extends coverage of the Federal Employees' Compensation Act to all Civil Air Patrol cadets 18 years of age and older, thereby making benefits under that Act their sole remedy against the government for injuries received during an Air Force directed mission. The Air Force is restating its definition of a single base general court-martial jurisdiction to eliminate a prior ambiguity.

List of Subjects in 32 CFR Part 842

Claims, Law, Foreign claims, Tort claims, Government property.

PART 842—ADMINISTRATIVE CLAIMS; PERSONAL INJURY AND PROPERTY DAMAGE

Accordingly, the Department of the Air Force is amending 32 CFR 842.2(1), 842.31 (b), (c), (c)(2), 842.32(j), 842.136 (b), (c)(2), and 842.139 to read as follows:

1. The authority citation for Part 842 reads as follows:

Authority: Sec. 8012, 70A Stat. 488, as amended; 10 U.S.C. 8012, except as otherwise noted.

2. Section 842.2(l) is revised to read as follows:

§ 842.2 Definitions

* * * * *

(l) *Single Base General Court-Martial (GCM) Jurisdiction.* For claims purposes, a base legal office serving the commander exercising GCM authority over that base or that base and other bases.

* * * * *

3. Sections 842.31 (b) and (c) are revised as follows:

§ 842.31 Claims payable.

* * * * *

(b) Losses at quarters and other authorized places. Pay for personal propety damage or loss caused by fire, explosion, theft, vandalism, Acts of God (lightning, flood, earthquake, tornado) and unusual occurrences.

(c) Privately-owned vehicles (POVs). Pay for damage to or loss of POVs caused by government negligence under Subparts F or K as appropriate. Pay under this subpart for damage or loss incident to:

(1) * * *

(2) Hit and run damage to parked vehicles if there is clear and convincing evidence that the incident occurred on the installation or at off base housing overseas. Pay only for incidents occurring on or after 1 August 1983.

* * * * *

4. Section 842.32(j) is revised to read as follows:

§ 842.32 Claims not payable.

* * * * *

(j) Appraisal fees unless the settlement authority requires one to adjudicate the claim. HQ USAF/JACC must authorize appraisals for more than $100.

* * * * *

5. Sections 842.136 (b) and (c)(2) are revised to read as follows:

§ 842.136 Definitions.

* * * * *

(b) *Air Force directed mission.* Those CAP missions performed under direction of the Department of the Air Force and under written authorization by competent authority covering a specific assignment within a prescribed time limit. These may be either operational or training missions. In fulfilling such missions, CAP functions as an instrumentality of the United States.

(c) * * *

(2) *Seniors.* Adults 18 years of age or older (there is no maximum age) who have not retained cadet status.

* * * * *

6. Section 842.139 is revised to read as follows:

§ 842.139 Improper claimants.

CAP members 18 years of age or older for personal injury or death incurred while on an Air Force directed mission. FECA is the exclusive remedy in such cases.

Winnibel F. Holmes,

Air Force Federal Register Liaison Officer.

[FR Doc. 84-13676 Filed 5-21-84; 8:45 am]

BILLING CODE 3910-01-M

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32 CFR Part 881

Determination of Active Military Service and Discharge for Civilian or Contractual Personnel

AGENCY: Department of the Air Force, DOD.

ACTION: Final rule.

SUMMARY: The Department of the Air Force is revising its rule which

prescribes policy and procedures for processing individual applications for discharge of persons claiming membership in a group that has been determined by the Secretary of the Air Force to have performed active military service with the US Air Force or a predecessor organization. It is being revised to incorporate changes in Air Force procedures due to the revision of a DOD Instruction, which this rule implements. The intended effect is to provide current information on Air Force policy and procedures.

EFFECTIVE DATE: May 22, 1984.

FOR FURTHER INFORMATION CONTACT: Mr. Lopez, Headquarters Air Force Manpower and Personnel Center/MPCAKP, Randolph AFB TX 78150. Telephone (512) 652–4545.

SUPPLEMENTARY INFORMATION: This revision implements new procedures established by DODD 1000.20, June 9, 1983. It states that a paygrade determination is needed only in cases when an individual was killed or received service-related injuries or disease; provides the applicant the opportunity to appeal the characterization of service to the Secretary of the Air Force; and establishes a requirement to issue a DD Form 1300, Report of Casualty, if a member was killed during the period of equivalent active military duty. Because this part implements a higher directive, it was not published as proposed for public comment. It is published as a final rule for information purposes. The Department of the Air Force has determined that this part is not a major rule as defined by Executive Order 12291; is not subject to the relevant provisions of the Regulatory Flexibility Act of 1980 (Pub. L. 96–354); and does not contain reporting or recordkeeping requirements under the criteria of the Paperwork Reduction Act of 1980 (Pub. L. 96–511).

List of Subjects in 32 CFR Part 881

Military personnel, Veterans.

Accordingly, 32 CFR Part 881, is revised as follows:

PART 881—DETERMINATION OF ACTIVE MILITARY SERVICE AND DISCHARGE FOR CIVILIAN OR CONTRACTUAL PERSONNEL

Sec.

881.1 Explanation of terms.
881.2 General guidance.
881.3. Application procedures.
881.4 Application screening.
881.5 Individiual Service Review Board.
881.6 Application processing.
881.7 Disposition of documents.

Authority: Sec. 8012, Sec. 401, Pub. L. 95–202.

Note.—This part is derived from the Air Force Regulations 30–45, 15 December 1983. Note: Part 806 of this chapter states the basic policies and instructions governing the disclosure of records and tells members of the public what they must do to inspect or obtain copies of the material referenced herein.

§ 881.1 Explanation of terms.

(a) *Active Military Service.* The same as in Section 101, Title 38, United States Code.

(b) *Applicant.* A person who applies for a discharge based on membership in a group determined by the Secretary of the Air Force to have performed active military service with the US Air Force or a predecessor organization. An application may be made on behalf of such a person, if he or she is deceased or mentally incompetent, by the spouse, next of kin, or legal representative.

(c) *Certified Group.* A group that has been determined by the Secertary of the Air Force to have rendered service that constituted active military service.

(d) *Characterization of Service.* A determination reflecting a member's behavior and performance of duty during a specific period of service. Under this part, service may be characterized as: (1) Honorable, or (2) Under Honorable Conditions (General Discharge).

(e) *Discharge.* Complete severance from the active military service on which the application for discharge is based. Also, the assignment of a reason for such discharge and characterization of service.

(f) *Group.* An organization similar to the Women's Air-forces Service Pilots, and whose members rendered service to the Armed Forces of the United States in a capacity considered civilian employment or contractual service at the time such service was rendered.

§ 881.2 General guidance.

(a) *Group Determinations.* Acting as the Executive Agent for the Secretary of Defense, the Secretary of the Air Force will determine whether the service rendered by a group shall be considered active military service for the purpose of all laws administered by the Veterans Administration.

(b) *Individual Applications for Discharge.*

(1) Following the determination by the Secretary of the Air Force that the service of a group is considered active military service, individuals claiming to have been members of that group may apply for discharge to the appropriate military department. Applications made to the Department of the Air Force will be processed according to this part.

(2) If an applicant is determined to have been a member of a certified group, during the dates of its qualification, and the characterization of service is honorable or under honorable conditions, the Secretary of the Air Force or designee will issue a discharge certificate and a DD Form 214, Certificate of Release or Discharge From Active Duty, to the applicant.

§ 881.3 Application procedures.

(a) *Who May Apply.* Any person who claims to be a member of a certified group may apply for discharge. An application may be made on behalf of such a person, if he or she is deceased or mentally incompetent, by the spouse, next of kin, or legal representative. Proof of death or mental incompetency, as appropriate must accompany such an application.

(b) *Where To Apply.* An application for discharge from the Air Force may be sent to Headquarters Air Force Manpower and Personnel Center, Directorate of Manpower and Personnel Data Systems, Records Management Division, Airman Actions Branch, Boards and Correction Section (HQ AFMPC/MPCDOAI), Randolph AFB TX 78150.

(c) *How To Apply.*

(1) An application may be made using DD Form 2168, Application for Discharge of Member or Survivor of Member of Group Certified To Have Performed Active Duty With the Armed Forces of the United States, or in narrative form.

(2) Forms are available on request by writing to HQ AFMPC/MPCDOAI, Randolph AFB TX 78150, or to the National Personnel Records Center (NPRC), 9700 Page Boulevard, St Louis MO 63132.

(3) Applications should be as complete as possible. The burden of proof is on the applicant. The applicant should provide all available evidence to support a claim for membership in the group and to determine the character of service performed. The Individual Service Review Board will have available a copy of the report of the Advisory Panel to the DOD Civilian/Military Service Review Board, which may contain information pertinent to individual service.

(4) Documentation may include, but is not limited to, separation or discharge certificates, mission orders, identification cards, contracts or personnel action forms, employment records, education certificates, diplomas, pay vouchers, certificates of

awards, casualty information, and any other supporting evidence of membership, or character of service performed.

(5) The Air Force will not provide representation by counsel for the applicant, nor will it defray costs of such representation under any circumstances.

(d) *When To Apply.* There is no specific time for submitting an application for discharge.

§ 881.4 Application screening.

HQ AFMPC/MPCDOAI will acknowledge receipt of each application. The application will then be reviewed to see if it is proper and complete.

(a) An application that should be considered by another military department will be referred to that department, and the applicant will be sent a written notice or a copy of the referral letter.

(b) If the Secretary of the Air Force has not made a determination concerning the particular group in which an applicant claims membership, the applicant will be returned without prejudice. An application may be resubmitted after Secretarial determination that the group is certified.

(c) Applications made by a group (or individuals on behalf of a group) are not processed under this part. If such applications are received, they are to be referred to the Secretary of the Air Force, Manpower, Reserve Affairs and Installations, Personnel Council (SAF/MIPC), The Pentagon, Washington D.C. 20330, for further review.

(d) Incomplete applications will be returned to the applicant without prejudicing later consideration.

(e) All proper, complete applications will be referred to the Individual Service Review Board for further consideration.

§ 881.5 Individual Service Review Board.

(a) *Purpose.* The Individual Service Review Board is established by the Secretary of the Air Force at AFMPC to:

(1) Review applications for discharge under this part.

(2) Make findings of fact based on evidence submitted; and,

(3) Based on those findings, act further on the application as outlined in section 6 of this part.

(b) *Composition.* The Board consists of military members in grade lieutenant coloniel or higher, and civilian members, grade GS–12 or higher, appointed by the Assistant Deputy Chief of Staff, Manpower and Personnel for Military Personnel (HQ USAF/MPC). Three members constitute a quorum. The senior member acts as Board chairperson. A nonvoting recorder keeps a record of the Board's actions concerning an application.

(c) *Administrative Support.* The Directorate of Personnel Program Actions, Separation Programs and Procedures Branch (HQ AFMPC/MPCAKP), Randolph AFB TX 78150, provides administrative support to the Board.

§ 881.6 Application processing.

(a) *Individual Service Review Board.* The Board meets in closed session and considers the application, all evidence submitted, and other relevant information available. Applicants or their representatives do not have the right to appear before the Boards.

(b) *Board Findings.* The Board makes findings of fact based on the evidence and information available, and determines whether the applicant was a member of a certified group during the dates of its qualification and, accordingly, whether the application for discharge should be approved or disapproved.

(c) *Board Determinations.* The Board determines that the application for discharge should be approved; the Board also determines the period and character of the applicant's service.

(d) *Approved Applications.*

(1) If the Board approves an application for discharge and determines that the service characterization should be DD Form 256 AF, Honorable Discharge, and a DD Form 214, under AFR 35–6. A military grade will be entered on the DD Form 214 only upon an individual request from the administrator of Veteran's Affairs. For the purpose of Veteran's Administration benefits, a pay grade is needed only in cases when an individual was killed or received service-related injuries or disease during the approved period of service. Proof of grade criteria, in order of importance, is cited in DOD 1000.20, Section G, paragraph 5.

(2) If the Board approves an application for discharge but determines that the service characterization should be "Under Honorable Conditions" (General Discharge), the case is forwarded to the SAF/MIPC for a final decision. After the final decision on the case, HQ AFMPC/MPCDOAI issues the appropriate discharge certificate and a DD Form 214 to the applicant.

(3) If the applicant challenges the characterization of a discharge issued by the Air Force, the applicant may appeal the characterization by submitting DD Form 149, Application for Correction of Military or Naval Records, to the Secretary of the Air Force through HQ AFMPC/MPCDOAI.

(4) If member was killed during the period of equivalent active military duty, the Assistant for Casualty and Mortuary Matters, Casualty Division (HQ AFMPC/MPCCA) will issue a DD Form 1300, Report of Casualty, including military pay grade, according to DODI 1300.9 (AFR 30–25, Casualty Services).

(e) Application Denial Actions:

(1) If the Board determines that an application for discharge should be denied because there is insufficient evidence to show that the applicant was a member of a qualifying group, or if the Board determines that the applicant's service cannot be characterized at least under honorable conditions, HQ AFMPC/MPCDOAI notifies the applicant of the determination.

(2) The applicant has 60 days from the date of this notice to submit additional evidence or information to HQ AFMPC/MPCDOAI, Randolph AFB TX 78150, for the Board's consideration.

(3) After 60 days, the Board reviews the case again if additional evidence or information is submitted. If the Board determines that the application now merits approval, further action on the case follows as outlined in § 881.6(d).

(4) If the applicant fails to submit additional evidence or information or if, after review, the Board determines that the application should be denied, the case is sent to the SAF/MIPC for final decision on the question of discharge and character of service.

(i) The Airman Actions Branch (HQ AFMPC/MPCDOA) notifies the applicant of the final decision and, if appropriate, issues the discharge documents.

(ii) An application that is denied is returned to the applicant, without prejudicing any later consideration.

(f) Discharge Upgrade. If a General Discharge is approved, the recipient may apply to the Air Force Discharge Review Board for discharge upgrade under AFR 20–10 or to the Air Force Board for Correction of Military Records under AFR 31–3. HQ AFMPC/MPDOA will provide copies of these regulations and application forms to individuals who received a General Discharge.

§ 881.7 Disposition of documents.

(a) A copy of the application, supporting evidence, and DD Form 214 are filed permanently in the Master Personnel Records Groups maintained at the National Personnel Records Center, St. Louis MO 63132, for approved cases. Copies of DD Form 214 are also sent to the applicant, to the Veterans Administration, and to HQ AFMPC/MPCAKP, Randolph AFB TX 78150.

(b) A copy of each application is maintained at HQ AFMPC/MPCAKP for up to 3 years.

Winnibel F. Holmes,

Air Force Federal Register Liaison Officer.

[FR Doc. 84-13677 Filed 5-21-84; 8:45 am]

BILLING CODE 3910-01-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 160

[OPP-250056; PH-FRL 2578-4]

Good Laboratory Practice Standards; Effective Date

Correction

In FR Doc. 84-11797 beginning on page 18738 in the issue of Wednesday, May 2, 1984, third column, fifth line of the **SUPPLEMENTARY INFORMATION,** "136 a" should read "136a".

BILLING CODE 1505-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

42 CFR Part 58

Grants for Graduate Programs in Health Administration and Grants for Traineeships in Health Administration, Hospital Administration, or Health Policy Analysis and Planning at Public or Nonprofit Private Educational Institutions Other Than Schools of Public Health

AGENCY: Public Health Service, HHS.

ACTION: Amendments to final regulations.

SUMMARY: These amendments conform provisions in 42 CFR Part 58, Subpart A, "Grants for Graduate Programs in Health Administration," and Subpart D, entitled "Grants for Traineeships in Health Administration, Hospital Administration, or Health Policy Analysis and Planning at Public or Nonprofit Private Educational Institutions Other Than Schools of Public Health" to statutory amendments made by the Orphan Drug Act, Publ. L. 97-414; the Omnibus Budget Reconciliation Act of 1981, Pub. L. 97-35; and Pub. L. 94-241, the Commonwealth—Covenant to Establish—Northern Mariana Islands.

EFFECTIVE DATE: May 22, 1984.

FOR FURTHER INFORMATION CONTACT: Joseph Kadish, Ed.D., Chief, Public Health Professions Branch, Division of Associated and Dental Health Professions, Bureau of Health Professions, Health Resources and Services Administration, Parklawn Building, Room 8-95, 5600 Fishers Lane, Rockville, Maryland 20857, (301) 443-6896.

SUPPLEMENTARY INFORMATION: These amendments change the following health professions regulations to conform them to amendments made by Pub. L. 97-414, Pub. L. 97-35, and Pub. L. 97-241. These changes are discussed below.

42 CFR Part 58

Subpart A—Grants for Graduate Programs in Health Administration

This rule amends Subpart A to:

(1) Revise the definition of "Nonprofit" to comply with Pub. L. 97-35.

(2) Revise the definition of "School of public health" to comply with Pub. L. 97-35.

(3) Add "the Commonwealth of" to the title of "the Northern Mariana Islands" to comply with Pub. L. 94-241, which changed the status of "the Northern Mariana Islands" from "a territory" to "a Commonwealth."

(4) Revise § 58.3, *"Who is eligible to apply for a grant?"*, to conform to the definition of "Accredited" set out in Pub. L. 97-35.

(5) Amend § 58.4, *"What assurances must be provided in an application?"*, to conform with Pub. L-414 by deleting paragraphs (a) (3) and (b) relating to enrollment increases.

(6) In § 58.9, *"What additional Department regulations apply to grantees?"*, delete the footnote "When issued." from the reference to 45 CFR Part 91.

(7) Cite the Office of Management and Budget (OMB) numbers in those sections which contain information collection requirements.

Subpart D—Grants for Traineeships in Health Administration, Hospital Administration, or Health Policy Analysis and Planning at Public or Nonprofit Private Educational Institutions Other Than Schools of Public Health

This rule amends Subpart D to:

(1) Revise § 58.221, *"To what grant program do these regulations apply?"*, by changing "section 749" to "section 791A" to comply with Pub. L. 97-35.

(2) Revise the definition of "Nonprofit" to comply with Pub. L. 97-35.

(3) Revise the definition of "School of public health" to comply with Pub. L. 97-35.

(4) Revise the definition of "State" by adding "the Commonwealth of" to the title of "the Northern Mariana Islands" to comply with Pub. L. 94-241, which changed the status of "the Northern Mariana Islands" from "a territory" to "a Commonwealth."

(5) Revise § 58.223, *"Who is eligible to apply for a grant?"*, to conform to the definition of "Accredited" set out in Pub. L. 97-35.

(6) Revise § 58.225, *"How is the amount of the award determined?"*, to change "section 749" to "section 791A" to comply with Pub. L. 97-35.

(7) Revise § 58.228, *"What are the requirements for traineeships and the appointment of trainees?"*, to change "postbaccalaureate" to "baccalaureate" to comply with Pub. L. 97-414.

(8) Revise § 58.229, *"Who is eligible for financial assistance as a trainee?"*, to add "the Commonwealth of" to Puerto Rico and to the Northern Mariana Islands, and add "the District of Columbia" and "American Samoa" to conform to the definition of "State" and comply with Pub. L. 94-241.

(9) In § 58.233, *"What additional Department regulations apply to grantees?"*, delete the footnote "When issued." from the reference to 45 CFR Part 91.

(10) Cite the Office of Management and Budget (OMB) numbers in those sections which contain information collection requirements.

Regulatory Flexibility Act and Executive Order 12291

The changes made by these regulations are technical in nature, and are necessary to bring existing rules in conformance with current legislation. Therefore, the Secretary has determined that there are negligible costs associated with this regulation, and a regulatory impact analysis is not required under Executive Order 12291. Further, the rule does not have an impact on small entities and therefore an analysis is not required under the Regulatory Flexibility Act.

Paperwork Reduction Act

The information and collection requirements in §§ 58.4, 58.5, 58.224, and 58.228 of 42 CFR Part 58 and the application forms and instructions for this grant program have been approved by the Office of Management and Budget (OMB) under section 3507 of the Paperwork Reduction Act of 1980. OMB approval number 0915-0060 for the competing application form is noted in the regulations after each affected section.

Justification for Omitting Notice of Proposed Rulemaking

These amendments conform these regulations to Pub. L. 97–414, 97–35, and 94–241, change references to section 749 to section 791A, and make minor nonsubstantive changes to §§ 58.9, 58.229 and 58.233. The Secretary has therefore determined, according to 5 U.S.C. 553 and Department policy, that it would be unnecessary to follow proposed rulemaking procedures or to delay the effective date of these regulations.

List of Subjects in 42 CFR Part 58

Educational study programs, Grant programs, Health, Health professions, Public health, Student aid.

Accordingly, Subparts A and D of 42 CFR Part 58 are amended and adopted as set forth below.

(*Catalog of Federal Domestic Assistance*, No. 13.963, Grants for Graduate Programs in Health Administration, and No. 13.962, Grants for Traineeships in Health Administration, Hospital Administration, or Health Policy Analysis and Planning at Public or Nonprofit Private Educational Institutions Other Than Schools of Public Health)

Dated: March 13, 1984.

E. N. Brandt, Jr.,

Assistant Secretary for Health.

Approved: May 1, 1984.

Margaret M. Heckler,

Secretary.

PART 58—[AMENDED]

Subpart A—Grants for Graduate Programs in Health Administration

1. The *Authority* for Subpart A is revised to read as follows:

Authority: Section 215 of the Public Health Service Act, 58 Stat. 690, 67 Stat. 631 (42 U.S.C. 216); section 791 of the Public Health Service Act, 90 Stat. 2303 (42 U.S.C. 295h).

2. Section 58.2 is amended by revising the following definitions to read as follows:

§ 58.2 Definitions.

* * * * *

"Nonprofit" refers to the status of an entity owned and operated by one or more corporations or associations no part of the net earnings of which inures, or may lawfully inure, to the benefit of any private shareholder or individual.

"School of public health" means public or private school in a State providing education leading to a graduate degree in public health or an equivalent degree, including advanced training related to public health, which is accredited as provided for in section 701(5) of the Act.

* * * * *

"State" means, in addition to the several States, only the District of Columbia, the Commonwealth of Puerto Rico, the Commonwealth of the Northern Mariana Islands, the Virgin Islands, Guam, American Samoa, and the Trust Territory of the Pacific Islands.

3. Section 58.3 is revised to read as follows:

§ 58.3 Who is eligible to apply for a grant?

Any public or nonprofit educational entity (excluding schools of public health) located in a State is eligible to apply for a grant to support a graduate educational program for the training of individuals for health services administration, hospital administration, or health planning which has been accredited as provided for in section 701(5) of the Act.

4. Section 58.4 is revised to read as follows:

§ 58.4 What assurances must be provided in an application?

The application must contain assurances satisfactory to the Secretary that:

(a) At least 25 individuals will complete the graduate educational programs of the applicant for which the application was made in the school year beginning in the fiscal year for which an applicant receives a grant; and

(b) The applicant will expend or obligate at least $100,000 in funds from non-Federal sources to conduct the graduate educational program for which the application was made (excluding expenditures for construction, but not excluding expenditures for alterations and renovation) in the school year beginning in the fiscal year for which an applicant receives a grant.

(Approved by the Office of Management and Budget under control number 0915–0060.)

5. Section 58.5 is amended by adding the following parenthetical statement at the end of the section:

§ 58.5 What activities must be addressed in an application?

* * * * *

(Approved by the Office of Management and Budget under control number 0915–0060.)

§ 58.9 [Amended]

6. Section 58.9 is amended by removing the Footnote to 45 CFR Part 91.

Subpart D—Grants for Traineeships in Health Administration, Hospital Administration, or Health Policy Analysis and Planning at Public or Nonprofit Private Educational Institutions Other Than Schools of Public Health

1. The Authority for Subpart D is revised to read as follows:

Authority: Section 215 of the Public Health Service Act, 58 Stat. 690, 67 Stat. 631 (42 U.S.C. 216); section 791A of the Public Health Service Act, 90 Stat. 2280 (42 U.S.C. 294s).

§ 58.221 [Amended]

2. Section 58.221 is amended by removing the phrase "section 749" and inserting in its place "section 791A."

3. Section 58.222 is amended by revising the following definitions to read as follows:

§ 58.222 Definitions.

* * * * *

"Nonprofit" refers to the status of an entity owned and operated by one or more corporations or associations no part of the net earnings of which inures, or may lawfully inure, to the benefit of any private shareholder or individual.

* * * * *

"School of public health" means a public or private school in a State providing education leading to a graduate degree in public health or an equivalent degree, including advanced training related to public health, which is accredited as provided for in section 701(5) of the Act.

"State" means, in addition to the several States, only the District of Columbia, the Commonwealth of Puerto Rico, the Commonwealth of the Northern Mariana Islands, the Virgin Islands, Guam, American Samoa, and the Trust Territory of the Pacific Islands.

* * * * *

4. Section 58.223 is revised to read as follows:

§ 58.223 Who is eligible to apply for a grant?

Any public or nonprofit private educational entity (excluding schools of public health) located in a State is eligible to apply for a grant to support traineeships in its graduate program in health administration, hospital administration, or health policy analysis and planning which has been accredited, or is about to be accredited, according to section 701(5) of the Act.

5. Section 58.224 is amended by adding the following parenthetical statement at the end of the section:

§ 58.224 How will applications be evaluated?

* * * * *

(Approved by the Office of Management and Budget under control number 0915–0060.)

6. Section 58.225 is amended by removing the phrase "section 749" and inserting in its place "section 791A."

7. Section 58.228 is amended by revising paragraph (a) and by adding the following parenthetical statement at the end of the section to read as follows:

§ 58.228 What are the requirements for traineeships and the appointment of trainees?

(a) The grantee must award at least 80 percent of its grant funds to individuals who have previously received a baccalaureate degree or have 3 years work experience in health services.

* * * * *

(Approved by the Office of Management and Budget under control number 0915–0060.)

8. Section 58.229 is amended by revising paragraph (a) to read as follows:

§ 58.229 Who is eligible for financial assistance as a trainee?

* * * * *

(a) The individual must be either a national of the United States, a lawful permanent resident of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Commonwealth of the Northern Mariana Islands, the Virgin Islands, Guam, American Samoa, or a permanent resident of the Trust Territory of the Pacific Islands.

* * * * *

§ 58.233 [Amended]

9. Section 58.233 is amended by removing the Footnote to 45 CFR Part 91.

[FR Doc. 84–13641 Filed 5–21–84; 8:45 am]

BILLING CODE 4160–16–M

Proposed Rules

Federal Register
Vol. 49, No. 100
Tuesday, May 22, 1984

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

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Parts 1006 and 1012

[Docket Nos. AO-356-A20 and AO-347-A23]

Milk in the Upper Florida and Tampa Bay Marketing Areas; Notice of Recommended Decision and Opportunity To File Exceptions on Proposed Amendments to Tentative Marketing Agreement and to Orders

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: This decision recommends a change in the Upper Florida and Tampa Bay milk orders. As recommended, the change in the plant location adjustment provisions will insure that the Class I milk price for fluid milk products transferred from a pool plant under the Upper Florida order or the Tampa Bay order that is located outside Florida to a pool plant regulated by another Federal milk order shall be not less than the Class I price under such other Federal milk order applicable at the location of the transferor plant. The proposed amendments were based on a proprietary handler's proposals considered at a public hearing held December 6, 1983.

DATE: Comments are due within 20 days after publication in the **Federal Register.**

ADDRESS: Comments (four copies) should be filed with the Hearing Clerk, Room 1077, South Building, United States Department of Agriculture, Washington, D.C. 20250.

FOR FURTHER INFORMATION CONTACT: Martin J. Dunn, Marketing Specialist, Dairy Divison, Agricultural Marketing Service, United States Department of Agriculture, Washington, D.C. 20250, 202/447-7311.

SUPPLEMENTARY INFORMATION: Prior documents in this proceeding:

Notice of hearing: Issued November 10, 1983; published November 17, 1983 (48 FR 52318).

Extension of time for filing briefs: Issued February 21, 1984; published February 27, 1984 (49 FR 7133).

Preliminary Statement

Notice is hereby given of the filing with the Hearing Clerk of this recommended decision with respect to proposed amendments to the tentative marketing agreements and orders regulating the handling of milk in the Upper Florida and Tampa Bay marketing areas. This notice is issued pursuant to the provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601 *et seq.*), and the applicable rules of practice and procedure governing the formulation of marketing agreements and marketing orders (7 CFR Part 900).

Interested parties may file written exceptions to this decision with the Hearing Clerk, U.S. Department of Agriculture, Washington, D.C. 20250, on or before 20 days after publication in the **Federal Register.** The exceptions should be filed in quadruplicate. All written submissions made pursuant to this notice will be made available for public inspection at the office of the Hearing Clerk during regular business hours (7 CFR 1.27(b)).

The proposed amendments set forth below are based on the record of a public hearing held at Orlando, Florida, on December 6, 1983, pursuant to notice thereof issued November 10, 1983 (48 FR 52318).

The hearing notice specifically invited interested persons to present evidence concerning the probable regulatory and informational impact of the proposals on small businesses. However, no participants at the hearing testified about any potentially adverse impact of the proposals on small businesses.

Further, William T. Manley, Deputy Administrator, Agricultural Marketing Service, has certified that under the standards of the Regulatory Flexibility Act (Pub. L. No. 96-354), the proposed amendments, if adopted, will not have a significant impact on a substantial number of small entities. The proposed amendments would promote orderly marketing of milk by producers and regulated handlers.

The material issues on the record relate to:

1. Location adjustments applicable to a supply plant at Dover, Delaware, but pooled under either the Upper Florida or Tampa Bay milk orders that also transfers bulk milk from the Dover location to a plant regulated under the Middle Atlantic order.
2. Whether an emergency exists to warrant the omission of a recommended decision and the opportunity to file written exceptions.

Findings and Conclusions

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

The plant location adjustment provisions of the Upper Florida and Tampa Bay milk orders should be changed to provide that milk transferred to an other order plant for Class I use from an Upper Florida or Tampa Bay pool plant located outside Florida would be subject to a Class I price that is not lower than that which would be applicable at the transferor plant if it were regulated under the other Federal order. The effect of this change would be to limit the amount of the location adjustment credit to Upper Florida and Tampa Bay handlers so that the Class I price for milk moved to other order plants would be comparable to the Class I price applicable to handlers competing with the transferee plants

The location adjustment provisions of the Upper Florida order reduce the Class I price by 10 cents outside the State of Florida and 70-85 miles from the nearer of Jacksonville and Tallahassee, plus 1.5 cents for each additional 10 miles. For the Tampa Bay order, the reduction is 1.5 cents per hundredweight for each 10 miles from Tampa, Florida. The basic purpose of these provisions is to provide a transportation allowance to handlers who assemble milk at plant locations outside the marketing area and move it to plants within the marketing area for use in Class I so that a handler's cost of milk so moved is more competitive with that for milk obtained locally.

Cumberland Farms Food Stores, Inc., (Cumberland) which operates distributing plants under the Southeastern Florida and Middle Atlantic federal milk orders, obtains most of its milk supply for its pool distributing plant at Riviera Beach, Florida from its supply plant located at Dover, Delaware. Since 1981, the Dover

plant, which is located within the Middle Atlantic (Order 4) marketing area, has delivered a large enough proportion of its receipts to the Riviera Beach plant each month to be a Southeastern Florida (Order 13) pool plant. However, for the month of August, 1983 the Riviera Beach plant, supplied in this manner, was regulated by the Upper Florida milk order (Order 6). The remainder of the Dover plant's milk receipts are delivered to the handler's fluid milk plant at Florence, New Jersey where the milk is allocated to Class I and Class II use according to the provisions of Order 4.

The issue raised in this proceeding is almost identical to an issue resolved in a final decision issued May 13, 1983 (48 FR 22303) concerning the Southeastern Florida milk order. That decision eliminated a Class I price advantage of $1.13 a hundredweight that Cumberland had in the Order 4 marketing area under the provisions of the Southeastern Florida order for milk transferred to Cumberland's Florence, New Jersey distributing plant from the Dover supply plant. The amendment resulting from the proceeding became effective August 1, 1983.

Proponents' Presentations

A. The proposed changes were initiated by the Southland Corporation (Southland) and were supported by other witnesses. The following points were made by the Southland witness in support of its proposals to change the plant location adjustment provisions of the Tampa Bay (Order 12) and Upper Florida (Order 6) milk orders.

1. Southland is a proprietary handler and operates distributing plants regulated by the Middle Atlantic, Tampa Bay and Southeastern Florida milk orders.

2. The Southland plant at Waldorf, Maryland is regulated by Order 4 and distributes fluid milk products in various segments of the Order 4 area. The fluid milk products distributed in the Philadelphia segment of the Order 4 market are custom-bottled for Southland by other Order 4 handlers.

3. The Southland plant at Winter Haven, Florida is regulated by Order 12 and distributes fluid milk products in the Order 6 and Order 12 marketing areas.

4. The Southland plant at Miami, Florida is regulated by Order 13 and distributes fluid milk products in the Southeastern Florida marketing area.

5. The Upper Florida and Tampa Bay milk orders should be amended to assure that handler operating a supply plant at Dover, Delaware and regulated by one of the Florida orders does not have a lower Class I price than the Order 4 price for milk transferred from Dover, Delaware to Florence, New Jersey.

6. This problem is a continuation of one that existed under Order 13 until that order was amended August 1, 1983 (48 FR 22303).

7. The location adjustment provisions of Order 13, prior to the 1983 amendment, provided Cumberland with a $1.13 a hundredweight Class I price advantage in the Order 4 marketing area.

8. When the Dover plant is regulated by Order 6, the price advantage is $0.96 a hundredweight.

9. For August 1983, the Order 6 blend price at Dover was 26 cents higher than the Order 4 blend price for base milk at that location. None of the 96-cent advantage had to be used by Cumberland to achieve a competitive blend price with Order 4 handlers.

10. Class I differentials under federal milk orders generally increase 1.5 cents for each 10 miles of distance from the Chicago milk production area. Under this system, Jacksonville, Florida (a basing point under Order 6) is in close alignment with the Chicago area. The Order 4 Class I alignment is somewhat higher than the distance from the Chicago area would warrant.

11. Even if the Class I differentials of Orders 4 and 6 were perfectly aligned with the Chicago area, they would not be aligned with each other.

12. The proposals need to be adopted to overcome the alignment problem and to provide uniform milk costs in the Order 4 marketing area.

13. The fact that Cumberland incurs some costs to operate the Dover plant is irrelevant to the issue.

B. Southland's proposals were supported by the New Jersey Milk Industry Association, Inc. and the Milk Distributors Association of the Philadelphia Area, Inc.

1. Association members are regulated by the New York-New Jersey (Order 2) or the Middle Atlantic orders.

2. Competition for milk sales among handlers in the New Jersey-Philadelphia segments of the Order 2 and Order 4 marketing areas is keen.

3. Consumers in this area pay some of ther lowest prices for milk in the nation, even though handlers pay relatively high Class I prices and labor costs are high.

4. Bidding for sales to large supermarkets, schools, and institutions is most keen. It is not unusual for the winning bidder to obtain the business at a low price determined by the fourth or fifth decimal point.

5. The cost of Class I milk constitutes, by far, the greatest cost element in such a bid price. Therefore, it is essential that regulated competing handlers in the Order 2 and Order 4 marketing areas be provided with equity in their regulated cost of milk.

6. The unique pricing problem under consideration at this hearing was not visualized when the orders were promulgated. The situation demonstrates how changes in milk marketing require that the orders be amended to ensure handler equity.

7. Substantial quantities of fluid milk products are moved between the New York-New Jersey and Middle Atlantic orders.

8. Although alignment of pricing between these two orders has been substantially achieved, any inequity of regulated pricing which occurs within one of these orders causes equal inequity among handlers regulated by the other order.

9. The 96-cent advantage that Cumberland has in the Order 4 marketing area amounts to better than 8 cents per gallon, and on the basis of the volume of milk distributed by its Florence, New Jersey, plant, has the potential of imparing competitive equity in the market.

C. Southland's proposals also were supported by the Upper Florida Milk Producers Association and Tampa Independent Dairy Farmers Association.

1. The associations are the major suppliers of milk to handlers regulated under Orders 6 and 12.

2. Even though the cost advantage obtained by Cumberland occurred in only one month under the Upper Florida order, it is reasonable to assume that it could occur again.

3. The Orlando area is a very fast growing part of the Upper Florida marketing area and Cumberland has stores in the Orlando area.

Opponents' Presentations

Southland's proposals were opposed by Eastern Milk Producers Cooperative Association, Inc. (Eastern), and Cumberland on the following basis:

1. Eastern is a regional cooperative association with more than 4000 members located throughout the Northeast, and it is the principal supplier to the Dover supply plant (approximately 100 members shipping to Dover).

2. The Dover supply plant was a pool plant under the Upper Florida order for August 1983 and it may on occasion be regulated by that order again.

3. Cumberland is a vertically integrated milk processing-convenience dairy store operation, and all of its fluid milk products are sold out of its own stores.

4. Southland's proposals are aimed at extending to Orders 6 and 12 the discriminatory provisions adopted under Order 13 on August 1, 1983.

5. Southland's proposals would raise the procurement cost of Class I milk to Cumberland and thereby discourage the use of milk shipped to the supply plant at Dover.

6. Prior to October 1981, Cumberland procured almost its entire supply of milk for the Riviera Beach plant, from the Independent Dairy Farmers Association (IDFA).

7. IDFA, because of its near monopoly over the supply of milk, exacted excessive over-order Class I prices from Cumberland as well as from other handlers.

8. The Dover supply plant is an integral part of the supply system for the Riviera Beach plant, and milk not needed at the Riviera Beach plant is transferred from the Dover plant to Cumberland's distributing plant at Florence, New Jersey.

9. The Florence, New Jersey plant receives most of its milk supply from sources other than the Dover supply plant.

10. All of the milk processed at the Florence, New Jersey plant is distributed entirely to Cumberland's stores located in New Jersey, Pennsylvania and Delaware.

11. There is no disorderly marketing in the Middle-Atlantic or Florida order areas attributable to the current provisions of the orders.

12. The proposals, if adopted, could cause Cumberland to cease purchasing milk from the Dover supply plant for the use of the Riviera Beach plant, resulting in the "dumping" of milk in the already over-supplied Order 4 pool.

13. Cumberland, in order to operate the Dover supply plant, incurs additional costs, e.g., transportation from plant to plant, shrinkage, receiving and cooperative handling charges, none of which are reflected in order prices.

14. These additional costs incurred by Cumberland, reduce the alleged price advantage in the Order 4 area to such an extent that they cannot serve as a justification for adopting either of Southland's proposals.

15. The Secretary would be derelict in his duty if he fails to take these relevant costs into consideration.

16. In order to have price differences that would justify order amendments, such differences must translate into procurement cost differences of substance, impact on large quantities of milk and be passed on in the market place in a manner that causes disorderly marketing.

17. There is no evidence that the alleged cost advantage is reflected in market prices to the detriment of competing handlers.

18. There appears to be no concern by Order 4 handlers interfacing with Cumberland's stores in the Philadelphia-South Jersey-Delaware area regarding misalignment of order prices.

19. Southland's proposals represent a major departure from the procedure for pricing intermarket transfers by the Department. Following the 1962 Lehigh Valley decision, milk orders were revised to facilitate the movement of milk between federally regulated markets. Specifically, milk transferred from a plant regulated under one order to a plant regulated under another order is classified and priced in the shipping market (transferor plant location) where it is pooled in accordance with its assignment to classes under the order regulating the transferee plant. Southland's proposals would create another class of milk with its own price for milk transferred to another order plant.

20. Southland's proposals would benefit the producers in the transferor market, rather than the producers in the transferee market where the alleged misalignment problem supposedly exists.

21. Southland's proposals are discriminatory, predatory and would serve as a catalyst for disrupting the interorder pricing provisions used throughout the Federal order program.

22. Cumberland has not changed its out-of-store pricing since October 1981 by reason of the Dover plant operation—either in the Florida or the Middle Atlantic area.

23. Cumberland decided to acquire most of its milk supply for its Riviera Beach plant through the Dover supply plant in order to avoid the over-order premiums in the Southeastern Florida market.

24. Cumberland introduced an exhibit for the purpose of showing that their alleged price advantage of 96 cents should be reduced to approximately 18 cents per hundredweight because of additional costs.

Discussion of the Issues.

1. The chief issue raised by this proceeding is whether the Upper Florida and Tampa Bay milk orders, Orders 6 and 12, respectively, should be amended so that for milk transferred from a Dover, Delaware, supply plant to a Florence, New Jersey, distributing plant, the Class I price at Dover shall be not less than the Class I price of the Middle Atlantic milk order at the location of the Dover plant.

The Southland Corporation operates pool distributing plants under Orders 4, 12, and 13 and distributes fluid milk products in those marketing areas. It distributes fluid milk products in the Order 6 marketing area from its plant under Order 12. Southland claims that the Class I prices of Order 4 and the Florida orders are not precisely aligned and that this results in competitive inequity among handlers selling milk in the Order 4 marketing area. A number of handlers regulated by Orders 2 and 4 reiterated this view through a witness and stressed that any inequity of regulated pricing which occurs within any of these orders causes equal inequity among handlers regulated by the other order.

The Class I differentials of federal milk orders are aligned from a common basing point. The geographical structure of Class I differentials corresponds closely to a basing point system with Eau Claire, Wisconsin, as the base. The Class I differentials increase with the distance from the Upper Midwest region, the most important source of Grade A milk supplies in excess of regional fluid needs.

More specifically, Class I differentials under federal milk orders generally increase 1.5 cents for each 10 miles of distance from Eau Claire, Wisconsin. Because federal milk orders in the Northeast and in Florida are a considerable distance from Eau Claire, prices in those respective areas are about the same. The Class I differential at Philadelphia, Pennsylvania, under the Middle Atlantic milk order is $2.78, to which is added a 6-cent direct delivery differential for a total of $2.84. Under the Upper Florida milk order, the Class I differential is $2.85.

When Class I price differentials in federal milk order markets that are in different directions from Eau Claire are again adjusted 1.5 cents per 10 miles toward locations other than Eau Claire, substantial differences at a given plant location can result. When the Upper Florida order Class I differential ($2.85) is adjusted $1.15 to Dover, Delaware, the Order 6 Class I differential there is $1.70. At Dover, the Class I price differential under Order 4 is $2.66 ($2.78–$0.12). Milk at Dover, therefore, is available to the Middle Atlantic pool plant of Cumberland at Florence, New Jersey for Class I use at $0.96 a hundredweight less than the same milk would cost if the Dover plant were pooled under Order 4. As a result, the Florence plant has a competitive advantage in the Order 4 market of $0.96 a hundredweight on all milk moved from Dover to Florence which is assigned to Class I. The hearing

record evidence is that the volume may be as much as 2.5 million pounds a month.

An apparent misalignment between Class I prices would not necessarily lead to competive inequities in a market if a handler with a Class I price advantage had to pay more than the producer price required by the order under which he is pooled to attract milk from producers who normally would supply another market. However, the record established that the Upper Florida blend price adjusted to Dover is above the Order 4 price to producers for deliveries of base milk to the same location. Using August 1983 data, the Upper Florida blend price adjusted to Dover was $13.99 a hundredweight while the base price under Order 4 for that location was $13.73. The handler operating the Dover plant under Order 6 was able to attract a sufficient supply of producer milk by paying its producers a price at least equivalent to prices paid to neighboring producers by Order 4 handlers without giving up any of the price advantage it has on the portion of its reciepts which are used in Class I in the Order 4 area.

The Cumberland witness denied that the price discrepancy between Orders 4 and 6 at Dover results in any substantial procurement cost advantage for Cumberland. Also, the witness denied that the advantage impairs competitive equity between handlers, or that it affects a significant amount of milk. However, an examination of the record indicates that Cumberland has a substantial cost advantage on a significant quantity of milk. Cumberland has the capability of impairing competitive equity in the Order 4 and Order 2 markets.

For any length of time, the Class I price level of a market cannot exceed the cost of buying the milk in another supply area and transporting it to the consuming market. If a price advantage exists long enough for handlers to recognize the advantage of another supply, they will change their buying arrangements. An important guide to the proper level of Class I prices in a given market is the cost of alternative supplies. The milk moved from Dover to Florence may represent a small percentage of the total milk marketed in the Middle Atlantic marketing area, but when Cumberland's $0.96 price advantage is considered, the potential disruptive effect of the quantity of milk involved is not negligible. Under the provisions of Orders 4 and 6, there is clearly a price advanatage of $0.96 a hundredweight at Dover for a plant pooled under Order 6.

Cumberland introduced an exhibit to show that the alleged price advantage of 96 cents is reduced to about 18 cents a hundredweight because of costs incurred by the operator of the Dover plant.

Nearly all of the costs claimed by Cumberland would be incurred in operating the Dover plant under any federal milk order. If the Dover plant were on Order 4 supply plant, milk received there and used in Class I would be subject to the Order 4 price at that location, 96 cents more than the Class I price applicable under Order 6. No allowance would be made for the extra costs of operating a supply plant. The costs of operating a supply plant is one of the factors implicitly accepted by Cumberland in its decision to use that facility to supply milk to the Riviera Beach plant. The costs specified by Cumberland should not be considered as offestting the Order 6 price advantage at Dover.

Although, no separate presentation was made at the hearing for amending the Tampa Bay milk order as proposed by Southland in the hearing notice, there is ample evidence on the record to support such an amendment. The hearing record is abundantly clear that the inter-order price alignment problem that was corrected under Order 13 in a 1982 proceeding, and again occurred under Order 6 for August 1983 could conceivably happen under Order 12. The Class I differentials of Orders 4 and 12, the distance between the order areas, and the Class I utilization under the two orders all point towards a similar advantage for Cumberland if the Dover plant were regulated by Order 12.

Even though the Dover plant was regulated by Order 6 in only August 1983, such regulation could be repeated. The record established that Orlando, Florida is one of the fastest growing areas in Florida. Also, it is a popular resort area. These factors could generate a significant increase in fluid milk sales in the Order 6 area. This situation, combined with the fact that Cumberland has dairy stores in the Orlando area could set the stage for a repetition of regulation because the quantity of fluid milk sales by Cumberland in the Order 13 area and the Order 6 area are very similar.

Also, a decision by a competitor to reduce its fluid milk disposition in the Upper Florida or Tampa Bay areas could affect the pooling status of the Riviera Beach plant if Cumberland were to obtain a share of such sales. Under circumstances such as these, it is reasonable to conclude that the Riviera Beach plant of Cumberland Farms could become regulated under any of the three Florida milk orders.

The plant location adjustment provisions of Florida milk orders have been coordinated from the time they were promulgated, considering their close proximity. Under these circumstances, it would waste public and private resources to wait until the pooling of distant milk supplies that developed for Orders 13 and 6 also developed for Order 12 and then convene a hearing to consider the issue a third time. Accordingly, the Tampa Bay milk order also should be amended to establish all three Florida milk orders on the same basis concerning the possible regulation of the Dover, Delaware plant under any one of them.

The proposal to correct the problem of inequitable pricing in an other order area by amending Orders 6 and 12 to provide that the Class I price applicable on milk transferred to an other order plant be adjusted for location to a level no lower than the price applicable at that location under the other order is a reasonable and effective method of dealing with the situation. Adoption of the proposal would result in uniform prices paid by handlers regulated by Order 4. It is common practice to incorporate provisions under federal milk orders to ensure that handlers are faced with comparable costs for milk used in Class I irrespective of the source of such milk supply.

Adoption of the proposal would not establish a barrier to movements of milk between federal milk order marketing areas. The milk transferred from Dover to Florence does not move between federal order marketing areas but between plants regulated under different orders but located within the Order 4 marketing area. The adopted change would assure uniform pricing of milk to handlers located within the same area and by that assurance, would not inhibit milk transfers between those handlers.

Cumberland is not the exclusive target of the amendments adopted in this decision. Any handler with a plant located outside Florida but pooled under Order 6 or Order 12 who elects to sell milk for fluid use to nearby plants would be restrained from doing so at less than the local federally regulated price. The facility at Dover could be operated by any handler, even one who could establish a bottling and distributing operation there. Such opportunities for use of federal milk order provisions to obtain a position of competitive advantage in the market should be eliminated.

The fact that the additional money collected under the adopted proposals

would be paid into the Order 6 or Order 12 pools rather than into the Order 4 pool may be considered equitable even though the milk moved to Florence from Dover is considered surplus to the fluid needs of the Riviera Beach plant. If the Florida plant obtained a supply of milk from some other region, the milk not being moved to Florida from Dover likely would be added to the Order 4 pool.

In a post-hearing brief, Cumberland incoroprated by reference its post-hearing brief dated October 10, 1982 which was submitted in connection with the Order 13 proceeding. We must point out that while the issues of this proceeding for Orders 6 and 12 are similar to the issue considered for Order 13, the testimony and evidence of the two proceedings may not be identical. Accordingly, Cumberland's 1982 brief is not appropriate in all respects for consideration in the light of the particular evidence submitted by participants for the Order 6 and Order 12 proceeding.

In the brief, Cumberland said that Southland was the "ostensible" proponent of the proposals adopted herein. Cumberland said that although the Southland plant at Waldorf, Maryland, is regulated by Order 4, the handler has no significant competitive interaction with Cumberland's Order 4 plant at Florence, New Jersey. Cumberland concluded that in this proceeding, Southland has acted as the "alter ego," i.e., secondself or trusted friend, of IDFA, the cooperative operating in the Order 13 area.

Cumberland did not say specifically why it perceives Southland to be in this role. However, it did say in another part of the brief that if Cumberland were "forced," presumably by the amendments adopted herein, to buy its milk supply for the Riviera Beach plant from IDFA, Cumberland would once again be subject to over-order prices. It said that the IDFA over-order prices induced Cumberland to change its source of supply in the first place.

We cannot accept the view that Southland, apparently, is acting to force Cumberland to buy milk from IDFA at over-order prices. The fact is that when the Riviera Beach plant is regulated by Orders 6 or 12, Cumberland is provided with a price advantage on its fluid milk sales in Order 4. A similar advantage under Order 13 was eliminated by an amendment effective August 1, 1983 and previously cited herein. As the proponent of the proposals for Orders 6 and 12, Southland has identified the marketing problem and has proferred a reasonable solution. The proposals by Southland are supported by an association representing a substantial number of handlers who are regulated by Orders 2 and 4.

We believe that this view reflects the marketing conditions affecting the proposals to amend Orders 6 and 12. The changes proposed herein would not force Cumberland to buy milk from IDFA or from anyone else. The pricing of milk moved to Florida is not changed by the amendments adopted herein.

In the brief, Cumberland said that there are no disorderly marketing conditions in the Order 4 area that warrant the adoption of Southland's proposals. It stressed particularly that there has been no price cutting by handlers for fluid milk sales, that price competition out of stores is not severe and that the prices changed by stores in the Philidelphia area can be described as "healthy" competition.

The record established that there is no apparent price cutting for consumer sales. However, the witness for Order 2 and Order 4 handlers testified that bidding for sales to large supermarkets, schools and institutions is "most keen." He said that it is not unusual for the winning bidder to obtain business at a low price determined by the fourth or fifth decimal point. It is understandable that the handler witness would stress that it is essential that regulated competing handlers in the Order 2 and Order 4 marketing areas be provided with equity in their regulated cost of milk. We accept the view that the price advantage available to Cumberland, which stems from a technical flaw in the order provisions, is a potentially disruptive situation that should not result from federal milk regulation.

In the brief, Cumberland was uncertain about whether the Riviera Beach plant would be regulated by Order 6 again. At one place in the brief, Cumberland said that such regulation is not likely to occur again in the foreseeable future. In another place, it is stated that regulation of the plant under Order 6 was an isolated incident and not expected to recur. In another place, it is claimed that if the Southland proposals are adopted, a severe disruption of marketing conditions could occur if the Riviera Beach plant were regulated by Order 6. Presumably, this latter view is a reason that Cumberland opposes adoption of the proposals.

As stated earlier in this decision, we believe that the plant could be pooled under Order 6 or 12 in the future. This is one reason that the Southland proposals should be adopted. The chief reason is that adoption of the proposals will eliminate the technical flaw in Orders 6 and 12 that could provide a price advantage to any handler who met the conditions for exploiting it.

In the brief, Cumberland stressed that if it has to pay the same price for milk that Order 4 handlers must pay, it may have to raise prices to consumers. A chief purpose of federal milk Orders is to provide class prices that apply uniformly to handlers. Handlers must then compete with each other on the basis of their operating efficiencies. The changes adopted herein will assure the uniform application of Class prices that is required by the Agricultural Marketing Agreement Act of 1937, as amended.

Adoption of the changes provided herein does not create a special class of milk under Orders 6 and 12 as claimed by Cumberland in its testimony and reiterated in its brief. The changes adopted herein would eliminate the price advantage that could accrue to any handler similarly situated as Cumberland, and assure price uniformity among handlers competing for fluid milk sales under Order 4.

The changes adopted are neither radical nor discriminatory as claimed by Cumberland in its brief. It is common practice to incorporate provisions under federal milk orders to ensure that all handlers are faced with comparable costs for milk used in Class I irrespective of the source of such milk supply.

In its brief, Cumberland discussed several legal points which are not a subject of this decision.

A proposal was published in the hearing notice to consider increasing the plant location adjustment rate under Orders 6 and 12. No testimony was presented on the proposal, and no basis exists in the record for making any findings and conclusions concerning the merits of the proposal.

2. The omission of a recommended decision was not proposed at the hearing by any of the witnesses who testified on proposals No. 1 and 2. One witness testified that a decision should be issued promptly, but did not propose that a recommended decision be deleted. Further, no information of a compelling nature was presented on the record from which to conclude that the issuance of a recommended decision should be omitted. Accordingly, the proposal for emergency action is denied.

Rulings on Proposed Findings and Conclusions

Briefs and proposed findings and conclusions were filed on behalf of certain interested parties. These briefs, proposed findings and conclusions and the evidence in the record were

considered in making the findings and conclusions set forth above. To the extent that the suggested findings and conclusions filed by interested parties are inconsistent with the findings and conclusions set forth herein, the requests to make such findings or reach such conclusions are denied for the reasons previously stated in this decision.

General Findings

the findings and determinations hereinafter set forth are supplementary and in addition to the findings and determinations previously made in connection with the issuance of each of the aforesaid orders and of the previously issued amendments thereto; and all of said previous findings and determinations are hereby ratified and affirmed, except insofar as such findings and determinations may be in conflict with the findings and determinations set forth herein.

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

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

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

Recommended Marketing Agreements and Order Amending the Orders

The recommended marketing agreements are not included in this decision because the regulatory provisions thereof would be the same as those contained in the orders, as hereby proposed to be ameded. The following order amending the orders as amended regulating the handling of milk in the Upper Florida and Tampa Bay marketing areas are recommended as the detailed and appropriate means by which the foregoing conclusions may be carried out:

List of Subjects in 7 CFR Parts 1006 and 1012

Milk Marketing Orders, Milk, Dairy Products.

PART 1006—MILK IN THE UPPER FLORIDA MARKETING AREA

In § 1006.52(a), the text preceding the table is revised to read as follows:

§ 1006.52 Plant location adjustment for handlers.

(a) The Class I price for producer milk and other source milk at a plant located outside the State of Florida and more than 70 miles from the nearer of the City Halls of Jacksonville or Tallahassee, Florida, or with the State of Florida shall be adjusted at the rates set forth in the following schedule: *Provided,* that the resulting adjusted price for fluid milk products transferred from a pool plant to a plant regulated under another Federal order shall not be less than the Class I price under such other Federal order applicable at the location of the transferor plant:

* * * * *

PART 1012—MILK IN THE TAMPA BAY MARKETING AREA

In § 1012.52(a), the text preceding the table is revised to read as follows:

§ 1012.52 Plant location adjustments for handlers.

(a) The Class I price for producer milk and other source milk at a plant located outside the State of Florida or within the State of Florida but outside the defined marketing area shall be adjusted at the rates set forth in the following schedule: *Provided,* That the resulting adjusted price for fluid milk products transferred from a pool plant to a plant regulated under another Federal order shall not be less than the Class I price under such other Federal order applicable at the location of the transferor plant.

* * * * *

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

Signed at Washington, D.C., on May 17, 1984.

William T. Manley,

Deputy Administrator, Marketing Program Operations.

[FR Doc. 84–13719 Filed 5–21–84; 8:45 am]

BILLING CODE 3410–02–M

Farmers Home Administration

7 CFR Part 1942

Development Grants for Community Domestic Water and Waste Disposal Systems

AGENCY: Farmers Home Administration, USDA.

ACTION: Proposed rule.

SUMMARY: The Farmers Home Administration (FmHA) proposes to amend its regulation regarding development grants for community domestic water and waste disposal systems. Certain uses of and requirements regarding grant funds are not addressed in the current regulation. The intended effect of this proposed action is to address such uses and requirements in order to more effectively serve domestic water and waste disposal needs of rural areas.

DATE: Comments must be received on or before July 23, 1984.

ADDRESS: Submit written comments in duplicate to the Office of the Chief, Directives Management Branch, Farmers Home Administration, USDA South Agriculture Building, Room 6348, 14th and Independence Avenue SW., Washington, DC 20250. All written comments made pursuant to this notice will be available for public inspection during regular work hours at the address given above.

FOR FURTHER INFORMATION CONTACT: Jerry W. Cooper, Loan Specialist, Water and Waste Disposal Division, Farmers Home Administration, USDA Room 6328, South Agriculture Building, Washington, D.C. 20250, telephone: (202) 382–9589.

SUPPLEMENTARY INFORMATION: This action has been reviewed under USDA procedures established in Departmental Regulation which implements Executive Order 12291, and has been determined to be "nonmajor" since the annual effect on the economy is less than $100 million and there will be no significant increase in cost or prices, for consumers, individual industries, organizations, government agencies, or geographic regions. There will be no adverse affects 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. This action is not expected to substantially affect budget outlay, to affect more than one agency, or to be controversial. Additional efforts to

administer the proposed changes are expected to be minimal. Increased program costs are, therefore, not anticipated. The net result is expected to be a more efficient use of financial and natural resources.

The FmHA programs and projects which are affected by this instruction are subject to State and local review under section 401 of the Intergovernmental Cooperation Act and section 204 of the Demonstration Cities and Metropolitan Development Act.

This document has been reviewed in accordance with 7 CFR part 1901, Subpart G, "Environmental Impact Statements." It is the determination of FmHA that this action does not constitute a major Federal action significantly affecting the quality of the human enviroment, and in accordance with the National Environmental Policy Act of 1969, Pub. L. 91–190, an Environmental Impact Statement is not required.

Charles W. Shuman, Administrator, has determined that the proposed rule will not have a significant economic impact on a substantial number of small entities because the proposed action will only effect a small number of rural communities.

The Catalogue of Federal Domestic Assistance program affected is No. 10.418, Water and Waste Disposal Systems for Rural Communities.

This action outlines FmHA's policies and authorizations and sets forth the procedures for making and processing development grants. These grants assist in financing the development cost of domestic water and waste disposal systems to rural communities and other associations of farmers, ranchers, rural residents, and other rural users.

The following alternatives were considered in preparing this proposed rule:

Alternative 1 —Make no change in the regulation.

Effects:

1. Without eradicating numerous references to other regulations and forms which have become obsolete, the current regulation will continue to be difficult for the public and FmHA personnel to use. This will result in a loss of FmHA staff and the public's time.

2. Also without revising several sections of the regulation which are being misinterpreted or have not achieved the intended effect, program objectives will not be met.

3. Finally, new policies designed to achieve program objectives which are not in current regulations could not be put into effect.

Alternative 2—Revise the current regulation. This is the alternative chosen by FmHA. The majority of the proposed revisions will be editorial in nature. The substantial changes are as follows:

1. Authorize the use of grant funds to restore FmHA loan funds used to prepay eligible grant purposes.

2. Prohibit the use of grant funds to pay loan finder's fees.

3. Require that applicants be informed that any remaining FmHA project funds will be considered to be grant funds and refunded to FmHA.

4. Require that the funding needs of the applicant be reassessed prior to start of construction.

Effects:

1. The editorial revisions will improve the readability and comprehension of the regulations by the public and FmHA personnel.

2. The elimination of references to obsolete regulations and forms will remove the problems that this causes in processing grant applications.

3. During the construction of a project the need arises for using FmHA loan funds to pay for items that are to be paid by grant funds. The current regulation does not allow for the restoration of loan funds used to pay for items that are to be paid by grant funds. Using FmHA grant funds to restore loan funds used for eligible grant purposes will result in more orderly project processing

4. FmHA grant funds should not be used to pay loan or grant finder's fees. This restriction is presently in FmHA's loan regulation. This change will make the grant regulation consistent with this provision in the loan regulation.

5. On projects that involve both an FmHA loan and grant, the applicant must know how unused funds will be handled. Any misunderstanding can be eliminated by informing applicants prior to loan and grant approval that any funds remaining after all project costs have been provided or paid for will be considered grant funds and refunded to FmHA. If the amount of unused funds exceeds the FmHA grant then that part would be loan funds.

6. There have been cases where large amounts of FmHA funds have been left over after all original project costs have been paid or provided for. To reduce the problem of large amounts of grant funds obligated for a project and not needed, FmHA proposes to reassess the applicant's funding needs prior to start of construction. FmHA funds that are not needed will be deobligated prior to start of construction. This proposed change will help reduce the amount of unliquidated obligations that have been discussed in past audit reports.

This proposed action references certain proposed, new or renumbered sections of 7 CFR Part 1942, Subpart A which were published as a proposed rule in Volume 48, number 234, pages 54485 through 54499 of the **Federal Register**, December 5, 1983. This proposed action will not be published as a final rule until after 7 CFR Part 1942, Subpart A has been published as a final rule.

FmHA proposes to amend Subpart H of Part 1942, Chapter XVIII, Title 7, Code of Federal Regulations as follows:

(1) Add a new § 1942.358(f) that provides for the use of grant funds to restore FmHA loan funds.

(2) Add a mew § 1942.360(a)(2) that prohibits grant funds being used to pay loan or grant finder's fees.

(3) Renumber § 1942.357(c)(1) to § 1942.366(f)(1)(ii) and revise to require that the letter of conditions contain an item to inform the applicant that any remaining FmHA project funds will be considered to be FmHA grant funds and refunded to FmHA.

(4) Add a new § 1942.370 to provide that the funding needs of an applicant will be reassessed prior to start of construciton.

(5) Revise by making editorial changes in various sections.

List of Subjects in 7 CFR Part 1942

Community development, Grant programs—housing and community development, Rural areas, Waste treatment and disposal—domestic, Water supply—domestic.

Accordingly, as proposed, §§ 1942.351 through 1942.371 of Subpart H of Part 1942, Chapter XVIII, Title 7, Code of Federal Regulations are revised, and §§ 1942.372 through 1942.385 thereof are added to read as follows:

PART 1942—ASSOCIATIONS

* * * * *

Subpart H—Development Grants for Community Domestic Water and Waste Disposal Systems

* * * * *

Sec.

1942.351 General.
1942.352 [Reserved]
1942.353 Processing applications and docket preparation.
1942.354 [Reserved]
1942.355 Applicant eligibility and priority.
1942.356–1942.357 [Reserved]
1942.358 Use of grant funds.
1942.359 [Reserved]
1942.360 Grant limitations.
1942.361–1942.362 [Reserved]
1942.363 Determining the need for development grants.
1942.364–1942.365 [Reserved]
1942.366 Application review, approval and obligation of funds.
1942.367 [Reserved]

Sec.
1942.368 Borrower contracts.
1942.369 Preparation for grant closing.
1942.370 Actions prior to grant closing and start of construction.
1941.371 [Reserved]
1942.372 Grant closing and delivery of funds.
1942.373 Planning and performing development.
1942.374 [Reserved]
1942.375 Actions subsequent to grant closing.
1942.376 Grant servicing.
1942.377 Grant cancellation.
1942.378 [Reserved]
1942.379 Subsequent grants.
1942.380 Regional commission grants.
1942.381 [Reserved]
1942.382 Management assistance.
1942.383 State Supplements and guides.
1942.384 Delegation of authority.
1942.385 Special conditions under Public Law (PL) 98–8 (Emergency Jobs Bill).
1942.386–1942.400 [Reserved]

Authority: 7 U.S.C. 1989; 7 CFR 2.23, 7 CFR 2.70.

Subpart H—Development Grants for Community Domestic Water and Waste Disposal Systems

§ 1942.351 General.

(a) This subpart outlines the policies and authorizations and sets forth the procedures for making and processing grants to assist in financing the development cost of domestic water and waste disposal systems to rural communities and other associations of farmers, ranchers, rural residents, and other rural users. Farmers Home Administration (FmHA) will maintain continuous liaison and coordination with State and substate planning district officials. FmHA shall cooperate fully with appropriate State agencies in making grants in a manner which will assure maximum support of the State's strategies for development of rural areas. State and substate A–95 agencies may recommend priorities for application. FmHA will give due consideration to all A–95 agency review comments and priority recommendations in selecting applications for funding.

(b) Indian tribes on Federal and State reservations and other Federally recognized Indian tribes are eligible to apply for and are encouraged to participate in this program. Such tribes might not be subject to State and local laws or jurisdiction. However, any requirements of this subpart that affect applicant eligibility, the adequacy of FmHA's security or the adequacy of service to users of the facility and all other requirements of this subpart must be met. FmHA State Directors are reminded that funds allocated for use as prescribed in this subpart are to be considered for use by Indian tribes within the State regardless of whether State development strategies include Indian reservations within the State's boundaries. It is essential that Indians residing on such reservations have equal opportunity to participate in the benefits of these programs on as equal a basis as other residents of the State. This is intended to include an equal application of the outreach activities of FmHA County and District Offices.

(c) It is the policy that the County Office will normally be the entry point for preapplications and serve as the local contact point. However, applications will be filed and grants will be processed to the maximum extent possible by the District Office staff. The State Office staff will monitor grant making and servicing and will provide assistance to District Office personnel to the extent necessary to assure that the activities are being accomplished in an orderly manner consistent with FmHA regulations. The District Director will supply information on grant activity within the County Office service area to the County Supervisor at key points throughout the grant making process.

(d) It is the policy of FmHA to extend its financial program without regard to race, color, religion, sex, national origin, marital status, age, or physical/mental handicap (provided the participant possess the capacity to enter into legal contracts.)

§ 1942.352 [Reserved]

§ 1942.353 Processing applications and docket preparation.

(a) Preapplications and applications for water and waste disposal development grants will be processed in accordance with § 1942.2 of Subpart A of Part 1942 of this chapter.

(b) Grant dockets will be prepared in accordance with subpart and applicable portions of Subpart A of Part 1942 of this chapter.

§ 1942.354 [Reserved]

§ 1942.355 Applicant eligibility and priority.

(a) *Eligibility.* Applicant eligibility shall be determined in accordance with § 1942.17(b) of Subpart A of Part 1942 of this chapter. Also, grants shall not be made in connection with any project unless the project:

(1) Will serve a rural area which, if such project is carried out, is not likely to decline in population below that for which the project was designed.

(2) Is designed and constructed so that adequate capacity will or can be made available to serve the present population of the area to the extent feasible and to serve the reasonably foreseeable growth needs of the area to the extent practicable. Also, water systems must have sufficient capacity to provide for reasonable fire protection to the extent practicable.

(3) Is necessary or orderly community development consistent with a comprehensive community water, waste disposal, or other development plan of the rural area and not inconsistent with any planned development provided in any State, multijurisdictional, county, or municipal plan approved by competent authority for the area in which the rural community is located.

(b) *Applicant priorities.* Priority for grant funds will be given to applicants and projects in accordance with § 1942.17(c) of Subpart A of Part 1942 of this chapter.

§§ 1942.356–1942.357 [Reserved]

§ 1942.358 Use of grant funds.

Funds may be used only for the following purposes:

(a) To construct, enlarge, extend, or otherwise improve community water, sanitary sewage, solid waste disposal, and storm wastewater disposal facilities.

(b) To construct or relocate buildings, roads, bridges, fences, utilities, and to make such other public improvements necessary to the successful operation or protection of facilities authorized in paragraph (a) of this section.

(c) To relocate buildings, roads, bridges, fences, utilities, and to make such other private improvements necessary to the successful operation or protection of facilities authorized in paragraph (a) of this section.

(d) To use FmHA grant funds for the following when a necessary part of the project relating to those facilities in paragraph (a), (b), and (c) of this section.

(1) Reasonable fees and costs such as legal, engineering, architectural, fiscal advisory, recording, planning, establishing or acquiring rights.

(2) Costs of acquiring interest in land, rights such as water rights, leases, permits, rights of way and other evidence of land or water control which are necessary for development of the facility.

(3) Purchase or rent equipment necessary to install, maintain, extend, protect, operate or utilize facilities. (Subject to limitations contained in § 1942.360(a) of this subpart).

(4) Payment of tap fees and other utility connection charges when determined necessary to prevent a loss of, improve, or provide service.

(e) To use FmHA grant funds on projects where other types of financial assistance are available on all or part of the projects, provided the other assistance is on reasonable rates and terms. In such cases the maximum percentages allowed under other agencies' authorities will apply to their participation in the project. However, the FmHA grant may not exceed seventy-five percent (75%) of the eligible project development cost. The need for FmHA grant funds must meet the requirements of § 1942.363 of this Subpart after considering all project financing.

(f) To restore FmHA loan funds used in accordance with § 1942.17(d)(1)(iv)(G) of Subpart A of Part 1942 of this chapter.

§ 1942.359 [Reserved]

§ 1942.360 Grant limitations.

(a) Grant funds may not be used to:

(1) Finance facilities which are not modest in size, design, and cost.

(2) Pay loan or grant finder's fees.

(3) Pay for the construction of any new combined storm and sanitary sewer facilities.

(4) Pay any annually recurring costs including purchases or rentals that are generally considered to be operation and maintenance expenses.

(5) Construct or repair electric generating plants, electric transmission lines, or gas distribution lines to provide services for commercial sale.

(6) Purchase fire trucks, hoses, and other firefighting equipment or construct housing for such equipment.

(7) Pay rental for the use of equipment or machinery owned by the association.

(8) Pay for salesrooms or other purposes not directly related to operation and maintenance of the facility being installed or improved.

(9) Purchase existing systems.

(10) Refinancing existing indebtedness.

(11) Pay any portion of the cost of a facility when the annual reserve based on a typical year exceeds one-tenth of the average annual debt service requirement unless State regulatory agencies require a larger reserve, or when it is anticipated that facility replacement costs on a relatively short-term basis will require a higher reserve.

(12) Pay interest.

(13) Pay any portion of the cost of a facility which is not located in a rural area.

(14) Pay any costs of a project when the median household income of the service area is more than 85 percent of the nonmetropolitan median household income of the State.

(b) An FmHA development grant may not be made in excess of seventy-five percent (75%) of the eligible project development costs. Facilities previously installed will not be considered in determining the development costs.

§§ 1942.361–1942.362 [Reserved]

§ 1942.363 Determining the need for development grants.

(a) FmHA District Directors are responsible for determining applicant's eligibility for grants and the amount of such grants. Form FmHA 1942–51, "Water and Waste Disposal Development Grant Summary," will be used to determine the amount of FmHA grant assistance for which the applicant qualifies. A separate form will be used to record the determination of FmHA grant assistance for each water, sewer collection and treatment, solid waste, or storm drainage project.

(b) Grants will be used for water and waste disposal projects serving the most financially needy communities to reduce user costs to a reasonable level for farmers, ranchers, and other rural residents.

(1) *Other Users.* Other rural water and sewer users whose total water needs are met or, if there is no meter, could be met by a single residential size water meter also may be considered eligible. For example, a user on a waste system may be considered for a grant when the total water needs of the waste user are met or could be met by such residential-size meter.

(2) *Reasonable Rate.* Reasonable user rate is defined as that which is not less than existing prevailing rates in communities having similar economic conditions being served by an established system constructed at similar costs per user. Similar user costs shall include charges, taxes, and assessments attributable to the project.

(c) Grants will be determined in accordance with the following and will not result in a user rate below that deemed to be reasonable.

(1) Grants may not exceed seventy-five percent (75%) of the eligible project development costs listed in § 1942.358 of this Subpart.

(2) Applicants will be considered for grant assistance when the debt service portion of the average annual user cost, for users in the applicant service area, exceeds the following percentages of median household income:

(i) *.5 percent* when the median household income of the service area is below the poverty line. The poverty line will be that income prescribed by the Office of Management and Budget for a nonfarm family of four, as adjusted under Section 624 of the Economic Opportunity Act of 1964 (42 U.S.C. 2971d).

(ii) *1.0 percent* when the median household income of the service area is not more than 85 percent of the State's nonmetropolitan household income.

(iii) No FmHA grant funds will be used in any project when the median household income of the service area is more than 85 percent of the nonmetropolitan median household income of the State.

(3) In the exceptional cases where FmHA determines that a reasonable user cost has not been achieved due to unusually *high* operation and maintenance costs, construction or water acquisition costs, or other unusual factors, FmHA may proceed with a grant in an amount necessary to reduce the user cost to a reasonable level.

(4) If, after applying the formula described in paragraph (c)(2)(i), or (ii) of this section, FmHA determines that a reasonable average annual cost to the applicant for delivery of service to residential type users has not been achieved, FmHA may proceed with a grant in an amount necessary to reduce such cost to not below a reasonable user rate as defined in paragraph (b)(2) of this section. Reasonable average annual cost to the applicant is defined as that which is not less than existing prevailing costs in communities, being served by an established system, having similar economic conditions. This option is only available to an applicant:

(i) Where the annual cost to the applicant for delivery of service to residential type users is subsidized by either the state, commonwealth, or territory, and

(ii) Where uniform user charges are imposed for similar classes of service throughout the service area.

(5) When the applicant will be furnishing bulk service to rural residents served by another system (entity), a grant to such applicant may also be considered for an amount to reduce the user costs on a similar basis as provided in this section for users of such other system. An agreement between the applicant and the other system will be obtained that clearly shows that the benefit of the grant will accrue only to the users intended to be benefited by the grant. For purposes of grant determination, all other systems which will receive bulk service may either:

(i) Be considered as part of the total by averaging the median household incomes of the systems involved and averaging the debt service portion for the particular service of the other systems. Where this method is used, a uniform user rate schedule must be established for similar classes of users. For example, all systems involved

would have the same user rate schedule for residential users; or

(ii) Consider the median household income and the debt service portion for the particular service for each entity separately.

(d) The income data used to determine median household income should be that which most accurately reflects the income of the service area. The service area is that area reasonably expected to be served by the facility being financed by FmHA. The median household income of the service area or those reference communities used in comparing the proposed system with similar systems, and the nonmetropolitan median household income for the State will be determined from the U.S. Department of Commerce, Bureau of Census, Publication PC (1)—C Series, or from unpublished Bureau of Census data for individual enumeration districts. If there is reason to believe that the census data is not an accurate representation of the median household income within the area to be served, the resons will be documented on Form FmHA 1942–51 and the applicant may furnish, or FmHA may obtain, additional information regarding such median household income. Such information will consist of reliable data from local, regional, State or Federal sources or from a survey conducted by a reliable impartial source. The nonmetropolitan median household income of the State should be updated, using reliable data from State or Federal sources as such data becomes available.

(e) Financial information contained in preliminary engineering reports will be prepared without taking an FmHA grant into consideration.

§ 1942.364–1942.365 [Reserved]

§ 1942.366 Application review, approval and obligation of funds.

(a) When a grant only (no FmHA loan) is being made, only those applicable provisions of review and approval procedures outlined in § 1942.5 of Subpart A of Part 1942 of this chapter will apply which are necessary to assure that:

(1) The proposed development is completed in accordance with approved plans and specifications.

(2) Grant funds are expended for authorized purposes.

(3) The terms of the grant agreement can be complied with.

(b) When the grant approval official requires an appraisal, Form FmHA 442–10, "Appraisal Report—Water and Waste Disposal Systems," with appropriate supplements, may be used. Appraisal reports will be prepared by the FmHA engineer or, if desired by the grant approval official, another qualified appraiser.

(c) When an FmHA loan and grant are being processed simultaneously, the application review and approval procedures outlined in § 1942.5 of Subpart A of Part 1942 of this chapter will be followed.

(d) Grants will be approved in accordance with this Subpart and Exhibit B of FmHA Instruction 1901–A which is available in any FmHA office.

(e) All grants that require National Office review will be submitted in accordance with § 1942.5(b)(1) of Subpart A of Part 1942 of this chapter.

(f) Each letter of conditions involving a grant will contain the following:

(1) Insertions which read:

(i) "Attached is a copy of Form FmHA 1942–31, "Association Water or Sewer System Grant Agreement," for your review. You will be required to execute a completed form at the time of grant closing."

(ii) "The applicant contribution shall be considered as the first funds expended except (insert appropriate exceptions if funds from other sources make an exception necessary). After providing for all authorized costs, any remaining FmHA project funds will be considered to be FmHA grant funds and refunded to FmHA. If the amount of unused FmHA project funds exceeds the FmHA grant that part would be FmHA loan funds."

(2) All items contained in § 1942.5(a)(1) of Subpart A of Part 1942 of this chapter applicable to the grant funding.

(3) Other relative requirements.

(g) State Directors may obligate funds including Regional Commission grant funds when they are available, in accordance with § 1942.5(d) of Subpart A of Part 1942 of this chapter.

(h) A copy of Form FmHA 1942–51, along with the letter of conditions and Form FmHA 1942–45, "Project Summary—Water and Waste Disposal and Other Utility-Type Projects," (including the required copy of Forms FmHA 442–14, "Association Project Fund Analysis," and FmHA 442–7, "Operating Budget") will be submitted to the National Office, Attention: Water and Waste Disposal Division, by the State Director not later than the time the letter of conditions is issued.

§ 1942.367 [Reserved]

§ 1942.368 Borrower contracts.

The requirements of §§ 1942.4, 1942.17(1), and 1942.18 of Subpart A of Part 1942 of this chapter will be followed when concurring in agreements between grantees and third parties.

§ 1942.369 Preparation for grant closing.

Section 1942.6 of Subpart A of Part 1942 of this chapter will be followed when preparing for grant closing.

§ 1942.370 Actions prior to grant closing and start of construction.

The requirements of § 1942.17(n)(1) of Subpart A of Part 1942 of this chapter will be followed for water and waste disposal development grants.

§ 1942.371 [Reserved]

§ 1942.372 Grant closing and delivery of funds.

(a) Grants will be closed in accordance with instructions received from the Office of the General Counsel (OGC). FmHA policy is not to disburse grant funds from the Treasury until they are actually needed by the applicant. Borrower funds will be disbursed before the disbursal of any FmHA grant funds.

(1) FmHA loan funds will be disbursed before the disbursal of any FmHA grant funds except when:

(i) Interim financing of the total FmHA loan amount is arranged,

(ii) All interim funds have been disbused, and

(iii) FmHA grant funds are needed before the FmHA loan can be closed.

(2) If grant funds are available from other agencies and are transferred to the Finance Office for disbursement by FmHA, these grant funds shall be disbursed in accordance with the agreement govering such agencies' participation in the project.

(3) Any grant funds remaining will be handled in accordance with § 1942.17(p)(6) of Subpart A of Part 1942 of this chapter.

(b) FmHA grant funds will be disbursed by using multiple advances in accordance with § 1942.17(p)(2) of Subpart A of Part 1942 of this chapter.

(c) Payment for construction will be made in accordance with § 1942.17(p)(5) of Subpart A of Part 1942 of this chapter

(d) Form FmHA 1942–31 will be completed and executed in accordance with the requirements of grant approval and closing instructions. Both District Directors and State Directors are authorized to sign the grant agreement on behalf of FmHA. For grants that supplement FmHA loan funds, the grant should be closed simultaneously with the closing of the loan. However, when grant funds will be disbursed before loan closing as provided for in paragraph (a)(1) of this section, the grant will be closed not later than the delivery date of the first advance of grant funds.

The grant will be considered closed when Form FmHA 1942–31 has been properly executed. Incorporated as a part of this Subpart is Form FmHA 1942–31 which appears as Exhibit C in the Federal Register.

§ 1942.373 Planning and performing development.

Planning and performing development will be handled in accordance with §§ 1942.9 and 1942.18 of Subpart A of Part A of this chapter.

§ 1942.374 [Reserved]

§ 1942.375 Actions subsequent to grant closing.

Section 1942.8 of Subpart A of Part 1942 of this chapter will be followed for water and waste disposal development grants.

§ 1942.376 Grant servicing.

Grants will be serviced in accordance with Subpart E of Part 1951 of this chapter.

§ 1942.377 Grant cancellation.

The District Director or State Director may prepare and execute Form FmHA 1940–10, "Cancellation of U.S. Treasury Check and/or Obligation," in accordance with the Forms Manual Insert. If the docket has been forwarded to OGC, that office will be notified of the cancellation by a copy of Form FmHA 1942–10. The borrower's attorney and engineer, if any, should be notified of the cancellation. The borrower's attorney and engineer may be provided a copy of the notification to the applicant.

§ 1942.378 [Reserved]

§ 1942.379 Subsequent grants.

Subsequent grants will be processed in accordance with this subpart.

§ 1942.380 Regional commission grants.

Grants are sometimes made by regional commissions for projects eligible for FmHA assistance. FmHA has agreed to administer such funds in a manner similar to FmHA assistance.

(a) When FmHA has funds in the project, no charge will be made for administering commission funds.

(b) When FmHA has neither loan nor grant funds in the project, an administrative charge will be made pursuant to the Economy Act of 1932 (31 U.S.C. 686). A fee of five percent (5%) of the first $50,000 of a regional commission grant and one percent (1%) of any amount over $50,000 will be paid FmHA by the commission.

(1) *Appalachian Regional Commission.* Exhibit A of this Subpart will be followed in determining the responsibilities of FmHA. The Federal Cochairman and the State Director will provide each other with the necessary notification and certification.

(2) *Other regional commissions.* Title V of the Public Works and Economic Development Act of 1965 authorizes other commissions similar to the Appalachian Regional Commission. Exhibit B of this Subpart will be used to develop a separate project management agreement between FmHA and the commission separately for each project. The agreement should be prepared by the FmHA State Director as soon as notification is received that a commission grant will be made and the amount is confirmed.

(c) Regional commission grants should be obligated as soon as possible in accordance with § 1942.5(d) of Subpart A of Part 1942 of this chapter, except that the announcement procedure referred to in § 1942.5(d)(6) is not applicable. Regional commission grants will be obtained from the Finance Office in the same manner as FmHA funds are obtained.

§ 1942.381 [Reserved]

§ 1942.382 Management assistance.

Grant recipients will be supervised to the extent necessary to assure that facilities are constructed in accordance with approved plans and specifications and to assure that funds are expended for approved purposes.

§ 1942.383 State Supplements and guides.

This Subpart may be supplemented by State Supplements and guides in accordance with § 1942.16 of Subpart A of Part 1942 of this chapter.

§ 1942.384 Delegation of authority.

The State Director is responsible for the overall implementation of the authorities contained in this subpart and may redelegate any such authority to appropriate FmHA employees.

§ 1942.385 Special conditions under Public Law (Pub. L.) 98–8 (Emergency Jobs Bill).

Each project to be funded utilizing grant funds authorized by Pub. L. 98–8 (Emergency Jobs Bill) will be processed in accordance with Exhibit D of this Subpart. In Exhibit D of this Subpart, all references to other FmHA regulations and forms will be construed to mean the most current version of those regulations and forms, and the following:

(a) Grant funds shall be made available for projects and activities in civil jurisdictions with high unemployment, or in labor surplus areas, or in political units or in pockets of poverty that are currently or should meet the criteria to be eligible under the Urban Development Grant Action (UDAG program administered by the Department of Housing and Urban Development).

(b) Each letter of conditions that is issued utilizing FmHA loan and/or grants funds authorized by Pub. L. 98–8 will contain the following:

(1) Standard paragraphs in accordance with § 1942.5(a)(1)(ii) of Subpart A of Part 1942 of this chapter, and

(2) "The (i.e. town, district, authority) shall to the extent practicable utilize FmHA funds in a manner which maximizes immediate creation of new employment opportunities to individuals who were unemployed at least 15 of the 26 weeks prior to March 24, 1983. Such a condition will be made part of any construction contract awarded in support of FmHA funds."

(c) The following should be added to the Supplemental General Conditions of construction contracts involving Pub. L. 98–8 funds:

"To the extent practicable, the contractor shall hire needed new employees in a manner which maximizes immediate creation of new employment opportunities to individuals who were unemployed at least 15 of the 26 weeks prior to March 24, 1983."

§§ 1942.386–1942.400 [Reserved]

Dated: March 21, 1984.

Michael E. Brunner,

Acting Administrator, Farmers Home Administration.

[FR Doc. 84–13730 Filed 5–21–84; 8:45 am]

BILLING CODE 3410–07–M

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7 CFR Part 1980

Business and Industrial Loan Program

AGENCY: Farmers Home Administration, USDA.

ACTION: Proposed rule.

SUMMARY: The Farmers Home Administration (FmHA) proposes to amend its Business and Industrial (B&I) Loan Program regulations by permitting negotiated reductions in interest rates charged on guaranteed loans. This action is necessary because otherwise loan liquidations will result from borrowers' inability to repay loan installments due to interest rates not being compatible with existing market conditions. The intended effect of this proposed action is to permit the borrower, lender, and holder (if any) to collectively negotiate a reduced interest rate, thereby benefiting the borrower.

DATE: Comments must be received on or before June 21, 1984.

ADDRESSES: Submit written comments in duplicate to the Office of the Chief, Directives Management Branch, Farmers Home Administration, U.S. Department of Agriculture, South Agriculture Building, Room 6346, 14th and Independence Avenue SW., Washington, D.C. 20250. All written comments made pursuant to this notice will be available for public inspection during regular work hours at the address given above.

The collection of information requirements contained in this proposed rulemaking have been submitted to OMB for review under section 3504(h) of the Paperwork Reduction Act of 1980. Submit comments to the Office of Information and Regulatory Affairs, Office of Management and Budget. Attention: Desk Officer for the Farmers Home Administration, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Dwight A. Carmon, Loan Specialist, Business and Industry Division, USDA, and FmHA, 14th and Independence Avenue SW., Washington, D.C. 20250—Telephone: (202)475–3811

SUPPLEMENTARY INFORMATION: This proposed action has been reviewed under USDA procedures established in Departmental Regulation 1512–1, which implements Executive Order 12291 and has been determined to be "non-major" since the annual effect on the economy is less than $100 million and there will be no significant increase in costs or prices for consumers, individual industries, organizations, governmental agencies, or geographic regions. There will be no signficant 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.

This proposed action will affect Catalogue of Federal Domestic Assistance Number 10.422, Business and Industrial Loan.

The activities covered by this proposed rule are subject to the requirements for intergovernmental consultation as stated in 7 CFR Part 3015 Subpart V, "Intergovernmental Review of Department of Agriculture Programs and Activities."

This proposed action has been reviewed in accordance with FmHA Instruction 1940–G, "Environmental Program." FmHA has determined that this proposed action does not constitute a major Federal action significantly affecting the quality of the human environment and, in accordance with the National Environmental Policy Act of 1969, Pub. L. 91–190, and Environmental Impact Statement is not required.

Discussion of Proposed Rule

This proposed action establishes regulatory procedures for the reduction of interest rates charged on B&I guaranteed loans. Current regulations permit fixed or variable interest rates but do not provide for the reduction of interest rates except for variable rates which may rise and fall with the selected base rate. Variable rates can be changed no more often than quarterly.

There have been numerous inquiries addressing the need to adjust interest rates for the mutual accommodation of borrower and lender. There is an urgent need to define FmHA's position on the reduction of interest rates so that the borrower, lender, and the Government can accommodate to changing conditions.

Currently, the borrower may be prevented from receiving a reduced interest rate when market conditions warrant it or when weakened revenues require it. The lender does not now have latitude in reducing its interest rate, and is thus deprived of the opportunity to assist and retain its customer by virtue of its inability to meet its competition.

This proposed action will furnish means whereby interest may be reduced by collective action of the borrower, lender, and holder. It prohibits fixed rates from being changed to variable rates to reduce the interest rate to the borrower unless the variable rate has a ceiling which is less than the original fixed rate. No increase in interest rates will be permitted except under the normal fluctuations for approved variable interest rate loans.

List of Subjects in 7 CFR Part 1980

Loan programs— Business and industry, Rural development assistance, Rural areas.

PART 1980—[AMENDED]

Accordingly, FmHA proposes to amend § 1980.423 of Subpart E of Part 1980, Chapter XVIII, Title 7, Code of Federal Regulations by revising paragraph (a)(1), by adding paragraphs (a) (6) and (7), and by adding a paragraph entitled "Administrative" at the end of the Section to read as follows:

§ 1980.423 Interest rates.

(a) * * *

(1) A variable interest rate must be a rate that is tied to a base rate published periodically in a financial publication specifically agreed to by the lender and borrower. It must rise and fall with the selected base rate, and changes can be made no more often than quarterly. There will be no floor or ceiling or variable interest rates except as specified in paragraph (a)(6)(i) of this section. The lender must incorporate within the variable rate promissory note at loan closing the provision for adjustment of payment installments conincident with an interest rate adjustment. This will assure that the outstanding principal balance is properly amortized within the prescribed loan maturity to eliminate the possiblity of a balloon payment at the end of the loan.

* * * * *

(6) The borrower, lender and holder (if any) may collectively affect a permanent reduction in the interest rate of their B&I guaranteed loan at any time during the life of the loan upon written agreement by these parties. FmHA must be notified by the lender, in writing, within 10 days fo the change. If the guaranteed portion has been repurchased by FmHA, then FmHA is a holder and must affirm or reject interest rate change proposals. When FmHA is a holder, it will concur in such interest rate change only when it is demonstrated to FmHA that the change is a more viable alternative than initiating or proceeding with liquidation of the loan or continuing with the loan in its present state, and that the Government's financial interests are not adversely affected. Factors which will be considered in making such a determination will include whether the proposed interest rate will be below the Government's cost of borrowing money, whether continuing with the loan would realistically promote or enhance rural development and employment in rural areas, whether the monetary recovery would be increased by proceeding immediately to liquidation, if applicable, or allowing the borrower to continue at a reduced interest rate, and whether an in-depth financial analysis by the lender reasonably indicates that the business would be successful at a lower interest rate and reasonably indicates that the borrower could make the reduced payment and payoff amounts in arrears, if any. The FmHA file will reflect the documentation of the interest rate change decision.

(i) Fixed rates cannot be changed to variable rates to reduce the interest rate to the borrower unless the variable rate has a ceiling which is less than the original fixed rate.

(ii) Variable rates can be changed to reduced fixed rates. In a final loss settlement, when qualifying rate

changes were made with the required written agreements and notification, the interest will be calculated for the periods the given rates were in effect, except that interest claimed on a loan which originated at a variable rate can never exceed the amount which would have been eligible for claim had the variable interest remained in force. The lesser cost to the Government will always prevail. The lender must maintain records which adequately document the accrued interest claimed.

(iii) The lender is responsible for the legal documentation of interest changes by an allonge attached to the promissory note(s) or any other legally effective amendment of the rate(s). However, no new note(s) may be issued.

(7) No increases in interest rates will be permitted under the B&I loan guarantee except the normal fluctuations in approved variable interest rate loans.

* * * * *

Administrative: Par (a) (6) and (7).

The State Director will notify the Finance Office of any interest rate reduction by using Form FmHA 1980–47, "Guaranteed Loan Borrower Adjustments." The State Director will make corrections to the Rural Community Facility Tracking System (RCFTS) reflecting the interest rate change. The FmHA loan file, as well as the attachments to the copy of the promissory note in the file, will be documented by the State Director to reflect any change in the interest rate.

7 (U.S.C. 1989; Order of Secretary of Agriculture, 7 CFR 2.23; Order of Assistant Secretary for Rural Development, 7 CFR 2.70)

Dated: March 2, 1984.

Charles W. Shuman,

Administrator, Farmers Home Administration.

[FR Doc. 84–13729 Filed 5–21–84; 8:45 am]

BILLING CODE 3410–07–M

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 901

Reopening and Extension of Public Comment Period on Proposed Amendment to Alabama Permanent Regulatory Program

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

ACTION: Reopening and extension of public comment period.

SUMMARY: On November 28, 1983, the Alabama Surface Mining Commission (ASMC) submitted to OSM a set of regulatory amendments intended, in part, to meet its three remaining conditions for approval of the Alabama Permanent Regulatory Program. OSM published a notice in the **Federal Register** on January 12, 1984, announcing receipt of the amendment and inviting public comment on the adequacy of the proposed amendment (49 FR 1532). The public comment period ended on February 13, 1984.

A review of Alabama's proposed amendment by OSM identified several concerns relating to inspection of impoundments and placement of excess spoil. OSM notified the ASMC about its concerns and on May 3, 1984, the Division responded by submitting modifications to its proposed amendment. Accordingly, OSM is reopening and extending the comment period on Alabama's November 28, 1983 proposed amendment as modified on May 3, 1984. This action is being taken to provide the public an opportunity to reconsider the adequacy of the proposed amendment.

DATE: Written comments, data or other relevant information relating to this rulemaking not received on or before 4:00 p.m. June 6, 1984 will not necessarily be considered.

ADDRESSES: Written comments should be mailed or hand delivered to: John T. Davis, Director, Birmingham Field Office, Office or Surface Mining, 228 West Valley Avenue, Homewood, Alabama 35209.

Copies of the Alabama program, the proposed modifications to the program, and all written comments received in response to this notice will be available for public review at the OSM Field Office listed above and at the OSM Headquarters office and the office of State regulatory authority listed below, during normal business hours Monday through Friday, excluding holidays.

Office of Surface Mining, Administrative Record, Room 5124, 1100 L Street NW., Washington, D.C. 20240;

Alabama Surface Mining Commission, Central Bank Building, 2nd Floor, 811 Second Avenue, Jasper, Alabama 35501.

FOR FURTHER INFORMATION CONTACT: John T. Davis, Director, Birmingham Field Office, Office of Surface Mining, 228 West Valley Avenue, 3rd Floor, Homewood, Alabama 35209; Telephone: (205) 254–0890.

SUPPLEMENTARY INFORMATION: The Alabama State program was approved effective May 20, 1982, by notice published in the **Federal Register** (47 FR 22038). Information pertinent to the general badckground on the Alabama program, including a detailed explanation of the conditions of approval of the Alabama program, can be found in the May 20, 1982 **Federal Register.**

By letter dated November 28, 1983, Alabama submitted a proposed amendment which was intended, in part, to meet the remaining three conditions of approval. OSM announced receipt of the amendment and initiated a public comment period on January 12, 1984 (49 FR 1532). The public comment period ended on February 13, 1984. A public hearing scheduled for February 6, 1984 was not held because no one expressed a desire to present testimony.

During the review of Alabama's proposed amendment, OSM identified the following concerns:

1. Alabama rules 800–X–10C–.36(13)(b) and 880–X–10D–.33(13)(b) do not require the approval of the regulatory authority for disposal of coal processing waste in excess spoil fills, as do 30 CFR 816.71(h)(4) and 817.71(h)(4).

2. Alabama rules 880–X–10C–.36(15)(b) and 880–X–10D–.33(15)(b) do not specify that approval by the regulatory authority is discretionary for gravity transport of excess spoil. The Federal rules specify such a requirement at 30 CFR 816.74(e) and 817.74(e).

3. Alabama rules 880–X–10C.36(15)(b) and 880–X–10D–.33(15)(b) do not require that gravity transport courses be determined as part of the permit application nor do they require rehandling of any preexisting spoil that is disturbed. Such requirements are specified in 30 CFR 816.74(e) and 817.74(e).

4. Alabama rules 880–X–10C–.20(j) and 880–X–10D–.20(j) do not require that impoundments be inspected upon completion of construction, as do 30 CFR 816.49(a)(10) and 817.49(a)(10).

OSM notified Alabama about these concerns by letter dated April 23, 1984, and Alabama responded by letter dated May 3, 1984, by submitting a modification to its November 28, 1983 amendment. The modification is intended to address OSM's concerns and consists of a set of draft proposed rules. The full text of the proposed program amendment and the subsequent modification is available for review at the locations listed above under **ADDRESSES**. Accordingly, the Secretary of the Interior, through OSM, is now seeking public comments on the adequacy of Alabama's November 28, 1983 amendment in light of the State's May 3, 1984 modifications. The public comment period is hereby extended to June 6, 1984. All comments should be submitted to the location shown above under **ADDRESSES** in order to be

considered by the Secretary in this rulemaking.

(Pub. L. 95–87, 30 U.S.C. 1201 *et seq.*)

Dated: May 16, 1984.

William B. Schmidt,

Assistant Director, Program Operations and Inspection.

[FR Doc. 84–13695 Filed 5–21–84; 8:45 am]

BILLING CODE 4310–05–M

30 CFR Part 936

Receipt of a Petition To Initiate Rulemaking Submitted by State of Oklahoma; Correction

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

ACTION: Proposed rule; correction.

SUMMARY: This document corrects an oversight in the **Federal Register** notice published May 14, 1984, which announced receipt by OSM of a petition to initiate rulemaking submitted by the State of Oklahoma. (49 FR 20308).

In column one of that notice, under the heading **ADDRESSES,** OSM is providing an address to which interested parties should mail or hand deliver any comments concerning the Oklahoma petition.

EFFECTIVE DATE: May 22, 1984.

FOR FURTHER INFORMATION CONTACT: Carl C. Close, Special Assistant to the Assistant Director, Program Operations and Inspection, Office of Surface Mining, 1951 Constitution Avenue NW., Washington, D.C. 20240; Telephone: (202) 343–4225.

Dated: May 17, 1984.

William B. Schmidt,

Assistant Director, Program Operations and Inspection.

(Pub. L. 95–87, Surface Mining Control and Reclamation Act of 1977 (30 U.S.C. 1201 *et seq.*)

Accordingly, the Office of Surface Mining is correcting the Monday, May 14, 1984 **Federal Register** (49 FR 20308) by revising the Addresses paragraph to read as follows: **ADDRESSES:** Written comments should be mailed or hand delivered to Mr. Robert Markey, Director, Tulsa Field Office, Office of Surface Mining, Room 3432, 333 West 4th Street, Tulsa, Oklahoma 74103.

[FR Doc. 84–13696 Filed 5–21–84; 8:45 am]

BILLING CODE 4310–05–M

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 100

[CGD3–84–24]

Regatta; 1984 Cape May Classic

AGENCY: Coast Guard, DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: Special Local Regulations are being proposed for the 1984 Cape May Classic Regatta being sponsored by the Hobie Cat Fleet 416 of Center Valley, Pennsylvania to be held on June 23 and 24, 1984 between the hours of 9:00 a.m. and 5:00 p.m. The Coast Guard is considering the issuance of this regulation to provide for the safety of participants and spectators on navigable waters during the event.

DATE: Comments must be received on or before June 21, 1984.

ADDRESSES: Due to the shortened comment period, verbal comments submitted by telephone are encouraged. Written comments should be mailed to Commander (b), Third Coast Guard District, Governors Island, New York, NY 10004. The comments will be available for inspection and copying at the Boating Safety Office, Building 110, Governors Island, New York, NY. Normal office hours are between 8:00 a.m. and 4:30 p.m., Monday through Friday, except holidays. Comments may also be hand-delivered to this address.

FOR FURTHER INFORMATION CONTACT: LTJG D. R. Cilley, (212) 668–7974.

SUPPLEMENTARY INFORMATION: Interested persons are invited to participate in this proposed rulemaking by submitting their views, data, or arguments. Persons submitting written comments should include their names and addresses, identify this notice (CGD3–84–24) and the specific section of the proposal to which their comments apply, and give reasons for each comment. Receipt of comments will be acknowledged if a stamped, self-addressed postcard or envelope is enclosed. The rules may be changed in light of comments received. The comment period for this proposed rulemaking is less than the recommended 45 days because of the time constraints involved. Comments will be accepted up to two days before the event. 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 LTJG D. R. Cilley, Project Officer, Boating Safety Office, and Ms. MaryAnn Arisman, Project Attorney, Third Coast Guard District Legal Office.

Discussion of Proposed Regulations

The 1984 Cape May Classic is a Hobie Cat sailboat racing event to be held off Grant Beach and North Cape May on June 23 and 24, 1984. It is sponsored by the Hobie Cat Fleet 416 and is well known to the boaters and residents of this area. Nearly 180 Hobie Cat sailboats of all sizes are expected to participate in this event. The sponsor is providing in excess of 3 patrol vessels in conjunction with Coast Guard and local resources to patrol this event. In order to provide for the safety of life and property, the Coast Guard will restrict vessel movement in the race course area.

Economic Assessment and Certification

This proposed regulation is considered to be nonsignificant 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 this event will not block access to the coast and it will draw a large number of craft into the area for the duration of the event. This should easily compensate area merchants for the slight inconvenience of having navigation restricted. Based upon this assessment it is certified in accordance with Section 605(b) of the Regulatory Flexibility Act (5 U.S.C. 605(b)) that this regulation 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 100

Marine safety, Navigation (water).

Proposed Regulation

In consideration of the foregoing, the Coast Guard proposes to amend Part 100 of Title 33, Code of Federal Regulations by adding a temporary § 100.35–305 to read as follows:

PART 100—[AMENDED]

§ 100.35–305 1984 Cape May Classic.

(a) *Regulated Area.* New Jersey coastline between Grant Beach and Poverty Beach in Cape May, New Jersey from the shoreline to 3 miles offshore.

(b) *Effective Period.* This proposed regulation will be effective from 9:00 a.m. to 5:00 p.m. on June 23 and 24, 1984.

(c) *Special Local Regulations.* (1) All persons or vessels not registered with the sponsor as participants or not part of the regatta patrol are considered spectators.

(2) No spectator, commercial fishing or press boats may enter or remain in the regulated area unless authorized to be there by the sponsor or Coast Guard patrol personnel. Those vessels wishing to cross the regulated area shall contact the Coast Guard Patrol Commander.

(3) All persons and vessels shall comply with the instructions of U.S. Coast Guard patrol personnel. Upon hearing five or more blasts from a U.S. Coast Guard vessel, the operator of a vessel shall stop immediately and proceed as directed. U.S. Coast Guard patrol personnel include commissioned, warrant and petty officers of the Coast Guard. Members of the Coast Guard Auxiliary may be present to inform vessel operators of this regulation and other applicable laws.

(4) For any violation of this regulation, the following maximum penalties are authorized by law:

(i) $500 for any person in charge of the navigation of a vessel.

(ii) $500 for the owner of a vessel actually on board.

(iii) $250 for any other person.

(iv) Suspension or revocation of a license for a licensed officer.

(46 U.S.C. 454; 33 CFR 100.35 and 33 CFR 1.01–1)

Dated: May 11, 1984.

W. E. Caldwell,

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

[FR Doc. 84–13797 Filed 5–22–84; 8:45 am]

BILLING CODE 4910–14–M

Federal Highway Administration

National Highway Traffic Safety Administration

49 CFR Parts 393 and 571

[BMCS Docket No. MC–110; Notice No. 84–4; NHTSA Docket No. 84–06; Notice No. 1]

Parts and Accessories Necessary for Safe Operation; Federal Motor Vehicle Safety Standards

AGENCY: Federal Highway Administration (FHWA) and National Highway Traffic Safety Administration (NHTSA), DOT.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: Public comment is requested on a potential safety issue which has been raised by the International Brotherhood of Teamesters (IBT) in connection with the vehicle width provision found in the Surface Transportation Assistance Act of 1982. The IBT has petitioned for revising the Federal Motor Carrier Safety Regulations (FMCSR) and the Federal Motor Vehicle Safety Standards by adding a requirement that 102-inch wide trailers be equipped with axle tracks having a minimum axle width of 77 inches. This requirement would provide the trailers with an axle/tire track of 102 inches. All comments will be considered before further action is taken.

DATE: Comments must be submitted on or before August 20, 1984

ADDRESS: All comments should refer to the docket numbers and notice numbers that appear at the top of this document and should be submitted, preferably in quadruplicate, to room 3404, Bureau of Motor Carrier Safety (BMCS), 400 Seventh Street SW., Washington, 50590. The BMCS is responsible for compiling the information received in response to this notice. Written comments should be submitted only to the BMCS.

FOR FURTHER INFORMATION CONTACT: FHWA: Mr. Neill L. Thomas, Bureau of Motor Carrier Safety, (202) 426–9767; Mr. Thomas P. Holian, Office of Chief Counsel, (202) 426–0346, Federal Highway Administration, 400 Seventh Street SW., Washington, D.C. 20590; or NHTSA: Mr. Scott G. Shadle, Office of Vehicle Safety Standards, (202) 426–2720, National Highway Traffic Safety 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.

SUPPLEMENTARY INFORMATION:

Background

On January 6, 1983 the President signed into law the Surface Transportation Assistance Act of 1982 (STAA) (Pub. L. 97–424, 96 Stat. 2097). This Act was amended effective April 6, 1983, by Public Law 98–17 (97 Stat. 59). This Act has made several significant changes to provisions governing a vehicle's width, weight, and overall length. The vehicles affected are those which are used on the Interstate and other qualifying Federal-Aid Primary System highways. For the first time, the length of semitrailers and full trailers used in commercial motor vehicle operations on certain highway systems are addressed by the Federal statute. Vehicle width limitations have been changed and specific weight limits have been mandated to achieve national uniformity. Section 416 of the STAA requires that States allow the operation of 102-inch wide vehicles on the Interstate and other qualifying Federal-Aid Primary Systems highways.

The FHWA published a policy statement in the **Federal Register** on February 3, 1983 (48 FR 5210), requesting public comment on implementing the STAA. The FHWA subsequently received comments which dealt with the safety issue of using 102-inch wide vehicles having an axle/tire track designed for 96-inch wide vehicles.

On September 14, 1983, the FHWA published a Notice of Proposed Rulemaking (NPRM) (FHWA Docket No. 83–14) in the **Federal Register** (48 FR 41276). The FHWA requested public comment on the advantages and/or disadvantages of allowing the operation of 102-inch wide vehicles on axle tracks built for the narrower vehicles. The comments sent to Docket No. 83–14 in response to the issue will be considered in this rulemaking action.

The International Brotherhood of Teamsters (IBT) submitted a petition to the FHWA on November 7, 1983, and to the NHTSA on November 8, 1983. The IBT asked for a regulation requiring new 102-inch wide trailers to have axle/tire tracks which are also 102 inches wide. The axle width would change from 71 inches—71½ inches (found on the standard 96-inch wide trailer) to 77 inches—77½ inches. The IBT is requesting this change to increase the operating stability of the wider trailers.

The petition is based on the IBT's understanding that trailer manufacturers will provide buyers with 102-inch wide trailers built on 96-inch axle/tire tracks, if requested to do so. The petition indicates that these trailers will be used to accomodate intermodal shipments that previously used the 96-inch wide trailer. The IBT, in its petition, states that the trailer manufacturers are prepared to furnish the 102-inch wide trailers built on the narrower track

because the railroads will have a problem loading trailers with the wider axle/tire track on the flatbed rail cars as part of piggyback (trailer-on-flatcar) operations. Accordingly, the 102-inch wide trailers with the 96-inch axle/tire track will be used in both highway and rail transportation. The IBT believes that requiring the new trailers to have the wider axles will increase the safety of these vehicles.

The petition is also based on the formal position of the National Motor Carrier Advisory Committee which states:

> Noting that truck rollover accidents result in great loss of life and property damage each year, and further noting that there may exist a correlation between the increase in axle length and a reduction in truck rolls, the Committee makes the following recommendations:
>
> That the Secretary examine carefully the safety consequences of building and operating a newly-mandated 102-inch wide vehicle on 71½ inch long axle designed for 96-inch wide vehicles, both as to the effects of that use on the handling stability and general safe operation of these vehicles and as to whether an axle length increase commensurate with the increase of permitted vehicle width could result in safer operation.
>
> Upon finding either a degradation of safety resulting from the use of wider vehicle with existing axle lengths or an increase in safety made possible through the use of longer axles, the Secretary should require the axles of increased length commensurate with the increased width be used on newly manufactured trailers operated within the jurisdiction of the Secretary.[1]

Research

A recent study was completed by the University of Michigan on vehicle roll stability.[2] Tractor-semitrailer and tractor-multitrailer configurations were examined through computer simulation. Trailers and semitrailers were examined having the 102-inch width and axle/tire tracks of either 102 or 96 inches. The study estimated the rollover threshold of these vehicles and compared those having the 102-inch axle/tire track with those having the 96-inch axle/tire track The rollover threshold is a measure of a vehicle's susceptibility to rollover. It is a function of, among other things, a vehicle's center of gravity, axle/tire track width, and spring spacing. The vehicle with the higher threshold is less susceptible to rollover than the vehicle with the lower threshold.

The study found that the rollover threshold of the 102-inch wide semitrailer having a 102-inch axle/tire track is greater than the threshold of the same semitrailer having a 96-inch axle/tire track. This relationship was found to hold true for the tractor-multitrailer (doubles) combination also. Both semitrailers and doubles were compared using tractors having an axle/tire track of 96-inches. These vehicles had a gross weight rating of 80,000 pounds.

The study shows that using a 102-inch trailer with the wider track instead of the narrower track provides more vehicle stability. The study estimates that the improved stability will result in a 20-percent reduction in the rollover accident rate. In addition, the study described other factors influencing vehicle stability such as tractor width, cargo type, cargo density, and loading. The FHWA and NHTSA are seeking more information on these factors from commenters engaged in actual trucking operations or having the needed expertise in this particular area of consideration.

Questions

Based on the above information, comments are invited to assist in answering the following questions. Please include any available data and analyses to support your comments.

Question 1: What are the safety benefits and/or detriments to safety that would be derived from requiring 102-inch wide trailers to have axle/tire tracks of 102 inches?

Question 2: Do trailer buyers anticipate future purchases of trailers having a width of 102 inches?

Question 3: If the answer to Question 2 is yes, would these trailers be specified to have axle/tire tracks of 102 inches? Include in the answer the reason for the axle/tire track chosen.

Question 4: What are the increased costs to the manufacturer in producing the 102-inch trailer with the 102-inch axle/tire track?

Question 5: What are the increased costs to the buyer in obtaining the 102-inch trailer with the 102-inch axle/tire track?

Question 6: What are the economic effects of allowing the use of 102-inch wide trailers having 96-inch axle/tire tracks?

Question 7: Will the railroad industry or other transportation-related industries encounter significant problems in using 102-inch wide trailers having 102-inch axle/tire tracks?

Question 8: If the answer to Question 7 is yes, what are the problems and attendant costs to the industry that would be encountered?

Question 9: Have motor carriers encountered any refusal by railroads to provide service to vehicles with wider axle tracks? What relief, if any, should be provided, especially if wider axle tracks are required?

Question 10: If the wider axle tracks are required, what is the expected result of such a regulation to trailer-on flatcar operations?

Question 11: If wider axle/tire tracks are required on trailers, should tractors also be required to have the wider tracks? If so, why?

Question 12: Is there a loading problem for trailer-on-flatcar operations when the tractor and trailer have differing axle widths?

Question 13: How will using a tractor and trailer with differing axle widths affect handling and stability?

The FHWA and the NHTSA have determined that this document contains neither a major rule under Executive Order 12291 nor a significant regulation under the regulatory policies and procedures of the Department of Transportation. A draft regulatory evaluation will be prepared based upon the data received in response to this notice.

Based on the information available to the FHWA and the NHTSA at this time, the action taken in the rulemaking will not have a significant economic impact on a substantial number of small entities.

List of Subjects in 49 CFR Parts 393 and 571

Highways and roads, Highway safety, Imports, Motor carriers, Motor vehicle safety, Rubber and rubber products, Tires.

(49 U.S.C. 3102; 49 CFR 1.48 and 301.60; Secs. 103, 119, Pub. L. 89-563, 80 Stat. 718 (15 U.S.C. 1392, 1407), 49 CFR 1.50)

(Catalog of Federal Domestic Assistance Program Number 20.217, Motor Carrier Safety)

Issued on: May 14, 1984.

Kenneth L. Pierson,

Director, Bureau of Motor Carrier Safety, Federal Highway Administration.

Barry Felrice,

Associate Administrator for Rulemaking, National Highway Traffic Safety Administration.

[FR Doc. 84-13675 Filed 5-21-84; 8:45 am]

BILLING CODE 4910-22-M

[1] Motion passed at the National Motor Carrier Advisory Committee meeting of March 17 and 18, 1983. A copy of the minutes is in the public docket and is available for review.

[2] Ervin, R. D., Nisonger, R. L., MacAdam, C. C., Fancher, P. S.; "Influence of Size and Weight Variables on the Stability and Control Properties of Heavy Trucks," March 1983, University of Michigan Transportation Research Institute. A copy of this report is in the public docket and is available for review.

INTERSTATE COMMERCE COMMISSION

49 CFR Part 1139

[Ex Parte No. MC-82; Sub-1]

Procedures in Motor Carrier Revenue Proceedings; Intercity Bus Industry

AGENCY: Interstate Commerce Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: The National Bus Traffic Association, Inc., petitioned the Commission to amend 49 CFR 1139.20 to permit motor common carriers of passengers to file schedules proposing general increases in fares to be effective on 30 rather than 45-days' notice as presently required by § 1139.20. NBTA states that the proposed reduction in regulatory lag would benefit the financially weak bus industry. The Commission is considering granting the relief sought by petitioner and seeks comments from interested parties.

DATES: Comments are due on June 21, 1984. A reply is due on July 6, 1984.

ADDRESS: An original and, if possible, fifteen copies of comments should be sent to: Ex Parte No. 82 (Sub-1) (Petition to amend 49 CFR 1139.20), Case Control Branch, Office of the Secretary, Interstate Commerce Commission, Washington, D.C. 20423.

A copy of the comments should be sent to petitioner's representative: Charles A. Webb, 606 London House, 1001 Wilson Boulevard, Arlington, VA 22209.

FOR FURTHER INFORMATION CONTACT:

Leonard L. Arnaiz, (202) 275–7831

or

Howell I. Sporn, (202) 275–7691.

SUPPLEMENTARY INFORMATION: Additional information is contained in the Commission's decision. To purchase a copy of the full decision, write to T.S. InfoSystems, Inc., Room 2227, Interstate Commerce Commission, Washington, D.C. 20423, or call 289–4357 (D.C. Metropolitan area) or toll free (800) 424–5403. This action will not have an adverse effect on either the quality of the human environment or the conservation of energy resources.

Regulatory Flexibility Analysis

The Commission certifies that the proposed rule will not, if promulgated, have a significant economic impact on a substantial number of small entities. The rule change, if adopted, would reduce regulatory lag, without affecting the ability of small entities to challenge proposed fare changes.

List of Subjects in 49 CFR Part 1139

Motor carriers.

This notice is issued pursuant to 49 U.S.C. 10321 and 5 U.S.C. 553.

Dated: May 11, 1984.

By the Commission, Chairman Taylor, Vice Chairman Andre, Commissioners Sterrett and Gradison.

James H. Bayne,

Secretary.

[FR Doc. 84-13665 Filed 5-21-84; 8:45 am]

BILLING CODE 7035-01-M

Notices

Federal Register
Vol. 49, No. 100
Tuesday, May 22, 1984

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

Flue-Cured Tobacco Advisory Committee; First Meeting

The Flue-Cured Tobacco Advisory Committee will meet at the offices of the Tobacco Division, Agricultural Marketing Service, United States Department of Agriculture, Flue-Cured Tobacco Cooperative stablilzation Corporation, located at 1306 Annapolis Drive, Raleigh, North Carolina 27605, at 1:00 p.m., on Thursday, June 7, 1984.

The meeting will commence with an orientation of the newly reconstituted membership, distribution of informational materials and an explanation of the responsibilities of Committee members.

Immediately following the orientation session will be the election of officers, review of various regulations and proposed regulations issued under the Tobacco Inspection Act, 7 U.S.C. 511–511q, and discussion of the quantities of tobacco designated to warehouses in each marketing area for the 1984 flue-cured season.

The meeting is open to the public though space and facilities are limited. Public participation will be limited to written statements submitted before or at the meeting unless otherwise requested by the Committee Chairperson. Persons, other than members, who wish to address the Committee at the meeting should contact the Director, Tobacco Division, Agricultural Marketing Service, United States Department of Agriculture, Room 502 Annex Building, Washington, D.C. 20250, (202) 447–2567.

Dated: May 18, 1984.

William T. Mann,

Deputy Administrator, Marketing Program Operations.

[FR Doc. 84–13773 Filed 5–21–84; 8:45 am]

BILLING CODE 3410–02–M

The National Advisory Committee for Tobacco Inspection Services; First Meeting

National Advisory Committee for Tobacco Inspection Services will meet at the offices of the Tobacco Division, Agricultural Marketing Service, United States Department of Agriculture, Flue-Cured Tobacco Cooperative Stabilization Corporation, located at 1306 Annapolis Drive, Raleigh, North Carolina 27605, at 1:00 p.m., on Wednesday, June 6, 1984.

The meeting will commence with an orientation of the newly reconstituted membership, distribution of informational materials and an explanation of the responsibilities of Committee members.

Immediately following the orientation session will be a review of various regulations issued pursuant to the Tobacco Inspection Act (49 Stat. 731; 7 U.S.C. 511 *et seq.*) and discussion of the level of inspection and related services and the fees and charges associated with providing these services.

The meeting is open to the public though space and facilities are limited. Public participation will be limited to written statement submitted before or at the meeting unless otherwise requested by the Committee Chairperson. Persons, other then members, who wish to address the Committee at the meeting should contact the Director, Tobacco Division, Agricultural Marketing Service, United States Department of Agriculture, Room 502 Annex Building, Washington, D.C. 20250, (202) 447–2567.

Dated: May 18, 1984.

William T. Manley,

Deputy Administrator, Marketing Program Operations.

[FR Doc. 84–13772 Filed 5–21–84; 8:45 am]

BILLING CODE 3410–02–M

Food and Nutrition Service

Special Supplemental Food Program for Women, Infants and Children; Poverty Income Guidelines

AGENCY: Food and Nutrition Service, USDA.

ACTION: Notice.

SUMMARY: The Department announces adjusted poverty income guidelines to be used by State agencies in determining the income eligibility of persons applying to participate in the Special Supplemental Food Program for Women, Infants and Children (WIC Program). These poverty income guidelines are to be used in conjunction with the WIC Regulations, 7 CFR Part 246.

EFFECTIVE DATE: July 1, 1984.

FOR FURTHER INFORMATION CONTACT: Barbara Hallman, Branch Chief, Policy and Program Development Branch, Supplemental Food Programs Division, FNS, USDA, Park Office Center, Alexandria, Virginia 22302, (703) 756–3730.

SUPPLEMENTARY INFORMATION: This final action has been reviewed under Executive Order 12291, and has been determined to be nonmajor. The final action will not have an annual effect on the economy of $100 million or more, will not cause a major increase in costs or prices, and will not have a significant economic impact on competition, employment, investment, productivity, innovation or on the ability to compete with foreign-based enterprises in domestic or export markets. The final action has been reviewed in accordance with the requirements of Pub. L. 96–354, the Regulatory Flexibility Act, and the Administrator of the Food and Nutrition Service has certified that the action will not have a significant impact on a substantial number of small entities.

Section 17 of the Child Nutrition Act of 1966 (42 U.S.C. 1786) requires the Secretary to establish income criteria to be used with nutritional risk criteria in determining a person's eligibility for participation in the WIC Program. The law provides that persons will be eligible for the WIC Program only if they are members of families that satisfy the income standard prescribed for reduced-price school meals under Section 9 of the National School Lunch Act (42 U.S.C. 1758). Under Section 9, the

income limit for reduced-price school meals is 185 percent of the Office of Management and Budget (OMB) poverty income guidelines, as adjusted. No standard deduction or hardship deductions are allowed when calculating a family's income using 185 percent of the poverty income guidelines.

Section 9 also requires that these guidelines are revised annually for changes in the Consumer Price Index. The annual revision for 1984 was published by the Department of Health and Human Services (DHHS) in the **Federal Register** for February 27, 1984, at 49 FR 7151. Since the guidelines originated in OMB but are updated and issued by DHHS, references linking them exclusively to one organization or the other could lead to misunderstanding. Therefore, the guidelines will be referred to hereafter simply as the Federal poverty income guidelines.

The Department published a final rule on September 25, 1981, at 46 FR 47422 implementing the provisions of Pub. L. 95–627 and 97–35, which requires State agencies to set an income limit on eligibility to participate in the WIC Program. The rule specifies that State agencies may prescribe income guidelines not less than the State or local guidelines for free or reduced-price health care. However, in conforming WIC income guidelines to State or local health care guidelines, the State cannot establish WIC guidelines which exceed the guidelines established under Section 9 of the National School Lunch Act for reduced-price school meals or are less than 100 percent of the Federal poverty income guidelines.

Consistent with the method used to compute eligibility guidelines for reduced-price meals under the National School Lunch Program, the Federal poverty income guidelines were multiplied by 1.85 and the results rounded upward to the next whole dollar.

At this time the Department is publishing the maximum and minimum WIC poverty income limits by household size for the period July 1, 1984, to June 30, 1985. The first table of this notice contains the income limits by household size for the 48 contiguous States, the District of Columbia and all Territories, including Guam. Because the poverty income guidelines for Alaska and Hawaii are higher than for the 48 contiguous States, separate tables have been included for the convenience of the State agencies.

EFFECTIVE JULY 1, 1984–JUNE 30, 1985

Family size	Federal poverty income guidelines (100 pct) annual	FNS income guidelines for reduced-price lunches (185 pct) annual
48 States, District of Columbia, Puerto Rico, Virgin Islands, and Territories, including Guam:		
1	$4,980	$9,213
2	6,720	12,432
3	8,460	15,651
4	10,200	18,870
5	11,940	22,089
6	13,680	25,308
7	15,420	28,527
8	17,160	31,746
For each additional family member add	1,740	3,219
Alaska:		
1	6,240	11,544
2	8,410	15,559
3	10,580	19,573
4	12,750	23,588
5	14,920	27,602
6	17,090	31,617
7	19,260	35,631
8	21,430	39,646
For each additional family member add	2,170	4,015
Hawaii:		
1	5,730	10,601
2	7,730	14,301
3	9,730	18,001
4	11,730	21,701
5	13,730	25,401
6	15,730	29,101
7	17,730	32,801
8	19,730	36,501
For each additional family member add	2,000	3,700

This notice does not contain reporting or recordkeeping requirements subject to approval by OMB under the Paperwork Reduction Act of 1980 (44 U.S.C. 3587).

(Sec. 3, Pub. L. 95–627, 92 Stat. 3611 (42 U.S.C. 1786))

Dated: May 14, 1984.

Robert E. Leard,

Administrator, Food and Nutrition Service.

[FR Doc. 84–13645 Filed 5–21–84; 8:45 am]

BILLING CODE 3410–30–M

Forest Service

Transfer of Certain Lands; Correction

AGENCY: Forest Service, USDA.

ACTION: Transfer of certain lands; correction.

SUMMARY: This document corrects omissions in the legal description of certain lands transferred from the Superior National Forest, Forest Service, United States Department of Agriculture, to the Voyageurs National Park, United States Department of the Interior, as appeared at page 54211 in the **Federal Register** of Wednesday, October 1, 1975 (FR Document 75–26173).

FOR FURTHER INFORMATION CONTACT: Russell Dahl, Lands Staff, Forest Service, (703) 235–8212.

SUPPLEMENTARY INFORMATION: Accordingly, the Forest Service, USDA, corrects published legal descriptions by addition of the following:

(1) T. 68 N., R. 16 W., Sec. 31 lot 2.

(2) T. 68 N., R. 17 W., Sec. 10, unsurveyed island.

(3) T. 68 N., R. 18 W., Sec. 13 lot 2.

(4) The total aggregate acreage transferred to the National Park Service is 25,333.23 acres.

Dated: May 15, 1984.

R. Max Peterson,

Chief, Forest Service.

[FR Doc. 84–13728 Filed 5–21–84; 8:45 am]

BILLING CODE 3410–11–M

CIVIL AERONAUTICS BOARD

[Docket 42187]

Flight International Airlines Fitness Investigations; Assignment of Proceeding

This proceeding has been assigned to Administrative Law Judge William A. Kane, Jr. Future communications should be addressed to him.

Dated Washington, D.C., May 15, 1984.

Elias C. Rodriguez,

Chief Administrative Law Judge.

[FR Doc. 84–13078 Filed 5–21–84; 8:45 am]

BILLING CODE 6320–01–M

[Docket 42117]

Lusair International, Inc. Fitness Investigation; Hearing

Notice is hereby given that a hearing in the above-entitled matter is assigned to be held on May 30, 1984, at 10:00 a.m. (local time) in Room 1027, 1825 Connecticut Avenue, NW., Washington, D.C., before the undersigned administrative law judge.

Dated at Washington, D.C., May 16, 1984.

Ronnie A. Yoder,

Administrative Law Judge.

[FR Doc. 84–13706 Filed 5–2–84; 8:45 am]

BILLING CODE 6320–01–M

[Docket 42319]

Pride Air Fitness Investigation; Assignment of Proceeding

This proceeding has been assigned to Chief Administrative Law Judge Elias C. Rodriguez. Future communications should be addressed to him.

Dated Washington, D.C., May 15, 1984.
Elias C. Rodriguez,
Chief Administrative Law Judge.
[FR Doc. 84-13707 Filed 5-21-84; 8:45 am]
BILLING CODE 6320-01-M

Applications for Certificates of Public Convenience and Necessity and Foreign Air Carrier Permits Filed Under Subpart Q of the Board's Procedural Regulations (See, 14 CFR 302.1701 et seq.); Week Ended May 11, 1984

The due date for answers, conforming application, or motions to modify scope are set forth below for each application. Following the answer period the Board may process the application by expedited procedures. Such procedures may consist of the adoption of a show-cause order, a tentative order, or in appropriate cases a final order without further proceedings.

SUBPART Q APPLICATIONS

Date filed	Docket No.	Description
May 7, 1984	42183	Pan American World Airways, Inc., c/o David M. O'Connor, 1660 L Street NW.—Suite 901, Washington, D.C. 20036. Application of Pan American World Airways, Inc. pursuant to Section 401 of the Act and Subpart Q of the Board's Procedural Regulations requests renewal of its certificate of public convenience and necessity for Route 246 which enables Pan Am to engage in foreign air transportation of persons, property and mail— "Between the coterminal points Los Angeles, California; New York, New York; San Francisco, California; and Honolulu, Hawaii; the intermediate point Tokyo or another intermediate point in Japan; and the coterminal points Beijing and Shanghai, the People's Republic of China." Conforming Applications, Motions to Modify Scope and Answers may be filed by June 4, 1984.
Do	42185	Airpass Airlines, Inc., c/o Robert E. Cohn, Butler & Binion, 1747 Pennsylvania Avenue NW., Suite 900, Washington, D.C. 20006. Application of Airpass Airlines, Inc. pursuant to Section 401 of the Act and Subpart Q of the Board's Procedural Regulations requests issuance of a certificate of public convenience and necessity which would authorize it to engage in the interstate and overseas scheduled air transportation of passengers, property and mail between all points in the United States, its territories and possessions. Conforming Applications, Motions to Modify Scope and Answers may be filed by June 4, 1984.
May 10, 1984	42194	Air Via, Inc., c/o John W. Simpson, Kelley Drye & Warren, 1333 New Hampshire Avenue NW., Washington, D.C. 20036. Application of Air Via, Inc. pursuant to Section 401 of the Act and Subpart Q of the Board's Procedural Regulations applies for a certificate of public convenience and necessity to provide scheduled domestic and overseas air transportation of persons, property and mail. Conforming Applications, Motions to Modify Scope and Answers may be filed by June 7, 1984.
May 11, 1984	42197	Air Ontario Limited, c/o Elisabeth M. Pendleton, Shaw, Pittman, Potts & Trowbridge, 1800 M Street NW., Washington, D.C. 20036. Application of Air Ontario Limited pursuant to Section 402 of the Act and Subpart Q of the Board's Procedural Regulations to authorize it to engage in foreign scheduled air transportation of persons, property and mail between Hartford, Connecticut/Springfield, Massachusetts and Toronto, Ontario. Answers may be filed by June 8, 1984.
May 9, 1984	41713	Belize Air International Limited, c/o Mark Pestronk, Kaswell, Perazich & Watson, 1825 K Street NW., Suite 720, Washington, D.C. 20006. Amendment No. 1 to the Application of Belize Air International Limited to enable it to engage in foreign air transportation of property on a scheduled and charter basis as follows: Between the terminal points Antigua, Dominica, St. Christopher (St. Kitts)—Nevis—Anguilla, St. Lucia, St. Vincent, Belize, British Virgin Islands, Cayman Islands, Montserrat, Turks and Caicos Islands; via the intermediate points Bahamas, Barbados, Cuba, Dominican Republic, Grenada, Guadeloupe, Guyana, Haiti, Jamaica, Martinique, St. Maarten, St. Martin, and Trinidad and Tobago; and the terminal points Baltimore, Houston, Miami, New Orleans, Puerto Rico, Tampa, U.S. Virgin Islands, and Washington, D.C.
Do	42041	Horizon Air Industries, Inc. d/b/a Horizon Air and Horizon Airlines, c/o Stephen A. Alterman, 1050 Seventeenth Street NW., Twelfth Floor, Washington, D.C. 20036. Supplemental Exhibits of Horizon Air Industries, Inc. Answers may be filed by June 6, 1984.

Phyllis T. Kaylor,
Secretary.
[FR Doc. 84-13709 Filed 5-21-84; 8:45 am]
BILLING CODE 6320-01-M

DEPARTMENT OF COMMERCE

Bureau of the Census

Number of Employees, Payrolls, Geographic Location, Current Status, and Kind of Business for the Establishments of Multiestablishment Companies; Consideration of Surveys

Notice is hereby given that the Bureau of the Census proposes to conduct a Company Organization Survey for 1984 under the provisions of Title 13, United States Code, Sections 182, 224, and 225. This survey, which has been conducted for many years, is designed to collect information on the number of employees, payrolls, geographic location, current status, and kind of business for the establishments of multiestablishment companies. The information will be used to make company and establishment changes to the data for multiestablishment companies in the Standard Statistical Establishment List. The data will have significant application to the needs of the public and to governmental agencies and are not publicly available from nongovernmental or governmental sources.

The survey, if conducted, shall begin not earlier than December 1, 1984.

Copies of the proposed forms are available on request to the Director, Bureau of the Census, Washington, D.C. 20233.

Any suggestions or recommendations concerning the subject of the proposed survey submitted to the Director in writing within 60 days after the date of this publication will receive consideration.

Dated: May 17, 1984.
John G. Keane,
Director, Bureau of the Census.
[FR Doc. 84-13725 Filed 5-21-84; 8:45 am]
BILLING CODE 3510-07-M

International Trade Administration

[A-428-018]

Carbon Steel Plate From the Federal Republic of Germany; Re-Initiation of Antidumping Duty Investigation

AGENCY: International Trade Administration, Commerce.

ACTION: Notice.

SUMMARY: On the basis of a decision by the Court of International Trade reversing and remanding an earlier rescission of notice of initiation, we are re-initiating an antidumping investigation to determine whether

carbon steel plate from the Federal Republic of Germany (FRG) is being, or is likely to be, sold in the United States at less than fair value. We are notifying the United States International Trade Commission (ITC) of this action so that it may determine whether imports of this product are materially injuring, or are threatening to materially injure, a regional United States industry. If this investigation proceeds normally, we will make our preliminary determination on or before October 1, 1984.

EFFECTIVE DATE: May 22, 1984.

FOR FURTHER INFORMATION CONTACT: Charles E. Wilson, Office of Investigations, Import Administration, International Trade Administration, United States Department of Commerce, 14th Street and Constitution Avenue NW., Washington, D.C. 20230; telephone (202) 377–5288.

SUPPLEMENTARY INFORMATION:

The Petition

On September 29, 1983, we received a petition from counsel for Gilmore Steel Corporation (Gilmore) on behalf of both the national and west coast carbon steel plate products industries. Notice of our initiation of an investigation was published on October 25, 1983 (48 FR 49322).

On November 7, 1983, the ITC determined there was a reasonable indication of injury to a national industry (US ITC Pub. No. 1451 (Nov. 1983)), making no determination as to the alleged regional industry. Subsequently, we published a rescission of our notice of initiation of investigation and dismissal of petition (49 FR 3503, January 27, 1984) on grounds that Gilmore had not properly filed on behalf of a national industry. Gilmore contested this action by filing suit in the Court of International Trade. The court upheld our rescission and dismissal insofar as the petition purported to be on behalf of a national industry, but reversed our action insofar as the petition was on behalf of an alleged regional industry and remanded this matter to us for further proceedings (*Gilmore Steel Corporation* v. *United States*, Court No. 84–2–00228, slip op. 84–45, April 23, 1984). Accordingly, we are re-initiating an antidumping investigation of carbon steel plate from the FRG.

In compliance with the filing requirements of § 353.36 of the Commerce Regulations (19 CFR 353.36), the original petition alleges that imports of the subject merchandise from the FRG are being, or are likely to be, sold in the United States at less than fair value within the meaning of section 731 of the Tariff Act of 1930, as amended (19 U.S.C. 1673 (the Act), and that these imports are materially injuring a regional United States industry. The allegation of sales at less than fair value is supported by comparisons of the lowest guidance prices under the Davignon Plan, which is used by European Economic Community countries to regulate internal sales prices of this merchandise, with the 1983 average FRG port value of carbon steel plate imported into the United States (as provided by U.S. Department of Commerce statistics).

Petitioner also alleges that this merchandise is being sold in the FRG home market at prices which are less than the cost of production.

Initiation of Investigation

We are initiating an antidumping investigation to determine whether carbon steel plate from the FRG is being, or is likely to be, sold at less than fair value in the United States. If our investigation proceeds, normally, we will make our preliminary determination by October 1, 1984.

Scope of Investigations

The merchandise covered by this investigation is hot-rolled carbon steel plate. The term "hot-rolled carbon steel plate" covers flat-rolled carbon steel products, whether or not corrugated or crimped, not pickled, not cold-rolled, not in coils, not cut, not pressed, and not stamped to non-rectangular shape, not coated or plated with metal and not clad, 0.1875 inch or more in thickness and over 8 inches in width, as currently provided for in items 607.6620 and 607.6625 of the *Tariff Schedules of the United States Annotated* (TSUSA).

Semifinished products of solid rectangular cross sections with a width at least four times the thickness and processed only through primary mill hot-rolling are not included. Carbon steel plate is used in the construction of bridges, mining equipment, pressure vessels, railroad freight and passenger cars, ships, line pipe, industrial machinery, machine parts, and a large variety of other products.

Notification to ITC

Section 732(d) of the Act requires us to notify the ITC and make available to it all nonprivileged and nonconfidential information. We will also allow the ITC access to all privileged and confidential information in our files, provided it confirms that it will not disclose such information either publicly or under an administrative protective order without the consent of the Deputy Assistant Secretary for Import Administration.

Preliminary Determinations by ITC

The ITC will determine whether there is a reasonable indication that imports of carbon steel plate from the FRG are materially injuring, or are likely to materially injure, a regional United States industry. If its determination is negative, this investigation will terminate; otherwise, it will proceed according to the statutory procedures.

Dated: May 16, 1984.

Alan F. Holmer,

Deputy Assistant Secretary for Import Administration.

[FR Doc. 84–13731 Filed 5–21–84; 8:45 am]

BILLING CODE 3510–DS–M

Minority Business Development Agency

Financial Assistance Application Announcement

The Minority Business Development Agency (MBDA) announces that it is soliciting applications under its Minority Business Development Center Program to operate a Center for a period of 10 months beginning September 1, 1984, in the Richmond/Virginia SMSA. Federal funds are estimated at $132,460. The project number is 03–10–84010–01. Catalog of Federal Domestic Assistance—11.800 Minority Business Development.

This announcement extends the closing date from May 31 to June 15; increases the period of performance to ten months beginning September 1; increases the total project costs to $155,830; federal share to $132,460; and the non-federal share to $23,370. The application number is 03–10–84010–01. An application kit is available on written request.

Stanley W. Tate,

Regional Director.

[FR Doc. 84–13651 Filed 5–21–84; 8:45 am]

BILLING CODE 3510–21–M

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

Requesting Public Comment on Bilateral Textile Consultations With the Government of Hong Kong To Review Trade in Categories 337 and 649

May 17, 1984.

On May 15, 1984 the Government of the United States requested consultations with the Government of Hong Kong with respect to Category 337 (cotton playsuits) and Category 649 (man-made fiber brassieres). This

request was made on the basis of the agreement of June 23, 1982, as amended, between the Government of the United States and Hong Kong relating to trade in cotton, wool and man-made fiber textiles and textile products.

The purpose of this notice is to advise the public that, if no solution is agreed upon in consultations between the two governments, the Committee for the Implementation of Textile Agreements may later establish limits for the entry and withdrawal from warehouse for consumption of textile products in Categories 337 and 649, produced or manufactured in Hong Kong and exported to the Untied States during the twelve-month period which began on January 1, 1984 and extends through December 31, 1984. The Government of the United States also reserves the right to control imports of this category at the established limits.

Anyone wishing to comment or provide data or information regarding the treatment of Categories 337 and 649 under the bilateral agreement, or on any other aspect thereof, or to comment on domestic production or availability of textile products included in these categories, is invited to submit such comments or information in ten copies to Mr. Walter C. Lenahan, Chairman, Committee for the Implementation of Textile Agreements, International Trade Administration, U.S. Department of Commerce, Washington, D.C. 20230. Because the exact timing of the consultations is not yet certain, comments should be submitted promptly. Comments or information submitted in response to this notice will be available for public inspection in the Office of Textiles and Apparel, Room 3100, U.S. Department of Commerce, 14th and Constitution Avenue NW., Washington, D.C., and may be obtained upon written request.

Further comment may be invited regarding particular comments or information received from the public which the Committee for the Implementation of Textile Agreements considers appropriate for further consideration.

The solicitation of comments regarding any aspect of the agreement or the implementation thereof is not a waiver in any respect of the exemption contained in 5 U.S.C. 553(a)(1) relating to matters which constitute "a foreign affairs function of the United States."

Ronald I. Levin,

Acting Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 84-13733 Filed 5-21-84; 8:45 am]

BILLING CODE 3510-DR-M

Requesting Public Comment on Bilateral Textile Consultations With Korea To Review Trade in Category 614

May 17, 1984.

On May 14, 1984, the Government of the United States requested consultations with the Government of the Republic of Korea with respect to Category 614 (woven fabrics, n.e.s.). This request was made on the basis of the agreement of December 1, 1982, as amended, between the Governments of the United States and the Republic of Korea relating to trade in cotton, wool and man-made fiber textiles and textile products.

The purpose of this notice is to advise the public that if no solution is agreed upon in consultations with Korea, the Committee for the Implementation of Textile Agreements may later establish a limit for the entry and withdrawal from warehouse for consumption of textile products in Category 614, produced or manufactured in Korea and exported to the United States during the twelve-month period which began on January 1, 1984 and extends through December 31, 1984.

Anyone wishing to comment or provide data or information regarding the treatment of Category 614 from Korea under the Bilateral Cotton, Wool and Man-Made Fiber Textile Agreement, or on any other aspect thereof, or to comment on domestic production or availability of textile products included in this category, is invited to submit such comments or information in ten copies to Mr. Walter C. Lenahan, Chairman, Committee for the Implementation of Textile Agreements, International Trade Administration, U.S. Department of Commerce, Washington, D.C. 20230. Because the exact timing of the consultations is not yet certain, comments should be submitted promptly. Comments or information submitted in response to this notice will be available for public inspection in the Office of Textiles and Apparel, Room 3100, U.S. Department of Commerce, 14th and Constitution Avenue NW., Washington, D.C., and may be obtained upon written request.

Further comment may be invited regarding particular comments or information received from the public which the Committee for the Implementation of Textile Agreements considers appropriate for further consideration.

The solicitation of comments regarding any aspect of the agreement or the implementation thereof is not a waiver in any respect of the exemption contained in 5 U.S.C. 553(a)(1) relating to matters which constitute "a foreign affairs function of the United States."

Ronald I. Levin,

Acting Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 84-13732 Filed 5-21-84; 8:45 am]

BILLING CODE 3510-DR-M

COMMODITY FUTURES TRADING COMMISSION

Chicago Board of Trade Long-Term Municipal Bond Index Futures Contract

AGENCY: Commodity Futures Trading Commission.

ACTION: Request for public comment on amended terms and conditions of proposed commodity futures contract.

SUMMARY: On February 7, 1984 the Commodity Futures Trading Commission ("Commission") in accordance with sections 2(a)(1)(B)(iii) and 2(a)(1)(B)(iv)(II) of the Commodity Exchange Act, 7 U.S.C. 2a(iii), 2a(iv)(II)(1983), published in the **Federal Register** a notice of availability of the contract terms and conditions contained in an application by the Chicago Board of Trade ("CBT") for designation as a contract market in a long-term municipal bond index. 49 FR 4543. The notice provided for a sixty-day comment period which ended on April 9, 1984. Subsequently, the CBT notified the Commission that it intended to propose several changes to the terms of the contract. The CBT requested that the Commission give notice of, and seek public comment on, these changes. In light of the nature of the intended contract modifications, the significance of the issues which they raise, and the interest in the contract previously expressed by the public, the Commission has concluded that, in this instance, an additional period for public comment is warranted.

DATE: Comments must be received on or before June 6, 1984.

ADDRESS: Interested persons should submit their views and comments to Jane K. Stuckey, Secretary, Commodity Futures Trading Commission, 2033 K Street NW., Washington, D.C. 20581. Reference should be made to the CBT long-term municipal bond index futures contract.

FOR FURTHER INFORMATION CONTACT: Ronald Hobson, Division of Economic Analysis, Commodity Futures Trading Commission, 2033 K Street NW., Washington, D.C. 20581, (202) 254-6990.

SUPPLEMENTARY INFORMATION: By letter dated May 15th, 1984, the CBT notified the Commission of its intent to propose modifications to its application for designation as a contract market in a long-term municipal bond index. The Commission previously published in the **Federal Register** a notice of availability of the contract terms and conditions of the proposed contract and provided a sixty-day comment period which ended on April 9, 1984. 49 FR 4543 (February 7, 1984). The CBT requested, "that the contemplated changes be published * * * for public comment * * * so that we can take into account public comment * * * in finalizing these changes." Moreover, the intended contract modifications amend features of the contract which have been the subject of significant interest to members of the public during the prior comment period. For these reasons, the Commission is of the opinion that an additional comment period to enable the public to consider the intended modifications and to express their views on them is in the public interest and is consistent with the objectives of the Commodity Exchange Act.

The contemplated changes in the design of the proposed long-term municipal bond index contract are as follows:

1. That the index consist of 50 rather than 75 bonds;

2. That no more than two rather than four issues of bonds by a single issuer be included in the index at any time;

3. That at least four rather than three municipal bond dealer-to-dealer brokers supply price information for the bonds in the index, with at least one additional broker added and a "best efforts" attempt made to add another for a total of six brokers pricing the index;

4. That housing bonds with prices equal to or greater than 102 for two consecutive days immediately preceding the date on which index composition is changed by dropped from the index first, rather than the oldest bond;

5. That following the date of the index composition change during the delivery month, i.e., on the 16th of the delivery month, and thereafter until the contract expires, the CBT will ask the brokers to supply two price quotes for each of the bonds in the index (thus, the Bond Buyer would publish the Index at about 12:00 p.m. and 3:15 p.m. Eastern Time); and

6. That the CBT will consider adopting a provision that permits the oldest bond in the index to remain if it is actively trading.

The Commission is requesting comment on the potential effects of these changes to the design of the contract. The Commission would appreciate commenters addressing, in particular, the possible effects of increased exchange discretion in the method of selecting older bonds to be retained in the index. Specifically, commenters should address whether such discretion creates undesirable uncertainty with respect to the composition of the index at any one time, and whether the other intended changes, such as a lower overall number of bonds in the index, which would include the most actively traded bonds, alleviates the need for such discretion. If such discretion is necessary, or desirable, commenters should address how that discretion is best exercised and what guidelines for its exercise are appropriate.

A copy of the CBT's letter of May 15, 1984, the terms and conditions of its proposed long-term municipal bond index futures contract, and copies of responses filed to the initial request for comments are available for inspection at the Office of the Secretariat, Commodity Futures Trading Commission, 2033 K Street NW., Washington, D.C. 20581. Copies of these documents can be obtained through the Office of the Secretariat by mail at the above address or by phone at (202)254–6314.

Any person interested in submitting written data, views or arguments on the above identified issues should send such comments to Jane K. Stuckey, Secretary, Commodity Futures Trading Commission, 2033 K Street NW., Washington, D.C. 20581, by the specified date. Such comment letters will be publicly available except to the extent that they are entitled to confidential treatment as set forth in 17 CFR 145.5 and 145.9.

Issued in Washington, D.C., on May 17, 1984.

Jane K. Stuckey,

Secretary of the Commission.

[FR Doc. 84–13704 Filed 5–21–84; 8:45 am]

BILLING CODE 6351–01–M

DEPARTMENT OF DEFENSE

Department of the Air Force

USAF Scientific Advisory Board; Meeting

The USAF Scientific Advisory Board Ad Hoc Committee of the Strategic Reconnaissance Technologies meeting scheduled for May 31, 1984 published in the **Federal Register**, Vol. 49, No. 77, pg 15599, Thursday, April 19, 1984 has been cancelled.

For further information contact the Scientific Advisory Board Secretariat at (202) 697–8845.

Winnibel F. Holmes,

Air Force Federal Register, Liaison Officer.

[FR Doc. 84–13671 Filed 5–21–84; 8:45 am]

BILLING CODE 3910–01–M

USAF Scientific Advisory Board; Meeting

May 17, 1984.

The USAF Scientific Advisory Board Ad Hoc Committee on the Effects of High Altitude Electromagnetic Pulse on Military Command, Control, and Communications in the Pentagon, Washington, D.C. on June 7, 1984.

The purpose of the meeting is to consolidate written inputs into a final report. The meeting will convene from 8:30 a.m. to 5:00 p.m.

The meeting concerns matters listed in section 552b(c) of Title 5, United States Code, specifically subparagraph (1) thereof, and accordingly, will be closed to the public.

For further information, contact the Scientific Advisory Board Secretariat at 202–697–8845.

Winnibel F. Holmes,

Air Force Federal Register Liaison Officer.

[FR Doc. 84–13568 Filed 5–21–84; 8:45 am]

BILLING CODE 3910–01–M

DEPARTMENT OF ENERGY

Economic Regulatory Administration

[Docket No. ERA–FC–84–007; OFP Case No. 61048–9245–20–24]

Powerplant and Industrial Fuel Use; Calcogen, Inc.; Order Granting Exemption

AGENCY: Economic Regulatory Administration, DOE.

ACTION: Order granting to Calcogen, Inc. exemption from the Prohibitions of the Powerplant and Industrial Fuel Use Act of 1978.

SUMMARY: The Economic Regulatory Administration (ERA) of the Department of Energy (DOE) hereby gives notice that it has granted a permanent cogeneration exemption from the prohibitions of Title II of the Powerplant and Industrial Fuel Use Act of 1978, 42 U.S.C. 8301 *et seq.* ("FUA" or "the Act") to Calcogen, Inc. (Calcogen or "the petitioner"). The permanent cogeneration exemption permits the use of natural gas as the primary energy source for a 27 MW (net, approximate)

combined cycle cogeneration facility designed to produce electricity and process steam at the Metropolitan State Hospital, Norwalk, California. The final exemption order and detailed information on the proceeding are provided in the **SUPPLEMENTARY INFORMATION** section, below.

DATES: The order shall take effect on July 20, 1984. The public file containing a copy of the order, other documents, and supporting materials on this proceeding is available upon request through DOE, Freedom of Information Reading Room, 1000 Independence Avenue, SW., Room 1E–190, Washington, D.C. 20585, Monday through Friday, 8:00 a.m. to 4:00 p.m., except Federal holidays.

FOR FURTHER INFORMATION CONTACT:
George C. Blackmore, Office of Fuels Programs, Economic Regulatory Administration, 1000 Independence Avenue, SW., Room GA–073L, Washington, D.C. 20585, Phone (202) 252–1774;
Marya Rowan, Office of the General Counsel, Department of Energy, Forrestal Building, Room 6A–141, 1000 Independence Avenue, SW., Washington, D.C. 20585, Phone (202) 252–6739.

SUPPLEMENTARY INFORMATION: On February 28, 1984, Calcogen petitioned ERA under section 212(c) of FUA and 10 CFR 503.37 for a permanent cogeneration exemption to permit the use of natural gas in a 27 MW (net, approximate) combined cycle cogeneration facility consisting of a gas turbine generator, waste heat recovery steam generator, and a steam extraction turbine generator. As all of the net annual generation of electric power from the unit will be sold to the Southern California Edison Company, the unit is, by definition, an electric powerplant under 10 CFR 500.2. The facility will produce approximately 12,625 pounds of steam per hour which will supply Metropolitan State Hospital's needs.

Basis for Permanent Exemption Order

The permanent exemption order is based upon evidence in the record including Calcogen's certification to ERA, in accordance with 10 CFR 503.37(a)(1), that:

1. The oil or natural gas to be consumed by the cogeneration facility will be less than that which would otherwise be consumed in the absence of such cogeneration facility, in accordance with 10 CFR 503.37(a)(1)(i); and

2. The use of a mixture of natural gas and coal or oil and coal in the cogeneration facility, will not be technically feasible, in accordance with 10 CFR 503.37(a)(1)(ii).

Procedural Requirements

In accordance with the procedural requirements of section 701(c) of FUA and 10 CFR 501.3(b), ERA published its Notice of Acceptance of Petition and Availability of Certification in the **Federal Register** on March 29, 1984 (49 FR 12302), commencing a 45-day public comment period.

A copy of the petition was provided to the Environmental Protection Agency for comments as required by section 701(f) of the Act. During the comment period, interested persons were afforded an opportunity to request a public hearing. The comment period closed on May 14, 1984; no comments were received and no hearing was requested.

NEPA Compliance

After review of the petitioner's environmental impact analysis, together with other relevant information, ERA has determined that the granting of the requested exemption does not constitute a major Federal action significantly affecting the quality of the human environment within the meaning of section 102(2)(C) of the National Environmental Policy Act (NEPA).

Order Granting Permanent Cogeneration Exemption

Based upon the entire record of this proceeding, RA has determined that Calcogen has satisfied the eligibility requirements for the requested permanent cogeneration exemption, as set forth in 10 CFR 503.37. Therefore, pursuant to section 212(c) of FUA, ERA hereby grants a permanent cogeneration exemption to Calcogen to permit the use of natural gas as the primary energy source for its cogeneration facility at the Metropolitan State Hospital, Norwalk, California.

Pursuant to section 702(c) of the Act and 10 CFR 501.69, any person aggrieved by this order may petition for judicial review thereof at any time before the 60th day following the publication of this order in the **Federal Register.**

Issued in Washington, D.C., on May 16, 1984.

Robert L. Davies,

Director, Coal & Electricity Division, Office of Fuels Programs, Economic Regulatory Administration.

[FR Doc. 84–13664 Filed 5–21–84; 8:45 am]

BILLING CODE 6450–01–M

Federal Energy Regulatory Commission

Columbia Gas Transmission Corp.; Request Under Blanket Authorization

[Docket No. CP84–375–000]

May 17, 1984.

Take notice that on April 30, 1984, Columbia Gas Transmission Corporation (Columbia), 1700 MacCorkle Avenue, S.E., Charleston, West Virginia 25314, filed in Docket No. CP84–375–000 a request pursuant to Section 157.205 of the Regulations under the Natural Gas Act (18 CFR 157.205) that Columbia proposes to construct and operate new delivery points and appurtenant facilities under the blanket authorization issued in Docket No. CP83–76–000, pursuant to section 7 of the Natural Gas Act, all as more fully set forth in the request on file with the Commission and open to public inspectionn.

Columbia proposes to provide six additional delivery points to three existing wholesale customers as summarized below.

Distributor	Delivery point (county, state)	End User	Usage (Mcf)	
			Daily	Annual
Columbia Gas of Ohio, Inc.	Athens, Ohio	Not Specified	70.0	6150
Do	Lorain, Ohio	Joseph Chilcher	1.5	150
Columbia Gas of Pennsylvania, Inc.	Clarion, PA	Stanley Vangorder	1.5	150
Columbia Gas of West Virginia, Inc.	Upshur, WV	James D.Bosley	1.5	150
Do	Wyoming, WV	Shirley Davis	1.5	150
Do	Kanawha, WV	Herbert A. Grose	1.5	150

The volumes shown are estimated to be the maximum, quantities of gas to be used. In each instance, the end use is stated to be residential. The volumes are within Columbia's currently authorized level of sales and such volumes would not affect the peak day and annual deliveries to Columbia's existing customers, it is asserted. The gas sales would be subject to Columbia's CDS (contract demand service) rate schedule which is on file with the Commission.

Any person or the Commission's staff may, within 45 days after issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention and pursuant to § 157.205 of the Regulations under the Natural

Gas Act (18 CFR 157.205) a protest to the request. If no protest is filed within the time allowed therefor, the proposed activity shall be deemed to be authorized effective the day after the time allowed for filing a protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for authorization pursuant to section 7 of the Natural Gas Act.

Kenneth F. Plumb,

Secretary.

[FR Doc. 84-13711 Filed 5-21-84; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. ER84-426-000]

Connecticut Light & Power Co.; Filing

May 17, 1984

The filing Company submits the following:

Take notice that on May 7, 1984, Connecticut Light and Power Company (CL&P) tendered for filing a proposed rate schedule with respect to a Transmission Agreement dated November 12, 1983 between (1) CL&P and Western Massachusetts Electric Company (WMECO and together with CL&P, the NU Companies) and (2) Westfield Gas and Electric Department (WG&E).

CL&P states that the Transmission Agreement provides for transmission services to WG&E for the wheeling of entitlements in units owned by Hudson Light and Power Department, Ipswich Municipal Electric Department, and Shrewsbury Municipal Light Plant during the period from November 12, 1983 to October 31, 1984.

CL&P further states that the transmission charge rate is a weekly equal to one-fifty-second of the estimated annual cost of transmission service on the electric transmission system of the NU Companies determined in accordance with Appendix A and Exhibits I, II and III thereto, of the Transmission Agreement. The weekly transmission charge is determined by the product of (i) the transmission charge rate ($/kW-week), and (ii) the number of kilowatts WG&E is entitled to receive during such week.

CL&P requests an effective date of November 12, 1983, and therefore requests waiver of the Commission's notice requirements.

Copies of this filing were served upon WMECO and WG&E.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, 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 31, 1984. 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. 84-13712 Filed 5-21-84; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. CP75-33-004]

Mountain Fuel Supply Co.; Petition to Amend

May 17, 1984.

Take notice that on April 27, 1984, Mountain Fuel Supply Company (Petitioner), 180 East First South Street, Salt Lake City, Utah 84139, filed in Docket No. CP75-33-004 a petition to amend the order issued September 22, 1983, in Docket Nos. CP74-33-002 and CP75-33-003 pursuant to section 7(c) of the Natural Gas Act to authorize (1) a delay of the drawdown of Chalk Creek Underground Storage Reservoir (Chalk Creek) until July 31, 1984, and (2) the injection of up to an additional 200,000 Mcf of natural gas into Chalk Creek, all as more fully set forth in the petition to amend which is on file with the Commission and open to public inspection.

Petitioner states that the Commission's September 22, 1983, order, among other things, specified that (1) reservoir drawdown would be completed as soon as it is deemed prudent following each heating season and (2) the operation of Chalk Creek would be limited to maximum total inventory of 1,980,000 Mcf of natural gas.

Petitioner states that it proposes to continue operating Chalk Creek as a peak-shaving facility through July 31, 1984, to help assure that service to Petitioner's distribution system customers would not be disrupted because of spring flooding and mudslides. It is explained that abnormally high snow pack, coupled with wet spring weather, is already beginning to cause flooding and mudslides as evidenced by the March 26, 1984, mudslide upstream of Chalk Creek which severed Petitioner's Main Line No. 1 and threatened Main Line Nos. 13 and 15.

It is further stated that the injection of up to an additional 200,000 Mcf of working gas into Chalk Creek would provide up to an average of 50,000 Mcf per day of deliverability for an additional four days.

Any person desiring to be heard or to make any protest with reference to said petition should on or before June 7, 1984, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a motion to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a motion to intervene in accordance with the Commission's Rules.

Kenneth F. Plumb,

Secretary.

[FR Doc. 84-13713 Filed 5-21-84; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. CP84-384-000]

National Fuel Gas Supply Corp.; Application

May 17, 1984.

Take notice that on May 2, 1984, National Fuel Gas Supply Corporation (Applicant), 308 Seneca Street, Oil City, Pennsylvania 16301, filed in Docket No. CP84-384-000 an application pursuant to section 7(c) of the Natural Gas Act for a certificate of public convenience and necessity authorizing a limited-term off-system sale of gas for resale to Delmarva Power and Light Company (Delmarva) for replacement of storage inventory, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

Applicant proposes to sell up to a total of 750,000 Mcf of natural gas, on an interruptible basis, to Delmarva during a period ending October 31, 1984. Applicant proposes to deliver the gas for the account of Delmarva to Penn-York Energy Corporation (Penn-York) at the interconnection of Applicant and Penn-

York near Ellisburg, Potter County, Pennsylvania, or at other such interconnections or at unspecified locations within Applicant's facilities being used by Penn-York to render storage service for Delmarva during the 1984–85 storage year. After storage by Penn-York, Delmarva would transport the gas to its service territory through existing or new arrangements. Applicant proposes to sell the gas to Delmarva pursuant to its Rate Schedule I–1 contained in a service agreement. This is a 100 percent load factor rate which is currently $3.4158 per Mcf., Applicant states.

Any person desiring to be heard or to make any protest with reference to said application should on or before June 7, 1984, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a motion to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to the proceeding or to participate as a party in any hearing therein must file a motion to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in the subject to jurisdiction conferred upon the Federal Energy Regulatory Commission by sections 7 and 15 of the Natural Gas Act and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission or its designee on this application if no motion to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate is required by the public convenience and necessity. If a motion for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for Applicant to appear or be represented at the hearing.

Kenneth F. Plumb,

Secretary.

[FR Doc. 84-13714 Filed 5-21-84; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. CP84-383-000]

National Fuel Gas Supply Corp.; Application

May 17, 1984.

Take notice that on May 2, 1984, National Fuel Gas Supply Corporation (Applicant), 308 Seneca Street, Oil City, Pennsylvania 16301, filed in Docket No. CP84–383–000 an application pursuant to section 7(c) of the Natural Gas Act for a certificate of public convenience and necessity authorizing a limited-term off-system sale of gas for resale to UGI Corporation (UGI) for replacement of storage inventory, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

Applicant proposes to sell up to a total of 3,800,000 Mcf of natural gas, on an interruptible basis, to UGI during a period ending October 31, 1984. Applicant proposes to deliver the gas for account of UGI to Penn-York Energy Corporation (Penn-York) at the interconnection of Applicant and Penn-York near Ellisburg, Potter County, Pennsylvania, or at other such interconnections, or at unspecified locations within Applicant's facilities being used by Penn-York to render storage service for UGI during the 1984–85 storage year. After storage by Penn-York, UGI would transport the gas to its service territory through existing or new arrangements. Applicant proposes to sell the gas to UGI pursuant to its Rate Schedule I–1 contained in a service agreement. This is a 100-percent load factor rate which is currently $3.4158 per Mcf, Applicant states.

Any person desiring to be heard or to make any protest with reference to said application should on or before June 7, 1984, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a motion to intervene or a protest in accordance with the requirements of the Commission's Rules and Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a motion to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to jurisdiction conferred upon the Federal Energy Regulatory Commission by sections 7 and 15 of the Natural Gas Act and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission or its designee on this application if no motion to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate is required by the public convenience and necessity. If a motion for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for Applicant to appear or be represented at the hearing.

Kenneth F. Plumb,

Secretary.

[FR Doc. 84-13715 Filed 5-21-84; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. CP76-492-032]

National Fuel Gas Supply Corp. and Penn-York Energy Corp.; Petition to Amend

May 17, 1984.

Take notice that on May 1, 1984, National Fuel Gas Supply Corporation (National), 10 Lafayette Square, Buffalo, New York 14203, and Penn-York Energy Corporation (Penn-York), 10 Lafayette Square, Buffalo, New York 14203, filed in Docket No. CP76–492–032 a petition to amend the order issued June 21, 1979, in Docket No. CP76–492 pursuant to section 7 of the Natural Gas Act so as to authorize the abandonment of a transportation service provided by National to UGI Corporation (UGI), all as more fully set forth in the petition which is on file with the Commission and open to public inspection.

National proposes to abandon transportation service to UGI provided under National's Rate Schedule X–30. It is indicated that the transportation service proposed to be abandoned has enabled UGI to transport gas stored by UGI with Penn-York. Specifically, it is indicated that pursuant to Rate Schedule X–30 National transports up to 36,364 Mcf of gas per day in either direction between the interconnection of National's facilities with those of Penn-York near Ellisburg in Potter County, Pennsylvania, and the interconnection of National's facilities with either Transcontinental Gas Pipe Line Corporation (Transco) near Wharton, Potter County, Pennsylvania, or Columbia Gas Transmission

Corporation (Columbia) near First Fork in Cameron County, Pennsylvania.

It is stated that the proposed abandonment would not become effective until (a) availability of alternative transportation for storage withdrawal gas through the new Penn-York/Columbia interconnection near Penn-York's Independence compressor station in Potter County, Pennsylvania, proposed in Docket No. CP83-478-000, (b) availability of the firm and interruptible transportation for UGI proposed by National in Docket No. CP76-492-031, and (c) the initiation of transportation service proposed in Docket No. CP76-492-031 by National for Transco. It is further stated that the proposed abandonment would enable UGI to reduce its cost of transportation of storage volumes and enable National to provide firm transportation of storage volumes for Transco.

Any person desiring to be heard to to make any protest with reference or said petition should on or before June 7, 1984, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a motion to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a motion to intervene in accordance with the Commission's Rules.

Kenneth F. Plumb,

Secretary.

[FR Doc. 84-13716 Filed 5-21-84; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. CP84-392-000]

Northwest Central Pipeline Corp.; Request Under Blanket Authorization

May 17, 1984.

Take notice that on May 7, 1984, Northwest Central Pipeline Corporation (Northwest Central), P.O. Box 25128, Oklahoma City, Oklahoma 73125, filed in Docket No. CP84-392-000, a request pursuant to Section 157.205 of the Commission's Regulations under the Natural Gas Act (18 CFR 157.205) that Northwest Central proposes to construct and operate a delivery point for the direct firm sale of natural gas to the Francis Auto Clinic in Washington County, Oklahoma, under the authorization issued in Docket No. CP82-479-000, as amended in Docket No. CP82-479-001, pursuant to Section 7 of the Natural Gas Act, all as more fully set forth in the request which is on file with the Commission and open to public inspection.

Northwest Central proposes to construct and operate a sales tap for Francis Auto Clinic which would enable Northwest Central to deliver approximately 245 Mcf of natural gas per year. The gas would be used for fuel requirements of an auto repair shop and office, it is submitted.

Northwest Central states that such sale would not significantly affect its overall gas supply or have any detrimental effect on existing customers. The gas would be delivered from system supply which, it is stated, is adequate to provide the service. Estimated cost of the proposed facilities is $1,230, which will be paid from available funds.

Any person or the Commission's staff may, within 45 days after issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention and pursuant to § 157.205 of the Regulations under the Natural Gas Act (18 CFR 157.205) a protest to the request. If no protest is filed within the time allowed therefor, the proposed activity shall be deemed to be authorized effective the day after the time allowed for filing a protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for authorization pursuant to section 7 of the Natural Gas Act.

Kenneth F. Plumb,

Secretary.

[FR Doc. 84-13717 Filed 5-21-84; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. CP84-122-001]

Texas Gas Transmission Corp.; Supplement To Request Under Blanket Authorization

May 17, 1984.

Take notice that on April 18, 1984, Texas Gas Transmission Corporation (Texas Gas), 3800 Frederica Street, Owensboro, Kentucky 42302, filed in Docket No. CP84-122-001 a supplement to a request filed December 9, 1983, in Docket No. CP84-122-000 pursuant to § 157.205 of the Regulations under the Natural Gas Act (18 CFR 157.205) requesting authority to extend the term of the transportation service for Armco Inc. (Armco) through June 30, 1985, and to provide for "flexible authority" to add and/or delete sources of gas and/or receipt/delivery points, all as more fully set forth in the supplement on file with the Commission and open to public inspection.

Texas Gas states that with respect to the "flexible authority" to add and/or delete sources of gas and/or receipt/delivery points, it would undertake within 30 days of the addition or deletion of any gas suppliers and/or receipt/delivery points, to file with the Commission the following information:

(1) A copy of the gas purchase contract between seller and end-user;

(2) A statement as to whether the supply is attributable to gas under contract to and released by a pipeline or distributor, and if so, identifiction of the parties and specification of the current contract price;

(3) A statement of the Natural Gas Policy Act (NGPA) pricing categories of the added supply, if released gas, and the volumes attributable to each category;

(4) A statement that the gas is not committed or dedicated within the meaning of the NGPA Section 2(18);

(5) Location of the receipt/delivery points being added or deleted;

(6) Where an intermediary participates in the transaction between the seller and the end-user, the information required by Section 157.209(c)(ix); and

(7) Identity of any other pipeline involved in the transportation.

Texas Gas asserts that any changes in sources and/or receipt/delivery points would be on behalf of the same end-user at the same end-use location and would be within the maximum daily and annual volumes authorized under Docket No. CP84-122-000. Texas Gas further asserts that such transportation would be rendered under the same terms and conditions authorized for the basic service with the exception of the requested extended term.

Any person or the Commission's staff may, within 45 days after issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention and pursuant to § 157.205 of the Regulations under the Natural Gas Act (18 CFR 157.205) a protest to the request. If no protest is filed within the time allowed therefor, the proposed activity shall be deemed to be authorized effective the day after the time allowed for filing a protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request shall

be treated as an application for authorization pursuant to section 7 of the Natural Gas Act.

Kenneth F. Plumb,

Secretary.

[FR Doc. 84-13718 Filed 5-21-84; 8:45 am]

BILLING CODE 6717-01-M

ENVIRONMENTAL PROTECTION AGENCY

[OPTS-51517; TSH-FRL 2580-8]

Certain Chemicals; Premanufacture Notices

Correction

In FR Doc. 84-11916 beginning on page 19110 in the issue of Friday, May 4, 1984, make the following corrections:

1. On page 19111, third column, *PMN 84-632*, third line, "Diisocylanate" should read "Diisocyanate".

2. On page 19112, second column, *PMN 84-638*, third line, "gloycol" should read "glycol"; also, remove the first "*PMN 84-639*".

3. On page 19113, first column, *PMN 84-648*, second line, "polymer" should read "Polymer".

4. On page 19114, first column, in the FR Doc. line the document number now reading "84-1196" should have read "84-11916".

BILLING CODE 1505-01-M

[PP 2G2660/T442; PH-FRL 2576-5]

Chlorothalonil; Renewal of Temporary Tolerance

Correction

In FR Doc. 84-11553 appearing on page 18780 in the issue of Wednesday, May 2, 1984, the Docket Number should have appeared as set forth above.

BILLING CODE 1505-01-M

FEDERAL MARITIME COMMISSION

Agreements Filed

The Federal Maritime Commission hereby gives notice that the following agreements have been filed with the Commission for approval pursuant to section 15 of the Shipping Act, 1916, as amended (39 Stat. 733, 75 Stat. 763, 46 U.S.C 814).

Interested parties may inspect and may request a copy of each agreement and the supporting statement at the Washington, D.C. Office of the Federal Maritime Commission, 1100 L Street, NW., Room 10325. Interested parties may submit protests or comments on each agreement to the Secretary, Federal Maritime Commission, Washington, D.C. 20573, within 20 days after the date of the **Federal Register** in which this notice appears. The requirements for comments and protests are found in § 522.7 of Title 46 of the Code of Federal Regulations. Interested persons should consult this section before communicating with the Commission regarding a pending agreement.

Any person filing a comment or protest with the Commission shall, at the same time, deliver a copy of the document to the person filing the agreement at the address shown below.

Agreement No.: T-3875-3.

Title: The Chicago Regional Port District and Ceres, Incorporated, amended Licensing Agreement.

Parties:

The Chicago Regional Port District (District)

Ceres, Incorporated (Ceres)

Synopsis: Agreement No. T-3875-3 amends the basic agreement between the parties which provided for the exclusive licensing of Ceres for the provisions of stevedoring and terminal functions at the Lakefront Sites in the Port of Chicago. The modification involves a change in the schedule of fees to permit a reduction in wharfage charges for U.S. government cargoes, iron and steel and metal products, containerized cargo, empty containers and all commodities in barges.

Filing party: John J. Serpico, Chairman, Chicago Regional Port District, Butler Drive-Lake Calumet, Chicago, Illinois 60633.

Agreement No.: T-4180

Title: The Board of Trustees of the Galveston Wharves and Lykes Bros. Steamship Co., Inc., Terminal and Berth Agreement.

Parties:

The Board of Trustees of the Galveston Wharves (Wharves)

Lykes Bros. Steamship Co., Inc. (Lykes)

Synopsis: Agreement No. T-4180 provides that Wharves will assign specific days of each week for a guaranteed berth for Lykes' Seabee vessels. Charges for use of the terminal and berth shall be at regular tariff rates as published in the Wharves' Terminal Tariff No. 1-B, FMC-T No. 12. The agreement provides for an annual wharfage and dockage sharing plan after the collection of $100,000. The agreement will run for three years with an option for two one-year extensions.

Filing party: Carl S. Parker, Jr., Traffic Manager, Galveston Wharves, Post Office Box 328, Galveston, Texas 77553.

By order of the Federal Maritime Commission.

Francis C. Hurney,

Secretary.

[FR Doc. 84-13692 Filed 5-21-84; 8:45 am]

BILLING CODE 6730-01-M

[Agreement No. T-3938-1]

Agreements Filed; City of Los Angeles and American President Lines, Inc.; Correction

Agreement No.: T-3938-1.

Title: The City of Los Angeles and American President Lines, Inc., Sale and Assignment of Container Cranes.

Parties:

The City of Los Angeles

American President Lines, Inc.

Synopsis: **Federal Register** Notice of April 10, 1984 (49 FR 14187), incorrectly indicated that the number of the Agreement was T-4175, whereas the correct number should have been T-3938-1.

Filing party: Raymond P. Bender, Assistant City Attorney, City of Los Angeles, Harbor Division, Post Office Box 51, San Pedro, California 90731-0151.

By order of the Federal Maritime Commission.

Dated: May 17, 1984.

Francis C. Hurney,

Secretary.

[FR Doc. 84-13889 Filed 5-21-84; 8:45 am]

BILLING CODE 6730-01-M

[Agreement No. T-3740]

Agreements Filed; Georgia Ports Authority and United States Lines, Inc.; Termination

Agreement No.: T-3740, As amended.

Title: The Georgia Ports Authority and United States Lines, Inc.

Parties:

The Georgia Ports Authority

United States Lines, Inc.

Synposis: The above referenced agreement has been terminated by Agreement No. T-4176 which became effective on May 1, 1984.

Filing party: Robert W. Goethe, Assistant Executive Director, Georgia Ports Authority, Post Office Box 2406, Savannah, Georgia 31402.

By order of the Federal Maritime Commission.

Dated: May 17, 1984.

Francis C. Hurney,

Secretary.

[FR Doc. 84-13691 Filed 5-21-84; 8:45 am]

BILLING CODE 6730-01-M

[Agreement No. T-4157]

Agreements Filed; Jacksonville Port Authority and Eller & Co., Inc.; Cancellation

Agreement No.: T-4157.

Title: The Jacksonville Port Authority and Eller & Company, Inc. Terminal Lease Agreement.

Parties:

The Jacksonville Port Authority

Eller & Company, Inc.

Synopsis: The above referenced agreement has been cancelled by the parties effective on May 8, 1984.

Filing party: John R. Mackroth, Managing Director, Jacksonville Port Authority, Post Office Box 3005, Talleyrand Avenue, Jacksonville, Florida 32206.

By order of the Federal Maritime Commission.

Dated: May 17, 1984.

Francis C. Hurney,

Secretary.

[FR Doc. 84-13690 Filed 5-21-84; 8:45 am]

BILLING CODE 6730-01-M

Security for Protection of Public; Financial Responsibility To Meet Liability Incurred for Death or Injury to Passengers or Other Persons on Voyages; Issuance of Certificate [Casualty]

Notice is hereby given that the following have been issued a Certificate of Financial Responsibility to Meet Liability Incurred for Death or Injury to Passengers or Other Persons on Voyages pursuant to the provisions of Section 2, Public Law 89-777 (80 Stat. 1356, 1357) and Federal Maritime Commission General Order 20, as amended (46 CFR Part 540): Fourth Transoceanic Shipping Co. Ltd., trading as Chandris Lines/ Chandris Cruises, c/o Chandris Incorporated, 666 Fifth Avenue, New York, New York 10019.

Dated: May 17, 1984.

Francis C. Hurney,

Secretary.

[FR Doc. 84-13693 Filed 5-21-84; 8:45 am]

BILLING CODE 6730-01-M

Security for Protection of Public; Financial Responsibility To Meet Liability Incurred for Death or Injury to Passengers or Other Persons on Voyages; Issuance of Certificate [Casualty]

Notice is hereby given that the following have been issued a Certificate of Financial Responsibility to Meet Liability Incurred for Death or Injury to Passengers or Other Persons on Voyages pursuant to the provisions of Section 2, Public Law 89-777 (80 Stat. 1356, 1357) and Federal Maritime Commission General Order 20, as amended (46 CFR Part 540): Fifth Transoceanic Shipping Co. Ltd., trading as Chandris Lines/ Chandris Cruises, c/o Chandris Incorporated, 666 Fifth Avenue, New York, New York 10019.

Dated: May 17, 1984.

Francis C. Hurney,

Secretary.

[FR Doc. 84-13694 Filed 5-21-84; 8:45 am]

BILLING CODE 6730-01-M

FEDERAL RESERVE SYSTEM

Cripple Creek Bancorporation, Inc.; Applications To Engage de Novo in Permissible Nonbanking Activities

The companies listed in this notice have filed an application under § 225.23(a)(1) of the Board's Regulation Y (49 FR 794) for the Board's approval under section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.21(a) of Regulation Y (49 FR 794) to commence or to engage *de novo*, either directly or through a subsidiary, in a nonbanking activity that is listed in § 225.25 of Regulation Y as closely related to banking and permissible for bank holding companies. Unless otherwise noted, such activities will be conducted throughout the United States.

Each application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices." Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

Unless otherwise noted, comments regarding the applications must be received at the the Reserve Bank indicated or the offices of the Board of Governors not later than June 11, 1984.

A. **Federal Reserve Bank of Kansas City** (Thomas M. Hoenig, Vice President) 925 Grand Avenue, Kansas City, Missouri 64198:

1. **Cripple Creek Bancorporation, Inc.**, Cripple Creek, Colorado; to engage in *de novo* in real estate financing including the origination of first and second mortgage loans secured by single and multi-family residences and commercial properties; the extension of credit for the construction or remodeling of single and multi-family and commercial structures; and the extension of credit for the development of single and multi-family and commercial real estate. These activities will be conducted in Teller, El Paso, and Park Counties, Colorado.

B. **Federal Reserve Bank of San Francisco** (Harry W. Green, Vice President) 101 Market Street, San Francisco, California 94105:

1. *United Bancorporation Alaska, Inc.*, Anchorage, Alaska; to continue to engage *de novo* through its subsidiary, UBA Mortgage Company, Inc., Anchorage, Alaska, in making or acquiring loans and other extension of credit such as would be made by a mortgage company and/or commercial financial company; servicing such loans for others; and acting as ageny or broker for credit related life, accident, health or unemployment insurance. This application is to expand the geographic scope of the subsidiary to include the entire United States.

Board of Governors of the Federal Reserve System, May 16, 1984.

William W. Wiles,

Secretary of the Board.

[FR Doc. 84-13652 Filed 5-21-84; 8:45 am]

BILLING CODE 6210-01-M

First National State Bancorporation; Application To Engage de Novo in Nonbanking Activities

The company listed in this notice has filed an application under § 225.23(a)(3) of the Board's Regulation Y (49 FR 794) for the Board's approval under section 4(c)(8) of the Bank Holding Company

Act (12 U.S.C. 1843(c)(8)) and § 225.21(a) of Regulation Y (49 FR 794), to engage *de novo* through a national bank subsidiary in deposit-taking, including the taking of demand deposits, and other activities specified below. The proposed subsidiary will not engage in commercial lending transactions as defined in Regulation Y. The Board has determined by order that such activities are closely related to banking. *U.S. Trust Company* (70 Federal Reserve Bulletin 371 (1984)). Although the Board is publishing notice of this application, under established Board policy and record of the application will not be regarded as complete and the Board will not act on the application unless and until a preliminary charter for the proposed national bank subsidiary has been submitted to the Board.

The application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices." Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

Comments regarding the application must be received at the Federal Reserve Bank or the offices of the Board of Governors not later than June 13, 1984.

A. **Federal Reserve Bank of New York** (A. Marshall Puckett, Vice President), 33 Liberty Street, New York, New York 10045:

1. *First National State Bancorporation*, Newark, New Jersey; to engage through a national bank subsidiary, First National State/Westchester, White Plains, New York, in consumer and mortgage lending; trust services and investment advisory services; and deposit-taking, including demand deposits. These activities will be conducted in White Plains, New York, and surrounding communities in Westchester County.

Board of Governors of the Federal Reserve System, May 16, 1984.

William W. Wiles,

Secretary of the Board.

[FR Doc. 84-13653 Filed 5-21-84; 8:45 am]

BILLING CODE 6210-01-M

Hayesville Bancshares, Inc.; Acquisition of Company Engaged in Permissible Nonbanking Activities

The organization listed in this notice has applied under § 225.23(a) (2) or (f) of the Board's Regulation Y (49 FR 794) for the Board's approval under section 4(c)(8) or the Bank Holding Company Act (12 U.S.C. 1843(c) (8)) and § 225.21(a) of Regulation Y (49 FR 794) to acquire or control voting securities or assets of a company engaged in a nonbanking activity that is listed in § 225.25 of Regulation Y as closely related to banking and permissible for bank holding companies. Unless otherwise noted, such activities will be conducted throughout the United States.

The application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweight possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices." Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

Comments regarding the application must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than June 13, 1984.

A. **Federal Reserve Bank of Chicago** (Franklin D. Dreyer, Vice President) 230 South LaSalle Street, Chicago, Illinois 60690:

1. *Hayesville Bancshares, Inc.*, Hayesville, Iowa; to acquire Mertz Insurance Agency, Hayesville, Iowa, and Gerald Fowler Insurance Agency, Delta, Iowa, to engage directly in acting as insurance agent or broker in offices at which the holding company of its subsidiary bank are otherwise engaged in business in Hayesville and Delta, Iowa, with respect to the sale of any insurance is a community that has a population not exceeding 5,000. These activities would be conducted in areas of approximately ten miles in radius surrounding Hayesville and eight miles in radius surrounding Delta.

Board of Governors of the Federal Reserve System, May 16, 1984.

William W. Wiles,

Secretary of the Board.

[FR Doc. 84-13654 Filed 5-21-84; 8:45 am]

BILLING CODE 6210-01-M

Metro Bancorp, Inc. et al.; Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied for the Board's approval under section 3 of the Bank Holding Company Act (12 U.S.C. 1842) and § 225.14 of the Board's Regulaton Y (49 FR 794) to become a bank holding company or to acquire a bank or bank holding company. The factors that are considered in acting on the applications are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

Each application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank or to the offices of the Board of Governors. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Unless otherwise noted, comments regarding each of these applications must be received not latter than June 13, 1984.

A. **Federal Reserve Bank of Boston** (Richard E. Randall, Vice President) 600 Atlantic Avenue, Boston Massachuetts. 02106:

1. *Metro Bancorp, Inc.*, Melrose, Massachusetts; to become a bank holding company by acquireing at least 80 percent of the voting shares of Metropolitan Bank and Trust Company Melrose, Massachusetts.

B. **Federal Reserve Bank of New York** (A. Marshall Puckett, Vice President) 33 Liberty Street, New York, New York 10045:

1. *Midlantic Banks, Inc.* Edison, New Jersey; to acquire 24.9 percent of the voting shares of statewide Bancorp, Toms River, New Jersey, thereby indirectly acquiring First National Bank of Toms River, Toms River, New Jersey.

C. **Federal Reserve Bank of Chicago** (Franklin D. Dreyer, Vice President) 230 South LaSalle Street, Chicago, Illinois 60690:

1. *Marion Bancorp,* Marion, Indiana: to become a bank holding company by acquiring 100 percent of the voting shares of First National Bank in Marion, Marion, Indiana.

2. *Northtown Bancshares Corporation,* Decatur, Illinois; to become a bank holding company by acquiring 100 percent of the voting shares of Northtown Bank in Decatur, Decatur, Illinois.

D. **Federal Reserve Bank of St. Louis** (Delmer P. Weisz, Vice President) 411 Locust Street, St. Louis, Missouri 63166:

1. *Continental Bancorporation, Inc.,* Sikeston, Missouri; to become a bank holding company by acquiring 80.47 percent of the voting shares of First National Bank of Sikeston, Sikeston, Missouri.

E. **Federal Reserve Bank of Kansas City** (Thomas M. Hoenig, Vice President) 925 Grand Avenue, Kansas City, Missouri 64198:

1. *Community Bank Corp of Oklahoma, Inc.,* Stillwater, Oklahoma; to become a bank holding company by acquiring at least 93.3 percent of the voting shares of Stillwater Community Bank, Stillwater, Okahoma.

2. *C.S.B. Co.* Cozad, Nebraska; to acquire 100 percent of the votng shares of St. Paul Naional Bank, St. Paul. Nebraska.

F. **Federal Reserve Bank of Dallas** (Anthony J. Montelaro, Vice President) 400 South Akard Street, Dallas, Texas 75222:

1. *American Bank Holding Company,* Corpus Christi, Texas; to become a bank holding company by acquiring 100 percent of the voting shares of American National Bank, Corpus Christi, Texas.

Board of Governors of the Federal Reserve System, May 16, 1984.

William W. Wiles,

Secretary of the Board.

[FR Doc. 84-13655 Filed 5-21-84; 8:45 am]

BILLING CODE 6210-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Ad Hoc Working Group To Develop Radioepidemiological Tables; Meeting

Pursuant to Pub. L. 92-463, notice is hereby given of the meeting of the Ad Hoc Working Group To Develop Radioepidemiological Tables, July 12, 1984, in Building 31A, Conference Room 3, National Institutes of Health, Bethesda, Maryland.

The meeting will be open to the public from 9:00 a.m. to approximately 5:00 p.m. to develop radioepidemiological tables in response to Public Law 97-414. Attendance by the public will be limited to space available.

For additional program information, summaries of the meeting and roster of the Committee members, contact Dr. Victor H. Zeve, Landow Building, Room 3A10, National Institutes of Health, Bethesda, Maryland 20205, (301) 496-5266.

Dated: May 15, 1984.

Betty J. Beveridge,

NIH Committee Management Officer.

[FR Doc. 84-13657 Filed 5-21-84; 8:45 am]

BILLING CODE 4140-01-M

Public Health Service

Advisory Committees; Meetings

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), announcement is made of the following National Advisory bodies scheduled to meet during the month of June 1984:

Name: Health Care Technology Study Section.

Date and Time: June 12-13, 1984, 2:00 p.m.

Place: Ramada O'Hare Inn, Salon A, 6600 North Mannheim Road, Rosemont, Illinois 60018.

Open June 13, 8:00 a.m. to 9:00 a.m.

Closed for remainder of meeting.

Purpose: The Committee is charged with the initial review of health research grant applications for Federal assistance in the program areas administered by the National Center for Health Services Research (NCHSR).

Agenda: The open session from 8:00 a.m. to 9:00 a.m. on June 13 will be devoted to a business meeting covering administrative matters and reports and a presentation by the Director, NCHSR. The closed portion of the meeting will be devoted to review of health services research grant applications relating to the delivery, organization, and financing of health services. The closing is in accordance with the provisions set forth in section 552b(c)(6), Title 5, U.S. Code, and the Determination by the Assistant Secretary for Health, pursuant to Pub. L. 92-463.

Anyone wishing to obtain a roster of members, minutes of meetings, or other relevant information should contact Dr. Alan E. Mayers, National Center for Health Services Research, Room 1-52, Park Building, 5600 Fishers Lane, Rockville, Maryland 20857, telephone (301) 443-3091.

Name: Health Services Research Review Subcommittee.

Date and Time: June 13-14, 1984, 8:00 a.m.

Place: Ramada O'Hare Inn, Salon B, 6600 North Mannheim Road, Rosemont, Illinois 60018.

Open June 13, 8:00 a.m. to 8:15 a.m.; June 13, 9:30 a.m. to 10:30 a.m.

Closed for remainder of meeting.

Purpose: The Subcommittee is charged with the initial review of grant applications for Federal assistance in the program areas administered by the National Center for Health Services Research (NCHSR).

Agenda: The open session of the meeting on June 13, 8:00 a.m. to 8:15 a.m. will be devoted to a business meeting covering administrative matters and reports. The open session from 9:30 a.m. to 10:30 a.m. will consist of a presentation by the Director, NCHSR. During the closed sessions, the Subcommittee will be reviewing research grant applications relating to the delivery, organization, and financing of health services. The closing is in accordance with provisions set forth in section 552(c)(6), Title 5, U.S. Code, and the Determination by the Assistant Secretary for Health, pursuant to Pub. L. 92-463.

Anyone wishing to obtain a roster of members, minutes of meetings, or other relevant information should contact Anthony Pollitt, Ph.D., National Center for Health Services Research, Room 1-52, Park Building, 5600 Fishers Lane, Rockville, Maryland 20857, telephone (301) 443-3091.

Name: Health Services Developmental Grants Review Subcommittee

Date and Time: June 21-22, 1984, 8:30 a.m.

Place: Linden Hill Hotel, Queensbury Room, 5400 Pooks Hill Road, Bethesda, Maryland 20814.

Open June 21, 8:30 a.m. to 9:30 a.m.

Closed for remainder of meeting.

Purpose: The Subcommittee is charged with the initial review of grant applications for Federal assistance in the program areas administered by the National Center for Health Services Research (NCHSR).

Agenda: The open session of the meeting on June 21 will be devoted to a business meeting covering administrative matters and reports and a presentation by the Director, NCHSR. During the closed sessions, the Subcommittee will be reviewing research grant applications relating to the delivery, organization, and financing of health services. The closing is in accordance with provisions set forth in section 552b(c)(6), Title 5, U.S. Code, and the Determination by the Assistant Secretary for Health, pursuant to Pub. L. 92-463.

Anyone wishing to obtain a roster of members, minutes of meetings, or other relevant information should contact Mr. Hoke S. Glover, National Center for Health Services Research, Room 1-52, Park Building,

5600 Fishers Lane, Rockville, Maryland 20857, telephone (301) 443–3091.

Agenda items are subject to change as priorities dictate.

Dated: May 15, 1984.

John E. Marshall,

Director, National Center for Health Services Research.

[FR Doc. 84–13720 Filed 5–17–84; 8:45 am]

BILLING CODE 4510–28–M

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

Announcement of Vacancy; Osage Tribal Education Committee

25 CFR 122.5(e)(5) states that any vacancies shall be filled in the same manner described by this section for the selection of committee members. The period of time for receiving applications shall not exceed 30 days with the expiration date to be announced by the Assistant Secretary. The Assistant Secretary may appoint any individual to serve for a temporary period of time until the vacancy is filled. However, such an appointment shall not exceed 45 days.

This notice announces that a vacancy has occured on the Osage Education Committee. The purpose of this announcement is to solicit nominations from individuals or from Osage organizations on behalf of nominees for the vacancy. The vacancy represents the member at large on the committee. The requirements state that the nominee must be an adult person of Osage Indian blood, who is an allottee or a descendant of an allottee and may include residents living anywhere in the United States. The nominee or his representative organization should submit a brief statement requesting that he/she be considered as a candidate for the vacancy and the reason for desiring to serve on the committee. If nominated by an Osage organization, a written statement from the nominee stating his/her willingness to serve on the committee must be included with the Osage organization. Applications and nominations shall be made no later than 30 days from the publishing date of this notice and shall be mailed to: Assistant Secretary-Indian Affairs, Attention: Director, Office of Indian Education Programs, Code 500, 18 & C Streets NW., Washington, D.C. 20240.

This notice is published in accordance with authority delegated by the Secretary of the Interior to the Assistant Secretary—Indian Affairs by 209 DM 8.

Dated: May 14, 1984.

Kenneth Smith,

Assistant Secretary—Indian Affairs.

[FR Doc. 84–13685 Filed 5–21–84; 8:45 am]

BILLING CODE 4310–02–M

Bureau of Land Management

[OR–36685 E]

Conveyance of Public Lands; Oregon

Notice is hereby given that, pursuant to section 203 and 209 of the Act of October 21, 1976 (90 Stat. 2743, 2750, 2757; 43 U.S.C. 1701, 1713, 1719), the following described public land in Gilliam County, was purchased by modified competitive sale and conveyed to the parties show:

Mr. & Mrs. Dallas L. Dalzell, P.O. Box 152, Condon, Oregon 97823

Williamette Meridian, Oregon

T. 3 S., R. 22 E.,
Sec. 25, SW¼SE¼, SE¼SW¼.

The purpose of this Notice is to inform the public and interested State and local governmental officials of the issuance of the conveyance document to Mr. & Mrs. Dalzell.

Dated: May 11, 1984.

Harold A. Berends,

Chief, Branch of Lands and Minerals Operations.

[FR Doc. 84–13667 Filed 5–21–84; 8:45 am]

BILLING CODE 4310–33–M

[OR–36615 E; OR–36615 F; OR–36615 G]

Conveyance of Public Lands; Oregon

Notice is hereby given that, pursuant to section 203 and 209 of the Act of October 21, 1976 (90 Stat. 2743, 2750, 2757; 43 U.S.C. 1701, 1713, 1719), the following described public land in Gilliam County, was purchased by both competitive and modified competitive sale and conveyed to the party shown:

Mannix Investments, Inc., 6235 Hollywood Blvd., Suite 613, Los Angeles, CA 90028

Willamette Meridian, Oregon

T. 1 S., R. 22 E.,
Sec. 12, NE¼SE¼;
Sec. 32, SW¼SW¼.
T. 2 S., R. 22 E.,
Sec. 17, NE¼NE¼.

The purpose of this Notice is to inform the public and interested State and local governmental officials of the issuance of the conveyance document to Mannix Investments, Inc.

Dated: May 11, 1984.

Harold A. Berends,

Chief, Branch of Lands and Minerals Operations.

[FR Doc. 84–13668 Filed 5–21–84; 8:45 am]

BILLING CODE 4310–33–M

[M–59125]

Exchange of Public and Private Lands in Custer, Dawson, and Garfield Counties, Montana

AGENCY: Bureau of Land Management, Miles City District Office, Interior.

ACTION: Notice of realty action M–59125, exchange of public and private lands in Custer, Dawson and Garfield Counties, Montana.

SUMMARY: The following described lands have been determined to be suitable for disposal by exchange under section 206 of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1716:

Principal Meridian, Montana

T. 19 N., R. 36 E.,
Sec. 2, NE¼SE¼;
Sec. 12, NE¼.
T. 19 N., R. 37 E.,
Sec. 7, Lot 1, N½NE¼, NE¼NW¼;
Sec. 9, SW¼NE¼;
Sec. 10, S½NW¼;
Sec. 15, SW¼NW¼;
Sec. 29, SE¼SW¼;
Sec. 35, W½NW¼.
Aggregating 634.17 acres.
T. 18 N., R. 57 E.,
Sec. 20, Lot 7–10;
Sec. 21, Lot 6.
Aggregating 202.81 acres.

In exchange for these lands, the United States Government will acquire the surface estate in the following described lands:

Principal Meridian, Montana

T. 9 N., R. 48 E.,
Sec. 30, Lots 5, 6, W¼SE¼ (portion lying westerly of Chicago, Milwaukee, St Paul and Pacific Railroad right-of-way.
Aggregating 74.38 acres.

The purpose of this exchange is to acquire the non-Federal lands for use in providing public access to waters of the Yellowstone River. The exchange is consistent with the Bureau's Planning for the lands involved and has been discussed with county commissioners of Custer, Dawson and Garfield Counties. They concurred in that there is no need for a public meeting to be held.

DATES: For a period of 45 days from the date of first publication of this notice, interested parties may submit comments to the District Manager, Bureau of Land

Management, Garryowen Road, P.O. Box 940, Miles City, Montana 59301.

Any adverse comments will be evaluated by the State Director, who may vacate or modify this realty action and issue a final determination. In the absence of any action by the State Director, this realty action will become the final determination of this department.

FOR FURTHER INFORMATION CONTACT: Information related to this exchange, including the environmental assessment and land report, is available for review at the Miles City District Office, Garryowen Road, Miles City, Montana.

SUPPLEMENTARY INFORMATION: The purpose of this exchange is to acquire a parcel of privately-owned land within a retention area. This land will be acquired to support a multiple-use federal program and the economy. The multiple-use values include, but are not limited to recreation, wildlife habitat and efficiency of management.

The exchange is consistent with the Bureau's planning for the lands involved and has been discussed with State and local officials. The public interest will be well served by making the exchange. The publication of this notice segregates the public lands described above from appropriation under the public land laws, including the mining laws, but not from exchange pursuant to Section 206 of the Federal Land Policy and Management Act of 1976.

The exchange will be made subject to:

1. A reservation to the United States of a right-of-way for ditches or canals constructed by the authority of the United States in accordance with 43 U.S.C. 945, for lands being transferred out of Federal ownership.

2. The reservation to the United States of oil and gas in the lands being transferred out of Federal ownership.

3. All valid existing rights (e.g. rights-of-way, easements, and leases of record).

4. Value equalization by cash payment or acreage adjustment.

5. The exchange must meet the requirements of 43 CFR 4110.4–2(b).

Dated: May 11, 1984.

Bruce G. Whitmarsh,

Acting District Manager.

[FR Doc. 84–13682 Filed 5–21–84; 8:45 am]

BILLING CODE 4310–DN–M

Intent To Prepare a Planning Analysis for State of Mississippi

AGENCY: Bureau of Land Management, Interior.

ACTION: Planning start for the State of Mississippi.

SUMMARY: Notice is hereby given that the Jackson District of the Eastern States Office is starting the preparation of a Planning Analysis for the Federal Mineral Ownership (FMO) under BLM jurisdiction in Mississippi. A planning analysis, hereafter referred to as the Plan, consists of an environmental assessment or an environmental impact statement, if necessary, plus any other data and analysis necessary to make an informed decision. The product is a document developed upon the analysis, display, and documentation requirements of the CEQ regulations. It is used to assess the impacts of the proposal and to provide a basis for a decision on the proposal. It will be prepared in accordance with Bureau of Land Management Planning Regulations (43 CFR Part 1600).

Geographic Area of the Plan

The Plan will consider FMO in the State of Mississippi. It encompasses approximately 1,600 acres of public land and 660,000 acres of FMO under Federal, state and private surface.

Anticipated Issues

The Plan will address several issues on which public comment would be beneficial. One issue is whether certain lands presently under BLM jurisdiction should be transferred to other Federal, state, or local government agencies or non-profit organizations, sold to private parties, or retained under BLM jurisdiction and managed according to multiple use management principles.

Issues that will be addressed in the Plan include but are not limited to the following: (1) The need to protect various wildlife and plant species (including endangered species); (2) the extent of and possible development of mineral deposits; (3) the need to protect valuable cultural resources; and (4) the need to protect Floodplains and Wetlands.

Interdisciplinary Team

The Plan will be developed by a Bureau of Land Management Interdisciplinary Team (IDT) located in Jackson, Mississippi. The team includes a geologist, hydrologist, realty specialist, geographer, environmental coordinator, soil scientist, natural resource specialist, archaeologist, and administrative personnel. Additional support will be supplied by personnel of BLM's Eastern States Office.

Planning Process

The preparation of a Plan and the evaluation of its impacts includes the following steps:

(1) Identification of issues and action that gives Federal agencies and state and local governments an opportunity at the outset of the planning process to suggest concerns, needs and resource use, development and protection opportunities for consideration in the Plan.

(2) Development of planning criteria to guide the development of the Plan to ensure that it is tailored to the issues previously identified and to ensure that unnecessary data collection is avoided; to guide the analysis of the management situation; to assist in the design and formulation of alternatives; and to estimate the effects of alternatives.

(3) Inventory data and information collection (including resources, environmental, social, economic and institutional data).

(4) Analysis of the management situation to determine the capability of public land resources to respond to: needs, concerns and opportunities identified through public participation and coordination with other publics; issues defined earlier in the planning process; and national and State Director guidance.

(5) Formulation of management alternatives for the resources in the planning area.

(6) Estimation of the effects of the alternatives.

(7) Selection of a preferred alternative, which is incorporated into the draft plan and draft environmental document (ED).

(8) Selection of a Plan which becomes the proposed Plan and is accompanied by a final ED.

(9) Monitoring and evaluation of the Plan.

Public Participation

The planning process is flexible and designed to accommodate the unique situations caused by the widely scattered nature of BLM's ownership pattern and the variety of affected publics. The plan generally follows a "grass roots" approach to public involvement, using localized, one-to-one contacts and extensive direct mailings, as well as continual coordination with local, state and other Federal agencies. In addition, news releases will accompany the publication of the draft plan and environmental document (30-day review and comment period) in August 1984; the publication of the proposed plan and final environmental

document (which will trigger a 30-day opportunity for protest) in October 1984; and the final notice and comment (as necessary) on any changes made as a result of action on a protest. This schedule is tentative, and may be changed as the planning process unfolds. Complete records of all public participation will be available for public review at all times throughout the development of the Plan.

Address comments and requests to: District Manager, Jackson District Office, Bureau of Land Management, P.O. Box 11348, Jackson, Mississippi 39213.

Additional Information

For information about BLM Planning in Mississippi—to review planning maps and narratives or other information or to offer data or assistance—Contact: Ed Roberson, Jackson District Office, (601) 960–4405.

Donald L. Libbey,

District Manager.

[FR Doc. 84–13686 Filed 5–21–84; 8:45 am]

BILLING CODE 4310–GJ–M

Minerals Management Service

Outer Continental Shelf (OCS) Oil and Gas Information Program; Availability of Reports

SUMMARY: The OCS Information Program has published five documents in accordance with the OCS Lands Act Amendments of 1978 and 30 CFR 252.4:

Mid-Atlantic Summary Report (October 1983)
South Atlantic Summary Report (December 1983)
Gulf of Mexico Summary Report (September 1983)
Bering Sea Summary Report (September 1983)
Pacific Summary Report (September 1983).

The reports are syntheses of recent data concerning OCS leasing activities, including oil and gas resource estimates, magnitude and timing of offshore development, oil and gas transportation strategies, and nature and location of nearshore and onshore facilities.

The next revisions of the Mid-Atlantic and South Atlantic Summary Reports, along with the North Atlantic, will be combined into one revision for those three planning areas—the "Atlantic Summary Report." It is expected to be published in December 1984. Revisions of the Gulf of Mexico, Pacific, and Bering Sea Summary Reports are expected to be published in October, July, and September 1984, respectively. An Arctic Summary Report revision is expected in November 1984. Another update to the "Gulf of Alaska Summary Report—July "1982" is to be published in June 1984.

ADDRESSES: Copies of the reports may be obtained from the OCS Information Program, Minerals Management Service, 12203 Sunrise Valley Drive, MS–640, Reston, Virginia 22091.

FOR FURTHER INFORMATION CONTRACT: William S. Cook, Chief, OCS Information Program, Minerals Management Service, 12203 Sunrise Valley Drive, MS–640, Reston, Virginia 22091, (703) 860–7186.

Dated May 15, 1984.

John B. Rigg,

Associate Director for Offshore Minerals Management.

[FR Doc. 84–13683 Filed 5–21–84; 8:45 am]

BILLING CODE 4310–MR–M

Outer Continental Shelf (OCS) Oil and Gas Information Program; Availability of Third Editions of Atlantic, Pacific, Gulf of Mexico, and Alaska Indexes

SUMMARY: Third editions of Indexes to the Atlantic, Pacific, Gulf of Mexico, and Alaska OCS leasing Regions have been published by the Minerals Management Service, Department of the Interior. The indexes are published annually.

The Indexes follow the same format as prior editions and are continuous of relevant lease sale data that have accumulated since their respective publication dates.

The standard format presents detailed information on OCS minerals leasing activities and on the 5-year OCS oil and gas leasing schedule process. Four programs that generate, review, or report OCS-related data used on a continuous basis from prelease activities through production are also presented: MMS's geological and geophysical surveys and analyses, the Regional Technical Working Group, the Environmental Studies Program, and the OCS Oil and Gas Information Program.

Appendixes include a listing of Federal Agencies, a listing of State agencies, a listing of Federal depository libraries, and additional OCS-related information.

The annual revision of the next Atlantic Index is underway and is expected to be complete by July 1984.

ADDRESSES: Copies of the reports may be obtained from the OCS Information Program, Minerals Management Service, 12203 Sunrise Valley Drive, MS–640, Reston, Virginia 22091.

FOR FURTHER INFORMATION CONTACT: William S. Cook, Chief, OCS Information Program, Minerals Management Service, 12203 Sunrise Valley Drive, MS–640, Reston, Virginia 22091, (703) 860–7166.

Dated: May 15, 1984.

John B. Rigg,

Associate Director for Offshore Minerals Management.

[FR Doc. 84–13684 Filed 5–21–84; 8:45 am]

BILLING CODE 4310–MR–M

National Park Service

National Register of Historic Places; Notification of Pending Nominations

Nominations for the following properties being considered for listing in the National Register were received by the National Park Service May 11, 1984. Pursuant to section 60.13 of 36 CFR Part 60 written comments concerning the significance of these properties under the National Register criteria for evaluation may be forwarded to the National Register, National Park Service, U.S. Department of the Interior, Washington, DC 20243. Written comments should be submitted by June 6, 1984.

Carol D. Shull,

Chief of Registration, National Register.

FLORIDA

St. Lucie County

Ft. Pierce, *Casa Caprona*, 2805 St. Lucie Blvd.

INDIANA

Marion County

Indianapolis, *Holy Cross-Westminster Historic District*, Roughly bounded by Michigan, Randolph, Washington, Highland, and Pine Sts.

Wayne County

Centerville vicinity, *Jones, Lewis, House*, College Corner and Eliason Rds.

LOUISIANA

Orleans Parish

New Orleans, *Hart House*, 2108 Palmer Ave.

MARYLAND

Allegany County

Cumberland vicinity, *Big Bottom Farm*, Hazen Rd.
Baltimore (Independent City)
Hutzler Brothers Palace Building, 210–218 N. Howard St.
Riemen Block, 617–631 W. Lexington St.

Cecil County

St. Augustine vicinity, *Great House*, 284 Great House Farm Rd.

Charles County

La Plata vicinity, *Exchange, The*, Spring Hill-Newtown Rd.

Garrett County

Swanton, *Anderson Chapel*, Swanton Hill and Pine Hill Rds.

Kent County

Betterton, *Betterton Historic District*, Roughly bounded by Sassafras River, Gut Marsh, 6th, and Ericsson Aves.

Queen Annes County

Centreville vicinity, *Lansdowne*, MD 305

Somerset county

Princess Anne vicintiy, *White Hall*, Cooley Rd.

Washington County

Hagerstown, *Western Maryland Railway Steam Locomotive No. 202*, City Park

NEVADA

Washoe County

Reno, *Barengo Building (DeLongchamps, Frederic J., Architecture TR)*, 151 N. Sierra St.
Reno, *Bell Telephone of Nevada (DeLongchamps, Frederic J., Architecture TR)*, 100 N. Center St.
Reno, *California Apartments (DeLongchamps, Frederic J., Architecture TR)*, 45 California Ave.
Reno, *Frandsen, Andrew, Apartment Building (DeLongchamps, Frederic J., Architecture TR)*, 432 W. 4th St.
Reno, *Reno National Bank (DeLongchamps, Frederic J., Architecture TR)*, 204 N. Virginia St.
Reno, *Riverside Hotel (DeLongchamps, Frederic J., Architecture TR)*, 17 S. Virginia St.
Reno, *Washoe County Courthouse (DeLongchamps, Frederic J., Architecture TR)*, 117 S. Virginia St.

NEW HAMPSHIRE

Belknap County

Sanbornton, *Bay Meeting House and Vestry*, Upper Bay and Steele Rds.

Carroll County

Wakefield, *St. John's Church, Rectory, and Parish Hall*, High St.

Cheshire County

Marlow, *Jones Hall*, Church St.

Grafton County

Kent, Moses, House.

Hillsborough County

Goffstown, *Kennedy Hill Farm*, Kennedy Hill Rd.
Hudson, *Hills Memorial Library*, 16 Library St.
Lyndeborough Center, *Lyndeborough Center Historic District*, Center Rd.

Rockingham County

Portsmouth, *Franklin Block*, 75 Congress St.

Strafford County

Dover, *Black River Farm*, Bay View Rd.
Dover, *St. Thomas Episcopal Church*, 5 Hale St

NEW JERSEY

Bergen County

Fairlawn, *Radburn-Fair Lawn Station (Operating Passenger Railroad Stations TR)*, Pollitt Dr.
Hakensack, *Anderson Street Station (Operating Passenger Railroad Stations TR)*, Anderson St.
Hillsdale, *Hillsdale Station (Operating Passenger Railroad Stations TR)*, Broadway and Hillsdale Ave.
Oradell, *Oradell Station (Operating Passenger Railroad Stations TR)*, 400 Maple Ave.
Park Ridge, *Park Ridge Station (Operating Passenger Railroad Stations TR)*, Hawthorne and Park Ave.
Ridgewood, *Ridgewood Station (Operating Passenger Railroad Stations TR)*, Garber Sq.
Rutherford, *Rutherford Station (Operating Passenger Railroad Stations TR)*, Station Sq.

Cape May County

Ocean City, *Ocean City 34th Street Station (Operating Passenger Railroad Stations TR)*, 34 St.
Ocean City, *Ocean City Tenth Street Station (Operating Passenger Railroad Stations TR)*, Between 9th and 10th Sts.
Tuckahoe, *Tuckahoe Station (Operating Passenger Railroad Stations TR)*, Railroad Ave.

Essex County

Bloomfield, *Bloomfield Station (Operating Passenger Railroad Stations TR)*, Washington St. and Glenwood Ave.
East Orange, *Ampere Station (Operating Passenger Railroad Stations TR)*, Ampere Plaza and Whitney Pl.
East Orange, *Brick Church Station (Operating Passenger Railroad Stations TR)*, Brick Church Plaza
East Orange, *(Operating Passenger Railroad Stations TR)*, 65 City Hall Plaza
Montclair, *Watchung Avenue Station (Operating Passenger Railroad Stations TR)*, Park St.
Newark, *Newark Broad Street Station (Operating Passenger Railroad Stations TR)*, Broad and University Sts.
Orange, *Orange Station (Operating Passenger Railroad Stations TR)*, 73 Lincoln Ave.
South Orange, *Mountain Station (Operating Passenger Railroad Stations TR)*, 449 Vose Ave.
South Orange, *South Orange Station (Operating Passenger Railroad Stations TR)*, 19 Sloan St.
Upper Montclair, *Mountain Avenue Station (Operating Passenger Railroad Stations TR)*, 451 Upper Mountain ave.
Upper Montclair, *Upper Montclair Station (Operating Passenger Railroad Stations TR)*, 451 Upper Mountain Ave.
Upper Montclair, *Upper Montclair Station (Operating Passenger Railroad Stations TR)*, 275 Bellvue Ave.

Hunterdon County

White House, *White House Station (Operating Passenger Railroad Stations TR)*, Main St.

Mercer County

Hopewell, *Hopewell Station (Operating Passenger Railroad Stations TR)*, Railroad Pl.
West Trenton, *West Trenton Station (Operating Passenger Railroad Stations TR)*, Sullivan Way

Middlesex County

New Brunswick, *New Brunswick Station (Operating Passenger Railroad Stations TR)*, Eaton Ave. and Albany St.
Perth Amboy, *Perth Amboy Station (Operating Passenger Railroad Stations TR)*, Between Smith and Market Sts.

Monmouth County

Bradley Beach, *Bradley Beach Station (Operating Passenger Railroad Stations TR)*, Between LaReine and Brimley Aves.
Little Silver, *Little Silver Station (Operating Passenger Railroad Stations TR)*, Sycamore and Branch Aves.
Matawan, *Matawan Station (Operating Passenger Railroad Stations TR)*, Between Main and Atlantic Aves.

Morris County

Madison, *Madison Station (Operating Passenger Railroad Stations TR)*, Kings Rd.
Millington, *Millington Station (Operating Passenger Railroad Stations TR)*, Long Hill Rd.
Morris Plains, *Morris Plains Station (Operating Passenger Railroad Stations TR)*, Speedwell Ave.

Somerset County

Bernardsville, *Bernardsville Station (Operating Passenger Railroad Stations TR)*, U.S. 202
Bound Brook, *Bound Brook Station (Operating Passenger Railroad Stations TR)*, E. Main St.
Far Hills, *Far Hills (Operating Passenger Railroad Stations TR)*, U.S. 202
Gladstone, *Gladstone Station (Operating Passenger Railroad Stations TR)*, Main St.
Lyons, *Lyons Station (Operating Passenger Railroad Stations TR)*, Lyons Rd.
Raritan, *Raritan Station (Operating Passenger Railroad Stations TR)*, Anderson and Thompson Sts.

Union County

Elizabeth, *Elizabeth Station (Operating Passenger Railroad Stations TR)*, Morris Ave., and Broad St.
Murray Hill, *Murray Hill Station (Operating Passenger Railroad Stations TR)*, The Circle
Plainfield, *Netherwood Station (Operating Passenger Railroad Stations TR)*, Between North and South Aves.
Plainfield *Plainfield Station (Operating Passenger Railroad Stations TR)*, North Ave.

NEW YORK

Suffolk County

Northville, *Hallock Homestead*, 163 Sound Ave.

Westchester County

Port Chester, *Capitol Theater*, 147—151 Westchester Ave.

PENNSYLVANIA

Cumberland County

Shippensburg, *Shippensburg Historic District*, Roughly bounded by Lutz Ave., Kenneth, Spring, and Fort Sts.

Jefferson County

Brookville, *Brookville Historic District*, Roughly bounded by RR tracks, Franklin Ave., Church and Main Sts.

PUERTO RICO

Guayama, *Casa Cautino*, Vicente Pales Ares St.

TEXAS

Nolan County

Sweetwater, *Sweetwater Commercial Historic District*, Roughly between 1st and 5th, and Ash and Texas and Pacific RR tracks

WISCONSIN

Dale County

Madison, *Thompson's Block*, 119 E. Main St.
Mount Horeb vicinity, *Donald Farm*, 1972 WI92

Jefferson County

Fort Atkinson, *Maine Street Historic District*, Roughly Main St. from Sherman Ave. to S. 3rd St.

Manitowoc County

Newton vicinity, *Lutze Houseborn*, 13634 S. Union Rd.

Outagamie County

Appleton, *Washington School*, 818 W. Lorain St.

[FR Doc. 84-13658 Filed 5-21-84 8:45 am]
BILLING CODE 4310-70-M

INTERSTATE COMMERCE COMMISSION

[Finance Docket No. 30462]

Burlington, Cedar Rapids & Northern Railway Co.; Exemption

AGENCY: Interstate Commerce Commission.

ACTION: Notice of exemption.

SUMMARY: The Interstate Commerce Commission exempts (a) the operation by the Burlington, Cedar Rapids and Northern Railway Company of a 38.92-mile rail line between Burlington and Columbus Junction, IA, from the requirement of prior approval under 49 U.S.C. 10901, and (b) the issuance by the Burlington, Cedar Rapids and Northern Railway Company of $10 million in notes, $4 million in preferred stock, and $1 million in common stock from the requirement of prior approval under 49 U.S.C. 11301.

DATES: This exemption shall be effective on May 22, 1984. Petitions to reopen must be filed by June 11, 1984.

ADDRESSES: Send pleadings referring to Finance Docket No. 30462 to:

(1) Office of the Secretary, Case Control Branch, Interstate Commerce Commission, Washington, D.C. 20423
(2) Petitioner's representative: William C. Evans, Suite 1000, 1660 L Street NW., Washington, D.C. 20036.

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 full decision, write to T.S. InfoSystems, Inc., Room 2227, Interstate Commerce Commission, Washington, D.C. 20423, or call 289-4357 (DC Metropolitan area) or toll free (800) 424-5403.

Decided: May 14, 1984.

By the Commission, Chairman Taylor, Vice Chairman Andre, Commissioners Sterrett and Gradison.

James H. Bayne,

Secretary.

[FR Doc. 84-13666 Filed 5-21-84; 8:45 am]
BILLING CODE 7035-01-M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importation of Controlled Substances; Application

Pursuant to Section 1008 of the Controlled Substance Import and Export Act (21 U.S.C. 958(h)), the Attorney General shall, prior to issuing a registration under this Section to a bulk manufacturer of a controlled substance in Schedule I or II, and prior to issuing a regulation under Section 1002(a) authorizing the importation of such a substance, provide manufacturers holding registrations for the bulk manufacture of the substance an opportunity for a hearing.

Therefore, in accordance with § 1311.42 of Title 21, Code of Federal Regulations (CFR), notice is hereby given that on January 19, 1984, First State Chemical Company, Inc., 803 Fourth Street, Wilmington, Delaware 19801, made application to the Drug Enforcement Administration to be registered as an importer of the basic classes of controlled substances listed below:

Drug	Schedule
Raw Opium (9600)	II.
Concentrate of Poppy Straw (9670)	II.

As to the basic classes of controlled substances listed above for which application for registration has been made, any other applicant therefor, and any existing bulk manufacturer registered therefor, may file written comments on or objections to the issuance of such registration and may, at the same time, file a written request for a hearing on such application in accordance with 21 CFR 1301.54 in such form as prescribed by 21 CFR 1316.47.

Any such comments, objections or requests for a hearing may be addressed to the Deputy Assistant Administrator, Drug Enforcement Administration, United States Department of Justice, 1405 I Street, N.W., Washington, D.C. 20537, Attention: DEA Federal Register Representative (Room 1203), and must be filed no later than June 21, 1984.

This procedure is to be conducted simultaneously with and independent of the procedures described in 21 CFR 1311.42(b), (c), (d), (e) and (f). As noted in a previous notice at 40 FR 43745-46 (September 23, 1975), all applicants for registration to import a basic class of any controlled substance in Schedule I or II are and will continue to be required to demonstrate to the Deputy Assistant Administrator of the Drug Enforcement Administration that the requirments for such registration pursuant to 21 U.S.C. 958(a), 21 U,S.C. 823(a), and 21 CFR 1311.42(a), (b), (c), (d), (e) and (f) are satisfied.

Dated: May 11, 1984.

Gene R. Haislip,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 84-13583 Filed 5-21-84; 8:45 am]
BILLING CODE 4410-09-M

Manufacturer of Controlled Substances; Registration

By Notice dated February 21, 1984, and published in the **Federal Register** on February 28, 1984; (49 FR 7306), E.I. Du Pont De Nemours and Company, Inc., d.b.a., Du Pont Pharmaceuticals, Pharmaceuticals Chemical Facility, Chambers Works Building J-24, Deepwater, New Jersey 08023, made application to the Drug Enforcement Administration to be registered as a bulk manufacturer of the basic classes of controlled substances listed below:

Drug	Schedule
Oxycodone (9143)	II.
Hydrocodone (9193)	II.
Oxymorphone (9652)	II.

No comments or objections have been received. Therefore pursuant to Section 303 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 and Title 21, Code of Federal Regulations, § 1301.54(e), the Deputy Assistant Administrator hereby orders that the application submitted by the above firm for registration as a bulk manufacturer of the basic classes of controlled substances listed above is granted.

Dated: May 11, 1984.

Gene R. Haislip,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 84-13584 Filed 5-21-84; 8:45 am]

BILLING CODE 4410-09-M

Manufacturer of Controlled Substances; Application

Pursuant to Section 1301.43(a) of Title 21 of the Code of Federal Regulations (CFR), this is notice that on December 27, 1983, Knoll Pharmaceutical Company, 30 North Jefferson Road, Whippany, New Jersey 07981, made application to the Drug Enforcement Administration (DEA) for registration as a bulk manufacturer of the basic classes of controlled substances listed below:

Drug	Schedule
Dihydromorphine (9145)	I.
Hydromorphone (9150)	II.

Any other such applicant and any person who is presently registered with DEA to manufacture such substances, may file comments or objections to the issuance of the above application and may also file a written request for a hearing thereon in accordance with 21 CFR 1301.54 and in the form prescribed by 21 CFR 1316.47.

Any such comments, objections or requests for a hearing may be addressed to the Deputy Assistant Administrator, Drug Enforcement Administration, United States Department of Justice, 1405 I Street, NW., Washington, D.C. 20537, Attention: DEA Federal Register Representative (Room 1203), and must be filed no later than June 21, 1984.

Dated: May 11, 1984.

Gene R. Haislip,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 84-13582 Filed 5-21-84; 8:45 am]

BILLING CODE 4410-09-M

Office of Juvenile Justice and Delinquency Prevention

Restitution Education, Specialized Training, and Technical Assistance (RESTTA) Program

AGENCY: Office of Juvenile Justice and Delinquency Prevention (OJJDP), Justice.

ACTION: Notice of issuance of solicitation for applications to develop and implement a comprehensive juvenile restitution training, technical assistance and information dissemination program.

SUMMARY: The Office of Juvenile Justice and Delinquency Prevention (OJJDP), pursuant to Sections 242 and 244 of the Juvenile Justice and Delinquency Prevention Act of 1974, as amended, is sponsoring a comprehensive juvenile restitution training, technical assistance and information dissemination program.

Private not-for-profit and for-profit organizations are invited to submit applications which demonstrate the capability to develop and deliver training and technical assistance in juvenile restitution programming and to collect and disseminate information pertaining to juvenile restitution on a national basis.

OJJDP will select the applicant which best demonstrates the organizational capability, knowledge of and experience in the field of juvenile restitution programming, and experience in developing and delivering training and technical assistance in juvenile justice and delinquency prevention to coordinate and implement this program on a national level.

I. Problem Addressed

The traditional responses of the juvenile justice system have not proven to be effective deterrents to crime. Juvenile courts, probation services, and correctional facilities have not been able to provide the kind of individualized justice that is needed nor the accountability for the commission of criminal acts. Consequently, public confidence in the juvenile justice system has decreased.

This disillusionment with the system sparked an intense search for effective interventions to utilize with juvenile offenders. As a result of recent Federal initiatives and the general appeal of the concept, restitution has emerged as a significant dispositional alternative which effectively addresses offender accountability. OJJDP is sponsoring this training program to increase the use of and refine the approaches to restitution as an alternative disposition in juvenile courts. The effort is designed to acquaint key system personnel with a range of juvenile restitution program models which have been demonstrated as promising strategies in response to the problems of juvenile crime.

Restitution is far from a new concept; however, there is a need to educate juvenile justice system personnel concerning recent applications of the concept in selected sites and to assist jurisdictions in addressing potential legislative, administrative, and implementation issues associated with restitution programming.

II. Program Strategy

OJJDP is seeking an organization to develop and implement a comprehensive training, technical assistance and information dissemination program on juvenile restitution. This organization will be referred to in this solicitation as the National Restitution Training Coordinator. The program is designed to reach an optimum number of practitioners and decision-makers in a variety of training milieus and to offer varying levels of technical assistance to those with specific needs. The approach includes six interrelated components:

A. National seminars will be directed at a cross section of juvenile court personnel and service providers.

B. Mini-seminars will be presented at conferences for selected national and state professional organizations involved in juvenile justice.

C. Intensive training will be offered at six host sites, which will be identified and selected by the National Restitution Training Coordinator and OJJDP. The host sites will exemplify a range of program models for adjudicated delinquents:

1. Offender accountability;
2. Offender treatment/rehabilitation;
3. Victim reparation/assistance; and
4. Various combinations of the above.

Representative from each of the host sites will also make summary presentations on their respective program models at the national seminars.

D. A National Restitution Resource Center will be established within the National Criminal Justice Reference Service in Rockville, Maryland to collect and disseminate information,

documentation, and evaluation data on restitution programs throughout the United States. The data will be catalogued and corss-referenced so that information on all aspects of restitution programming will be readily available.

E. Technical assistance will be available through two mechanisms:

1. A voucher system will be established to enable jurisdictions to obtain technical assistance at the host sites or to obtain on-site assistance in their own jurisdiction from host-site staff or from qualified technical assistance providers of their choice. Telephonic technical assistance or referral, written materials on existing programs, and general programming information will be available through the National Restitution Resource Center upon request.

III. Program Goals and Objectives

A. Goals

1. To promote the use of restitution as a viable dispositional alternative in juvenile courts.

2. To provide at least 800 jurisdictions with state-of-the-art training and technical assistance necessary to initiate or refine juvenile restitution programs in their jurisdictions.

3. To provide and maintain the most current and comprehensive information on juvenile restitution issues and activities across the country.

B. Objectives

1. To conduct four national seminars of 120 participants each.

2. To identify and select six host sites representing a range of restitution models which will in turn conduct eight one-day seminars, each designed around their unique models for approximately 20 participants.

3. To provide follow-up technical assistance in implementing the models presented in the national seminars and at the host sites.

4. To conduct a minimum of 20 mini-seminars at conferences for selected national and state professional organizations involved in juvenile justice.

5. To coordinate with the National Restitution Resource Center in the collection and dissemination of restitution information.

6. To establish and implement a voucher system which will permit at least 500 jurisdictions to "purchase" technical assistance appropriate to their needs in amounts up to $1,000.

7. To develop and disseminate a comprehensive restitution programming and implementation guide, which will serve as a self-contained training resource to assist jurisdictions in implementing a juvenile restitution program.

IV. Responsibilities of the Successful Applicant as the National Restitution Training Coordinator

The National Restitution Training Coordinator will be ultimately responsible for the successful implementation and completion of all functions and activities of this project and for the development of all products, whether handled directly by the National Restitution Training Coordinator or contracted to appropriate organizations or individuals. This includes:

A. Activities and Functions

1. Developing all products for national consumption and dissemination;

2. Developing all training materials;

3. Recruiting and training faculty;

4. Planning and scheduling the national seminars and ensuring that restitution mini-seminars are included on the agendas of selected national conferences;

5. Developing and implementing a strategy to promote and publicize the program;

6. Developing a resource pool organized by specialization to deliver technical assistance;

7. Developing, managing, and monitoring a technical assistance voucher system;

8. Coordinating with the National Criminal Justice Reference Service in the development and implementation of a cross-referenced classification system for information on juvenile restitution programming and a program directory for use by the National Restitution Resource Center;

9. Identifying and selecting six host sites which exemplify the range of program models outlined in Section II.D.;

10. Delivering the national seminars, the specialized training workshops and the mini-seminars;

11. Monitoring the quality and impact of the training provided at the national seminars, mini-seminars, and host sites; and

12. Preparing and submitting all quarterly and final programmatic and financial reports and any special reports required by OJJDP.

B. Products

1. A comprehensive restitution programming and implementation guide must be developed which explains the underlying philosophy and rationale of the restitution concept and contains practical information and instructions relating to the organization, administration (including suggested staffing patterns and model forms), and monitoring of a restitution program.

In addition to serving as a training resource, the restitution programming guide will be available to any jurisdiction interested in implementing a restitution program, regardless of whether or not that jurisdiction sends staff to the RESTTA training. Consequently, this manual must be comprehensive enough to stand on its own.

2. Trainer's manuals for the national seminars which include detailed outlines of the lecture and workshop subjects, reference and resource materials, and teaching aids must be developed and structured in a manner which will enable any member of the faculty to present any lecture or workshop, if necessary.

3. Participants' guides for the national seminar series must be developed which include outlines of the topics to be addressed, resumes of the faculty, handouts, worksheets, and supplemental reading materials.

The followed products will be developed in conjunction with the National Restitution Resource Center.

4. Brochures and promotional materials which explain all aspects of the RESTTA Program must be developed and distributed.

5. A monthly training calendar must be developed and disseminated.

6. A technical assistance resource list organized by specialization which includes complete addresses and telephone numbers must be compiled.

7. A restitution program directory organized by state must be compiled and kept current.

V. Eligibility Requirements

Applications are invited from not-for-profit and for-profit organizations. For-profit organizations must waive any management fee or profit. Applicant organizations may choose to submit joint proposals with other organizations as long as one organization is designated in the application as the applicant and any co-applicants are designated as such. Together co-applicants must meet at least one of the eligibility requirements specified in A. and B. below.

The applicant must have experience in the following areas in order to be eligible for consideration:

A. The development/delivery of training or technical assistance in the design and implementation or the management and operations of national adult or juvenile justice related programs; or

B. Applied research or evaluation of adult or juvenile justice related programs and policies.

The applicant must have the management and financial capability to effectively implement a project of this size and scope. Applicants who fail to demonstrate that they have the capability to manage this program will be ineligible for funding consideration.

VI. Target Audience

The RESTTA Program is designed primarily for juvenile court personnel and other related public and/or private sector personnel from jurisdictions which intend to initiate a restitution program or wish to refine and improve a program already in operation. The training curricula are aimed at a cross section of key personnel, including judges, probation officers, prosecutors, counselors, and other service providers. Abbreviated versions of the program will also be developed and presented to selected national and state professional organizations involved in juvenile justice as parts of the agendas for their national conferences.

VII. Dollar Amount and Duration

A. One cooperative agreement will be awarded.

B. The period for the project is 24 months. It is anticipated that the first six months will be devoted to planning and materials development. Intensive training and technical assistance will be provided during the next 15 months. Follow-up technical assistance and the preparation of the final reports and documents necessary to conclude the project will be completed during the final three months of the project period.

C. The cooperative agreement will be awarded in an amount up to $1.4 million.

VIII. Application Requirements

All applicants must submit a completed Standard Form 424, Application for Federal Assistance (SF-424), including a program narrative, a detailed budget, and a budget narrative. All applications must include the following information in Part IV, Program Narrative. The Program Narrative shall not exceed 60 double-space pages in length, excluding appendices.

In submitting applications which contain more than one organization, the relationships among the parties must be set forth in the application. As a general rule organizations which describe their working relationship in the development of products and delivery of services as primarily cooperative/collaborative in nature will be considered as co-applicants. Those organizations which are primarily procuring services or products from another organization would not be considered co-applicants. In the event of co-applicants, one co-applicant must be designated as the payee to receive and disburse project funds. However, under this arrangement each organization would agree to be jointly and severally responsible for all project funds.

A. Applicant Capability

Applicants must demonstrate that they are eligible to compete for this cooperative agreement on the basis of the eligibility criteria established in Section V of this solicitation.

1. Organizational Experience

Applicants must concisely describe their organizational experience with programs or services as specified in Section V above.

2. Financial Capability

In addition to the assurances provided in Part V, Assurances (SF-424), applicants must also demonstrate that their organization has or can establish fiscal controls and accounting procedures which assure that Federal funds available under this agreement are disbursed and accounted for properly. A copy of the Office of Justice Assistance, Research and Statistics (OJARS) Accounting System and Financial Capability Questionnaire (OJARS Form 7120/1) is provided in the application kit and must be prepared and submitted along with the application. *All* questions are to be answered regardless of instructions (Section C.1.b. note). The CPA certification is required *only* of those applicants who have not previously received Federal funding.

B. Program Strategy and Goals

Applicants must describe their approach to the delivery of training and technical assistance and dissemination of information in relation to the purposes of this program. For example, this would include a brief discussion of how their training philosophy and methodology best achieve the objectives of this program in Section III.B.

C. Program Implementation Plan

Applicants shall describe how they will allocate the available resources to implement the RESTTA program.

1. Applicants must develop an implementation plan which addresses the activities and functions described in Section IV.A. of the solicitation, Responsibilities of the National Restitution Training Coordinator. The plan must include:

a. An annotated organizational chart depicting the roles and describing the responsibilities of key organizational/functional components; and

b. A list of key personnel responsible for managing and implementing the six major components of the program. Applicants must present detailed position descriptions, qualifications, and selection criteria for each position. This documentation and individuals' resumes may be submitted as appendices to the application.

c. A concise discussion of the coordination and administration issues related to the program design and how their program strategy would address these issues.

2. Applicants must present a concise discussion of the major substantive—i.e., legal, administrative and implementation—issues affecting the operations of juvenile restitution programs and indicate how these issues will be addressed in the development of products specified in Section IV. B.

3. Applicants must develop a time-task plan for the 24-month project period, clearly identifying major milestones. This must include designation of organizational responsibility and a schedule for the completion of the products identified in Section IV. B.

D. Program Budget

Applicants shall provide a 24-month budget with a detailed justification for all costs, including the basis for computation of these costs. Applications submitted by co-applicants and/or those containing contract(s) must include detailed budgets for each organization's expenses.

IX. Criteria for Selection

Applications will be rated based on the extent to which they meet the following weighted criteria. The criteria fall into three groups: the demonstrated capability to meet the goals of the project on the part of the organization applying; the quality of the staff chosen to direct the project, scored in conjunction with a review of staff position descriptions; and a project plan, including an organizational plan for project staff, a product development plan, a budget, and a budget narrative. The selection criteria will be consistently applied to all applications.

A. Organizational Capability (20 Points)

1. The extent and quality of organizational experience in the development, delivery, or coordination of adult or juvenile justice related training or technical assistance,

conferences, seminars, or meetings which have been national in scope or impact. Special consideration will be given to the demonstration of organizational experience in the coordination of involved governmental agencies or departments. (10 points)

2. The presence and extent of adequate fiscal controls and accounting procedures to ensure that the applicant can effectively implement a project of this size and scope, and to ensure the proper disbursal and accounting of Federal funds. (10 points)

B. Project Staff (45 Points)

1. The calibre of staff identified to manage and implement the program including staff to be hired through contracts. (30 points)

2. The clarity and appropriateness of position descriptions, required qualifications and selection criteria relative to the specific functions set out in the Implementation Plan. (15 points).

C. Program Implementation Plan (35 Points)

Applicants must demonstrate their understanding and ability to carry out the program design by providing a clear and concise Program Implementation Plan to carry out the functions and activities of the program. As specified in Section VIII. C, the Plan must address organizational, substantive coordination, administration and budget issues and must include the following components:

1. Organizational Plan: An annotated organizational chart explaining the roles and responsibilities of key personnel and organizational components, along with a time task plan for the 24-month project period, clearly identifying major milestones. (10 points)

2. Product Development and Program Strategy: Identification of the major substantive issues affecting juvenile restitution programming and the major coordination and administration issues affecting the program design and an explanation of how the former will be incorporated into the product development and how the latter will be addressed to assure effective implementation of the program design. (20 points)

3. Budget/Budget Narrative: Applicants must include a 24-month budget with a detailed narrative justifying the costs as specified in Section VIII. D. Applications will be rated based on the completeness, reasonableness and appropriateness of the budget in relation to the tasks and services to be provided. (5 points)

X. Deadline for Submission of Applications

One signed original and two copies of the application must be mailed or delivered to the Office of Juvenile Justice and Delinquency Prevention (OJJDP), Room 703, 633 Indiana Avenue, NW, Washington, D.C. 20531, by 5:30 p.m. on June 29, 1984. Applications mailed to the above address by certified or registered mail, return receipt, must be postmarked no later than June 29, 1984. Date of receipt is evidenced by the U.S. Postal Service postmark. The necessary forms for applications may be obtained by writing to OJJDP.

A Notification of Intent to apply for this program is included in the application kit. Organizations which intend to submit applications must return a completed Notification of Intent to OJJDP at the above address by June 8, 1984.

XI. Civil Rights Compliance

A. All recipients of OJJDP assistance must comply with:

1. Section 815(c) of the Justice System Improvement Act (JSIA) and its implementing regulations, found at 28 CFR 42.201, et. seq.;

2. Title VI of the Civil Rights Act of 1964, and its implementing regulation, found at 28 CFR 42.101, et seq.;

3. Section 504 of the Rehabilitation Act of 1973, as amended, and its implementing regulations;

4. The Age Discrimination Act of 1975, as amended, and its implementing regulations; and

5. Executive Order 12138, 44 FR 29637 (May 22, 1979), requiring recipients of Federal financial assistance to take appropriate affirmative action in support of women's business enterprise.

B. Each recipient of OJJDP assistance within the criminal justice system that has 50 or more employees and that has received grants or subgrants totaling $25,000 or more since the enactment of the Omnibus Crime Control and Safe Streets Act of 1968, as amended, and that has a service population with a minority representation of 3% or more is required to formulate, implement and maintain an Equal Employment Opportunity Program (EEOP). Where a recipient has 50 or more employees, and has received grants or representation of less than 3%, such recipient is required to formulate, implement and maintain an EEOP relating to employment practices affecting women. This requirement shall be satisfied prior to the award. An applicant for OJJDP assistance of $500,000 or more must submit its EEOP with the application. Rights Compliance prior to award. Failure to address this requirement will result in rejection of the proposal.

C. Applicants that do not meet any of the criteria in (2) above, educational institutions and private not-for-profit organizations shall maintain such records and submit to the OJJDP upon request timely, complete and accurate data establishing the fact that no person or persons will be or have been denied or prohibited from participation in, benefits of, or denied or prohibited from obtaining employment in connection with any program activity funded in whole or in part with funds made available under this program because of their race, national origin, sex, religion, handicap or age. In the case of any program under which a primary recipient of Federal funds extends financial assistance to any other recipient or contracts with any other person(s) or group(s), such other recipient, person(s) or group(s) shall also submit such compliance reports to the primary recipient as may be necessary to enable the primary recipient to assure its civil rights compliance obligations under any grant award.

Alfred S. Regnery,

Administrator, Office of Juvenile Justice and Delinquency Prevention.

[FR Doc. 84-13743, Filed 5-21-84; 8:45 am]

BILLING CODE 4410-18-M

National Institute of Justice

National Institute of Justice Advisory Board; Meeting

Notice is hereby given that the National Institute of Justice Advisory Board will hold meetings on June 7, 1984 from 9:00 A.M. to 5:00 P.M. and on June 8, 1984 from 9:00 A.M. to 12:00 P.M. at the Holiday Inn Alexandria Old Town Motel, 480 King Street, Alexandria, Virginia.

The major items of business will include a status report of FY 1984 funding activities, FY 1984 Advisory Board activities, and a panel presentation on the American Prosecutor: A View From Within.

The meeting is open to the public. For further information, please contact Betty M. Chemers, National Institute of Justice, U.S. Department of Justice, Washington, D.C. 20531 (202/724-2942).

Dated: May 14, 1984.

James K. Stewart,

Director, National Institute of Justice.

[FR Doc. 84-13674 Filed 5-21-84; 8:45 am]

BILLING CODE 4410-18-M

DEPARTMENT OF LABOR

Office of the Secretary

Labor Advisory Committee for Trade Negotiations and Trade Policy, Steering Subcommittee; Meeting

Pursuant to the provisions of the Federal Advisory Commitee Act (Pub. L. 92–463 as amended), notice is hereby given of a meeting of the Steering Subcommittee of the Labor Advisory Committee for Trade Negotiations and Trade Policy.

Date, time and place: June 12, 1984, 9:30 a.m., Rm. S4215 A & B Frances Perkins, Department of Labor Building, 200 Constitution Avenue NW., Washington, D.C. 20210.

Purpose: To discuss trade negotiations and trade policy of the United States.

This meeting will be closed under the authority of Section 10(d) of the Federal Advisory Committee Act. The Committee will hear and discuss sensitive and confidential matters concerning U.S. trade negotiations and trade policy.

For further information, contract: Fernand Lavalle, Executive Secretary, Labor Advisory Committee, Phone: (202) 523–6565. May 14, 1984.

Signed at Washington, D.C., this 14th day of May 1984.

Robert W. Searby,

Deputy Under Secretary International Affairs.

[FR Doc. 84–13746 Filed 5–21–84; 8:45 am]

BILLING CODE 4510–28–M

Employment and Training Administration

Investigations Regarding Certifications of Eligibility To Apply for Worker Adjustment Assistance; Forest City Foundries Co. et al.

Petitions have been filed with the Secretary of Labor under Section 221(a) of the Trade Act of 1974 ("the Act") and are identified in the Appendix to this notice. Upon receipt of these petitions, the Director of the Office of Trade Adjustment Assistance, Employment and Training Administration, has instituted investigations pursuant to Section 221(a) of the Act.

The purpose of each of the investigations is to determine whether the workers are eligible to apply for adjustment assistance under Title II, Chapter 2, of the Act. The investigations will further relate, as appropriate, to the determination of the date on which total or partial separations began or threatened to begin and the subdivision of the firm involved.

The petitioners or any other person showing a substantial interest in the subject matter of the investigations may request a public hearing, provided such request is filed in writing with the Director, Office of Trade Adjustment Assistance, at the address shown below, not later than June 1, 1984.

Interested persons are invited to submit written comments regarding the subject matter of the investigations to the Director, Office of Trade Adjustment Assistance, at the address shown below, not later than June 1, 1984.

The petitions filed in this case are available for inspection at the Office of the Director, Office of Trade Adjustment Assistance, Employment and Training Administration, U.S. Department of Labor, 601 D Street NW., Washington, D.C. 20213.

Signed at Washington, D.C., this 14th day of May 1984.

Marvin M. Fooks,

Director, Office of Trade Adjustment Assistance.

APPENDIX

Petitioner: Union/workers or former workers of—	Location	Date received	Date of petition	Petition No.	Articles produced
Forest City Foundries Co., Div. of Lamson & Sessions Co. (workers)	Cleveland, OH	5/8/84	5/1/84	TA–W–15–321	Iron, grey castings, aluminum.
Pierrette (ILGWU)	North Bergen, NY	5/1/84	4/26/84	TA–W–15,322	Blazers, ladies'.
Republic Steel Corp., Drainage Products (workers)	Canton, OH	5/23/84	4/23/84	TA–W–15,323	Pipe, culvert, liners, tunnel, seats, tractor, plate, angles, bands, barrier, sound, wall, terra.
Rodson Shipping, Inc. (workers)	Coral Gables, FL	5/1/84	4/23/84	TA–W–15,324	Manage vessels for transporting cargo from United States and other places.
Alongi Oldsmobile, Inc. (UAW)	Niagara Fall, NY	5/10.84	5/7/84	TA–W–15,325	Oldsmobile dealership.
C.M. Offray & Son, Inc. (workers)	Hughesville, PA	4/24/84	4/19/84	TA–W–15,326	Narrow fabrics, knitted items for interior decorating (ribbons, fringe, etc).
Fick Foundry Co. (workers)	Tocoma, WA	3/20/84	3/15/84	TA–W–15,327	Steel castings.

[FR Doc. 84–13744 Filed 5–21–84; 8:45 am]

BILLING CODE 4510–30–M

Determinations Regarding Eligibility To Apply for Worker Adjustment Assistance; Giddings and Lewis Machine Tool Co. et al.

In accordance with Section 223 of the Trade Act of 1974 (19 U.S.C. 2273) the Department of Labor herein presents summaries of determinations regarding eligibility to apply for adjustment assistance issued during the period May 7, 1984–May 11, 1984.

In order for an affirmative determination to be made and a certification of eligibility to apply for adjustment assistance to be issued, each of the group eligibility requirements of Section 222 of the Act must be met.

(1) That a significant number or proportion of the workers in the workers' firm, or an appropriate subdivision thereof, have become totally or partially separated,

(2) That sales or production, or both, of the firm or subdivision have decreased absolutely, and

(3) That increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

Negative Determinations

In each of the following cases the investigation revealed that criterion (3) has not been met. A survey of customers indicated that increased imports did not contribute importantly to worker separations at the firm.

TA–W–15,069; Giddings and Lewis Machine Tool Co., Fond du Lac, WI

TA–W–15,114; Selmer Co., Main Street Plant and Warehouse, Elkhart, IN

TA–W–15,096; Parts Distribution Center, International Harvester Co., Columbus, OH

Affirmative Determinations

TA–W–14,912; Village Industries, Inc., Garden City Park, NY

A certification was issued covering all workers separated on or after October 22, 1982 and before May 31, 1984.

TA–W–15,086; Phelps Dodge Brass Co., Los Angeles Tube Mill, Los Angeles, CA

A certification was issued covering all workers separated on or after October 24, 1982.

TA–W–15,058; Illinois Glove Co., Good Luck Div., Georgianna, AL

A certification was issued covering all workers separated on or after September 30, 1982.

TA–W–15,116; Farrel Co., Emhart Machinery Group, Ansonia and Derby, CT

A certification was issued covering all workers separated on or after December 16, 1983

TA–W–15,115; Winer Manufacturing Co., Hammond, IN

A certification was issued covering all workers separated on or after November 11, 1982.

TA–W–15,028; FMC Corp., Industrial Chemical Group, Modesto, CA

A certification was issued covering all workers engaged in employment related to the production of barium carbonate separated on or after September 22, 1982.

I hereby certify that the aforementioned determinations were issued during the period May 7, 1984–May 11, 1984. Copies of these determinations are available for inspection in Room 9120, U.S. Department of Labor, 601 D Street NW., Washington, D.C. 20210 during normal business hours or will be mailed to persons who write to the above address.

Dated: May 15, 1984.

Marvin M. Fooks,

Director, Office of Trade Adjustment Assistance.

[FR Doc. 84–13745 Filed 5–21–84; 8:45 am]

BILLING CODE 4510–30–M

LIBRARY OF CONGRESS

American Folklife Center Board of Trustees; Meeting

In accordance with Pub. L. 94–463, the Board of Trustees of the American Folklife Center announces its meeting to be held in Washington, D.C. on Friday, June 15, from 9:30 a.m. to 4:30 p.m. in the Wilson Room of the Library of Congress. The meeting will be open to the public. It is suggested that persons planning to attend this meeting as observers contact Eleanor Sreb, American Folklife Center (202) 287–6590.

The American Folklife Center was created by the U.S. Congress with passage of Pub. L. 94–201, the American Folklife Preservation Act, in 1976. The Center is directed to "preserve and present American folklife" through programs of research, documentation, archival preservation, live presentation, exhibition, publications, dissemination, training, and other activities involving the many folk cultural traditions of the United States. The Center is under the general guidance of a Board of Trustees composed of members from Federal agencies and private life widely recognized for their interest in American folk traditions and arts.

The Center is structured with a small core group of versatile professionals who both carry out programs themselves and oversee projects done by contract by others. In the brief period of the Center's operation it has begun energetically to carry out its mandate with programs that provide coordination, assistance, and model projects for the field of American folklife.

Raymond L. Dockstader,

Deputy Director, American Folklife Center.

[FR Doc. 84–13681 Filed 5–21–84; 8:45 am]

BILLING CODE 1410–01–M

NATIONAL CAPITAL PLANNING COMMISSION

Proposed Master Plan Submission Requirements

AGENCY: National Capital Planning Commission.

ACTION: Notice of availibility of proposed requirements.

SUMMARY: The Proposed Master Plan Submission Requirements list the contents and procedures for the submission of master plans for Federal installations in the National Capital Region and for District of Columbia installations. The proposed requirements are based on the Master Plan Submission Requirements used by the Commission since 1965. The principal changes relate to procedures and documentation required by laws enacted since that time.

DATE: Any interested persons or agencies may submit written comments on or before July 9, 1984.

ADDRESS: Copies of the proposed requirements may be obtained from and written comments should be addressed to: Daniel H. Shear, Secretary, National Capital Planning Commission, 1325 G Street NW., Washington, D.C. 20576, Telephone (202) 724–0170.

FOR FURTHER INFORMATION CONTACT: Robert E. Gresham, Director, Review and Implementation Division, National Capital Planning Commission, 1325 G Street NW., Washington, D.C. 20576, Telephone (202) 724–0170.

Daniel H. Shear,

Secretary to the Commission.

[FR Doc. 84–13669 Filed 5–21–84; 8:45 am]

BILLING CODE 7520–01–M

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

Inter-Arts Advisory Panel (Folk Arts Section); 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 Inter-Arts Advisory Panel (Folk Arts Section) to the National Council on the Arts will be held on June 6–7, 1984, from 9:00 a.m.–10:30 p.m.; on June 8, 1984, from 9:00 a.m.–5:30 p.m.; and on June 9, 1984, from 9:00 a.m.–3:30 p.m. in Room 730 of the Nancy Hanks Center, 1100 Pennsylvania Avenue, NW., Washington, D.C. 20506.

A portion of this meeting will be open to the public on June 9 from 10:30 a.m.–12:30 p.m. to discuss Policy Review.

The remaining sessions of this meeting on June 6–7 from 9:00 a.m.–10:30 p.m.; on June 8 from 9:00 a.m.–5:30 p.m.; on June 9 from 9:00 a.m.–10:30 a.m. and from 1:30 p.m.–3:30 p.m. 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. 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) 682–5433.

Dated: May 15, 1984.

John H. Clark,

Director, Office of Council and Panel Operations, National Endowment for the Arts.

[FR Doc. 84–13673 Filed 5–21–84; 8:45 am]

BILLING CODE 7537–01–M

President's Committee on the Arts and Humanities; Meeting

Plenary Meeting VI of the President's Committee on the Arts and the

Humanities will convene at 9:00 a.m. on Tuesday, June 12, 1984 in the Council Room, Nancy Hanks Center, 1100 Pennsylvania Avenue, NW., Washington, D.C. This is a regularly scheduled meeting at which committee activities will be reviewed and progress reported.

The Committee, charged with exploring ways to increase private support for the arts and the humanities, has generated private funds to augment their operational costs and to support projects and programs initiated by the President's Committee as well.

Agenda items on June 12 will include:

—A presentation by National Endowment for the Arts Chairman Hodsoll on the NEA Five Year Plan;
—A report on the tax proposals initiated by the President's Committee by Secretary Chapoton of the Treasury Department and Leonard Silverstein;
—A presentation on Libraries and Literacy by Vartan Gregorian, President, New York Public Library.

In addition, the following projects and programs will be reviewed: Community Foundations, Private Sector Action, Emerging Arts Institutions, National Clearinghouse for Shared Resources, Media and the Humanities, National Committee for the Humanities, Museum Sharing, National Medal of Art, New Alliances for Secondary Schools, Partnership of Presidents, Matching Gifts Program, International Exchange Program, and Leadership Conference on Arts Education, and other business. The meeting is expected to adjourn before lunch.

Please notify the President's Committee (202/682-5409 or 212/883-6764) if you wish to attend.

Dated: May 15, 1984.

John H. Clark,

Director, Office of Council and Panel Operations, National Endowment for the Arts.

[FR Doc. 84-13672 Filed 5-21-84; 8:45 am]

BILLING CODE 7537-01-M

NUCLEAR REGULATORY COMMISSION

Applications for Licenses to Export Nuclear Facilities or Materials

Pursuant to 10 CFR 110.70(b) "Public notice of receipt of an application" please take notice that the Nuclear Regulatory Commission has received the following applications for export licenses. Copies of the applications are on file in the Nuclear Regulatory Commission's Public Document Room located at 1717 H Street NW., Washington, D.C.

A request for a hearing or petition for leave to intervene may be filed within 30 days after publication of this notice in the **Federal Register.** Any request for hearing or petition for leave to intervene shall be served by the requestor or petitioner upon the applicant, the Executive Legal Director, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, the Secretary, U.S. Nuclear Regulatory Commission, and the Executive Secretary, U.S. Department of State, Washington, D.C. 20520.

In its review of applications for licenses to export production or utilization facilities, special nuclear materials or source material, noticed herein, the Commission does not evaluate the health, safety or environmental effects in the recipient nation of the facility or material to be exported. The table below lists all new major applications.

For the Nuclear Regulatory Commission

Dated this 16th day of May 1984, at Bethesda, Maryland.

James V. Zimmerman,

Assistant Director, Export/Import and International Safeguards, Office of International Programs.

NRC EXPORT AND IMPORT APPLICATIONS

Name of applicant, date of application, date received, application No.	Material type (percent)	Material in kilograms		End-use	Country of destination
		Total element	Total isotope		
Transnuclear, Inc., Apr. 26, 1984, Apr. 26, 1984, XSNMO2145.	3.30	24,405.9 enriched uranium.	871.395	For conversion of UF_6 to UO_2, and return to U.S. (for ultimate use as reload fuel for ASCO I).	United Kingdom.
Edlow International Co., Apr. 26, 1984, May 24, 1984, XSNMO2146.	3.65	13,327	487	Reload fuel for Takahama	Japan.
Transnuclear, Inc., May 7, 1984, May 8, 1984, XSNMO2028, Amend. #01.	4.0	Additional 23,655.000 enriched uranium.	Additional 721.200	Additional fuel for Forsmark I	Sweden.

[FR Doc. 84-13700 Filed 5-21-84; 8:45 am]

BILLING CODE 7590-01-M

[Docket Nos. 50-250 and 50-251]

Florida Power and Light Co., Issuance of Amendments to Facilities Operating Licenses and Final Determination of No Significant Hazards Consideration

The U.S. Nuclear Regulatory Commission (the Commission) has issued Amendment No. to Facility Operating License No. DPR-31, and Amendment No. to Facility Operating License No. DPR-41 issued to Florida Power and Light Company (the licensee), which revised Technical Specifications for operation of Turkey Point Plant, Unit Nos. 3 and 4 (the facilities) located in Dade County, Florida. The amendments are effective as of the date of issuance for Unit 3 and startup of Cycle 10 for Unit 4.

These amendments change the Technical Specifications to support the integrated program for vessel flux reduction to resolve the pressurized thermal shock issue and to take credit for operation with the new steam generators in an unplugged (maximum of five (5) percent tube plugging) configuration. The Technical Specification changes: (1) Increase the hot channel $F_{\Delta H}$ limit from 1.55 to 1.62; (2) increase the total peaking factor F_Q limit from 2.30 to 2.32; (3) change the overpower ΔT setpoints and thermal-hydraulic limit curves; and (4) delete restrictions and limits placed on the old steam generators which allowed operation with tubes plugged in excess of five percent.

The application for these 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 these license amendments.

Notice of Consideration of Issuance of Amendments and Proposed No Significant Hazards Consideration Determination and Opportunity for Hearing in connection with this action was published in the **Federal Register**

(48 FR 45862) on October 7, 1983. A request for a hearing was filed on November 7, 1983 by the Center for Nuclear Responsibility, Inc. and Joette Lorion.

Under its regulations, the Commission may issue and make an amendment immediately effective, notwithstanding the pendency before it of a request for a hearing from any person, in advance of the holding and completion of any required hearing, where it has determined that no significant hazards consideration is involved.

The Commission has applied the standards of 10 CFR 50.92 and has made a final determination that these amendments involve no significant hazards consideration. The basis for this determination is contained in the Safety Evaluation related to this action. Accordingly, as described above, these amendments have been issued and made immediately effective for Unit 3 and effective upon startup Cycle 10 for Unit 4 and any hearing will be held after issuance.

The Commission has determined that the issuance of the 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 the amendments.

For further details with respect to the action see (1) the application for amendments dated August 19, 1983, as supplemented September 9, 1983, September 20, 1983, October 4, 1983 and December 17, 1983 (2) Amendment Nos. and to Facility Operating License Nos. DPR–31 DPR–41 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 Environmental and Urban Affairs Library, Florida International University, Miami, Florida 33199. 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 23rd day of December, 1983.

For the Nuclear Regulatory Commission.

Steven A Varga,

Chief, Operating Reactors Branch No. 1, Division of Licensing.

[FR Doc. 84–13701 Filed 5–21–84; 8:45 am]

BILING CODE 7590–01–M

[Docket Nos. 50–424 OL, 50–425 OL; ASLBP No. 84–499–01 OL]

Georgia Power Co., el. al. (Vogtle Electric Generating Plant, Units 1 and 2); Conference

May 15, 1984.

Further Notice of Special Prehearing Conference

Notice is hereby given, pursuant to our Order of April 27,1984, that the special prehearing conference scheduled to commence May 30, 1984, and to continue through the following day, if necessary, will begin at 9:30 a.m. o'clock local time at the Richmond County Municipal Building, Room 315, 530 Green Street, Augusta, Georgia.

Dated at Bethesda, Maryland, this 15th day of May, 1984.

For the Atomic Safety and Licensing Board.

G. A. Linenberger,

Administrator Judge.

[FR Doc. 84–13702 Filed 5–21–84; 8:45 am]

BILLING CODE 7590–01–M

Advisory Committee on Reactor Safeguards, Subcommittee on Advanced Reactors; Meeting

The ACRS Subcommittee on Advanced Reactors will hold a meeting on June 13, 1984, Room 1167, 1717 H Street, NW., Washington, D.C. The Subcommittee will review NRC activities related to LMFBR research.

In accordance with the procedures outlined in the **Federal Register** on September 28, 1983 (48 FR 44291), oral or written statements may be presented by members of the public, recordings will be permitted only during those portions of the meeting when a transcript is being kept, and questions may be asked only by members of the Subcommittee, its consultants, and Staff. Persons desiring to make oral statements should notify the Designated Federal Employee as far in advance as practicable so that appropriate arrangements can be made to allow the necessary time during the meeting for such statements.

The entire meeting will be open to public attendance.

The agenda for subject meeting shall be as follows: *Wednesday, June 13, 1984—2:00 p.m. until the conclusion of business.*

During the initial portion of the meeting, the Subcommittee, along with any of its consultants who may be present, may exchange preliminary views regarding the topics to be discussed.

The Subcommittee will then hear presentations by and hold discussions with representatives of the NRC Staff, their consultants, and other interested persons regarding this review.

Further information regarding topics to be discussed, whether the meeting has been cancelled or rescheduled, the Chairman's ruling on requests for the opportunity to present oral statements and the time allotted therefor can be obtained by a prepaid telephone call to the cognizant Designated Federal Employee, Mr. Paul Boehnert (telephone 202/634–3267) between 8:15 a.m. and 5:00 p.m., e.d.t.

Dated: May 17, 1984.

John C. Hoyle,

Advisory Committee Management Officer.

[FR Doc. 84–13688 Filed 5–21–84; 8:45 am]

BILLING CODE 7590–01–M

Advisory Committee on Reactor Safeguards, Subcommittee on Regulatory Activities; Meeting

The ACRS Subcommittee on Regulatory Activities will hold a meeting on June 12, 1984 in Room 1046, 1717 H Street NW., Washington, D.C. The Subcommittee will review Regulatory Guide 1.35, Revision 3, "Inservice Inspection of Ungrouted Tendons in Prestressed Concrete Containments;" Regulatory Guide 1.35.1, "Determining Prestressing Forces for Inspection of Prestressed Concrete Containments;" and proposed general revisions to Appendix J to 10 CFR 50, "Leak Tests for Primary and Secondary Containments of Light-Water-Cooled Nuclear Power Plants."

In accordance with the procedures outlined in the **Federal Register** on September 28, 1983 (48 FR 44291), oral or written statements may be presented by members of the public, recordings will be permitted only during those portions of the meeting when a transcript is being kept, and questions may be asked only by members of the Subcommittee, its consultants, and Staff. Persons desiring to make oral statements should notify the Designated Federal Official as far in advance as practicable so that appropriate arrangements can be made to allow the necessary time during the meeting for such statements.

The entire meeting will be open to public attendance.

The agenda for subject meeting shall be as follows: *Tuesday, June 12, 1984—8:30 a.m. until the conclusion of business.*

The Subcommittee will hear presentations from the NRC Staff and will hold discussions with this group pertinent to the following:

(1) Regulatory Guide 1.35, Revision 3, "Inservice Inspection of Ungrouted Tendons in Prestressed Concrete Containments;"

(2) Regulatory Guide 1.35.1, "Determining Prestressing Forces for Inspection of Prestressed Concrete Containments;" and

(3) Proposed general revisions to Appendix J to 10 CFR 50, "Leak Tests for Primary and Secondary Containments of Light-Water-Cooled Nuclear Power Plants."

Other matters which may be of a predecisional nature relevant to reactor operation or licensing activities may be discussed following this session.

Persons wishing to submit written statements regarding Regulatory Guides 1.35, Revision 3, and 1.35.1 may do so by providing a readily reproducible copy to the Subcommittee at the beginning of the meeting. However, to ensure that adequate time is available for full consideration of these comments at the meeting, it is desirable to send a readily reproducible copy of the comments as far in advance of the meeting as practicable to Mr. Sam Duraiswamy, the Designated Federal Official for the meeting, in care of ACRS, Nuclear Regulatory Commission, Washington, DC 20555 or telecopy them to the Designated Federal Official (202/634-3319) as far in advance of the meeting as practicable. Such comments shall be based upon documents on file and available for public inspection at the NRC Public Document Room, 1717 H Street NW., Washington, DC 20555.

Further information regarding topics to be discussed, whether the meeting has been cancelled or rescheduled, the chairman's ruling on requests for the opportunity to present oral statements and the time allotted therefor can be obtained by a prepaid telephone call to the Designated Federal Official for this meeting, Mr. Sam Duraiswamy, (telephone 202/634-3267) between 8:15 a.m. and 5:00 p.m., e.d.t.

Dated: May 17, 1984.

John C. Hoyle,

Advisory Committee Management Officer.

[FR Doc. 84-13699 Filed 5-21-84; 8:45 am]

BILLING CODE 7590-01-M

OFFICE OF PERSONNEL MANAGEMENT

Excepted Service

AGENCY: Office of Personnel Management.

ACTION: Notice.

SUMMARY: This gives notice of positions placed or revoked under Schedules A, B, and C in the excepted service, as required by Civil Service Rule VI, Exceptions from the Competitive Service.

FOR FURTHER INFORMATION CONTACT: Tracy Spencer, 202-632-6000.

SUPPLEMENTARY INFORMATION: The Office of Personnel Management published its last monthly notice updating appointing authorities established or revoked under the Excepted Service provisions of 5 CFR Part 213 on April 24, 1984 (49 FR 17630). Individual authorities established or revoked under Schedules A, B, or C between April 1, 1984 and April 30, 1984 appear in a listing below. Future notices will be published on the fourth Tuesday of each month or as soon as possible thereafter. A consolidated listing of all authorities will be published as of June 30 of each year.

Schedule A

No Schedule A exceptions were established or revoked during April.

Schedule B

The following exceptions are established:

National Endowment for the Humanities

One Humanist Administrator, Humanities Projects in Media, Division of General Programs. Effective April 27, 1984.

One Humanist Administrator, Office of Challenge Grants. Effective April 27, 1984.

Schedule C

The following exceptions are established:

Department of Agriculture

One Confidential Assistant to the Assistant Secretary for Governmental and Public Affairs. Effective April 23, 1984.

One Confidential Assistant to the Administrator, Rural Electrification Administration. Effective April 24, 1984.

One Confidential Assistant to the Administrator, Cooperative State Research Service. Effective April 24, 1984.

One Confidential Assistant to the Deputy Secretary of Agriculture. Effective April 24, 1984.

Department of Commerce

One Special Assistant to the Secretary of Commerce. Effective April 19, 1984.

One Congressional Liaison Officer to the Director, Office of Congressional Relations, Economic Development Administration. Effective April 10, 1984.

One Director, Office of Congressional Relations, Economic Development Administration. Effective April 16, 1984.

One Special Assistant to the Assistant Administrator for Oceanic and Atmospheric Research, National Oceanic and Atmospheric Administration. Effective April 26, 1984.

Department of Defense

One Chauffeur of the Secretary of the Interior. Effective April 5, 1984.

Department of Education

One Secretary's Regional Representative to the Under Secretary in Dallas Texas, Office of the Under Secretary. Effective April 10, 1984.

One Special Assistant to the Secretary. Effective April 10, 1984.

One Special Assistant to the Deputy Assistant Secretary for Special Education and Rehabilitative Services. Effective April 13, 1984.

One Special Assistant to the Deputy Assistant Secretary for Operations, Office of Civil Rights. Effective April 16, 1984.

One Confidential Assistant to the Director, National Institute of Education. Effective April 16 1984.

One Confidential Assistant for Advisory Committees to the Executive Assistant to the Secretary. Effective April 17, 1984.

One Special Assistant to the Assistant Secretary, Office of Vocational and Adult Education. Effective April 24, 1984.

One Confidential Assistant to the Deputy Assistant Secretary for Public Affairs, Office of Legislation and Public Affairs. Effective April 24, 1984.

One Special Assistant to the Director, Intergovernmental Affairs Staff, Office of the Deputy Under Secretary for Intergovernmental and Interagency Affairs. Effective April 24, 1984.

One Special Assistant to the Deputy Under Secretary for Management. Effective April 27, 1984.

One Confidential Assistant to the Director, Intergovernmental Affairs Staff, Office of the Deputy Under Secretary for Intergovernmental and Interagency Affairs. Effective April 27, 1984.

One Confidential Assistant to the Deputy Under Secretary for Management. Effective April 27, 1984.

Department of Energy

One Special Assistant to the Assistant Secretary for Fossil Energy. Effective April 4, 1984.

One Staff Assistant to the Assistant Secretary for Management and Administration. Effective April 6, 1984.

One Secretary (Confidential Assistant) to the Deputy Secretary. Effective April 17, 1984.

One Legal Advisor to a Member, Federal Energy Regulatory Commission. Effective April 19, 1984.

One Director, Division of Congressional Liaison, Federal Energy Regulatory Commission. Effective April 19, 1984.

One Confidential Assistant (Secretary) to the Manager, Congressional Liaison Staff, Federal Energy Regulatory Commission. Effective April 19, 1984.

One Private Secretary to a Member, Federal Energy Regulatory Commission. Effective April 27, 1984.

Department of Health and Human Services

One Special Assistant to the Director, Office of Community Services. Effective April 16, 1984.

One Director, Public Affairs to the Regional Director, Region IX in San Francisco, California. Effective April 17, 1984.

One Director, Public Affairs to the Regional Director, Region VIII in Denver, Colorado. Effective April 17, 1984.

One Confidential Staff Assistant to the Secretary. Effective April 17, 1984.

One Director, Public Affairs to the Regional Director, Region II in New York, New York. Effective April 26, 1984.

Department of Housing and Urban Development

One Special Assistant to the Secretary. Effective April 13, 1984.

One Senior Assistant for Congressional Relations to the Deputy Assistant Secretary for Congressional Relations. Effective April 9, 1984.

One Executive Assistant to the Assistant Secretary for Fair Housing and Equal Opportunity. Effective April 9, 1984.

One Executive Assistant to the Deputy Assistant Secretary for Single Family Housing and Mortgage Activities, Office of Housing. Effective April 13, 1984.

One Special Assistant to the General Deputy Assistant Secretary for Housing/Federal Housing Commissioner, Office of Housing. Effective April 13, 1984.

One Special Assistant to the Assistant Secretary for Fair Housing and Equal Opportunity. Effective April 13, 1984.

One Senior Advisor for State Intergovernmental Relations to the Deputy Under Secretary for Field Coordination, Office of the Deputy Under Secretary for Intergovernmental Relations. Effective April 13, 1984.

One Associate Deputy Assistant Secretary for Multifamily Housing Programs, Office of Housing. Effective April 19, 1984.

One Staff Assistant to the President, Government National Mortgage Association. Effective April 20, 1984.

One Special Assistant to the Assistant Secretary for Community Planning and Development. Effective April 24, 1984.

Department of the Interior

One Special Assistant to the Counselor to the Secretary. Effective April 6, 1984.

One Special Assistant to the Congressional Liaison Officer, Bureau of Mines. Effective April 9, 1984.

One Special Assistant to the Director of Public Affairs, Office of the Secretary. Effective April 9, 1984.

One Special Assistant to the Counselor to the Secretary. Effective April 10, 1984.

One Confidential Assistant to the Deputy Solicitor, Office of the Solicitor. Effective April 19, 1984.

One Executive Assistant to the Under Secretary, Office of the Secretary. Effective April 24, 1984.

Department of Justice

One Special Assistant to the Deputy Assistant Attorney General, Civil Rights Division. Effective April 10, 1984.

One Special Assistant to the Deputy Assistant Attorney General for Legislation and Litigation, Civil Rights Division. Effective April 16, 1984.

One Special Assistant to the Assistant Attorney General, Office of Justice Assistance, Research and Statistics. Effective April 16, 1984.

Department of Labor

One Confidential Assistant to the Administrator, Pension and Welfare Benefit Programs. Effective April 6, 1984.

One Confidential Staff Assistant to the Administrator, Wage and Hour Division, Employment Standards Administration. Effective April 9, 1984.

One Staff Assistant to the Secretary of Labor. Effective April 9, 1984.

One Staff Assistant to the Deputy Assistant Secretary for Veterans' Employment and Training. Effective April 9, 1984.

One Regional Representative to the Deputy Under Secretary for Intergovernmental Relations in San Francisco, California. Effective April 13, 1984.

One Secretary (Typing) to the Regional Representative in Kansas City, Missouri. Effective April 13, 1984.

One Executive Assistant to the Deputy Under Secretary, Employment Standards Administration. Effective April 17, 1984.

One Special Assistant to the Deputy Under Secretary, Employment Standards Administration. Effective April 17, 1984.

One Assistant to the Deputy Under Secretary for Legislative Affairs. Effective April 24, 1984.

Department of State

One Foreign Affairs Officer (Protocol-Visits) to the Chief of Protocol, Office of the Chief of Protocol. Effective April 9, 1984.

One Special Advisor for Public Diplomacy to the Secretary of State. Effective April 10, 1984.

One Special Assistant to the Assistant Secretary for Human Rights and Humanitarian Affairs. Effective April 16, 1984.

One Director, Office of Intergovernmental and Public Liaison. Effective April 23, 1984.

One Congressional Liaison Officer to the Assistant Secretary for Legislative and Intergovernmental Affairs. Effective April 27, 1984.

Department of Transportation

One Receptionist to the Secretary. Effective April 9, 1984.

One Secretary (Typing) to the Coordinator for Minority Affairs. Effective April 9, 1984.

One Office Assistant to the Assistant Secretary for Public Affairs. Effective April 9, 1984.

One Staff Assistant to the Assistant Secretary for Public Affairs. Effective April 11, 1984.

One Special Assistant to the Administrator, Urban Mass Transportation Administration. Effective April 13, 1984.

One Research Assistant to the Director, Executive Secretariat. Effective April 17, 1984.

One Staff Assistant for Special Projects to the Administrator, Federal Aviation Administration. Effective April 24, 1984.

One Special Assistant to the Administrator, Federal Aviation Administration. Effective April 24, 1984.

Department of the Treasury

One Deputy Executive Secretary to the Executive Secretary. Effective April 9, 1984.

Administrative Office of the United States Courts

One Attorney-Adviser (Legislative) to the Legislative Affairs Officer. Effective April 19, 1984.

Commission on Civil Rights

One Confidential Assistant to a Commissioner. Effective April 18, 1984.

One Confidential Secretary to a Commissioner in New York, New York. Effective April 27, 1984.

Consumer Product Safety Commission

One Special Assistant (Legal) to a Commissioner. Effective April 24, 1984.

One Special Assistant to a Commissioner. Effective April 24, 1984.

Executive Office of the President

One Director for Public and Intergovernmental Affairs, United States Trade Representative. Effective April 2, 1984.

One Staff Assistant to the Associate Director, Office of Management and Budget. Effective April 9, 1984.

International Trade Commission

One Confidential Assistant to a Commissioner. Effective April 9, 1984.

One Staff Assistant (Economics) to a Commissioner. Effective April 19, 1984.

Office of Personnel Management

One Staff Assistant to the Deputy Director, Office of the Deputy Director. Effective April 13, 1984.

Pension Benefit Guaranty Corporation

One Secretary (Steno) to the Deputy Executive Director for Insurance Programs. Effective April 9, 1984.

Securities and Exchange Commission

One Secretary (Typing) to the Director of Economic and Policy Research. Effective April 10, 1984.

Small Business Administration

One Special Assistant to the Associate Administrator for Minority Small Business and Capital Ownership Development. Effective April 11, 1984.

One Assistant Administrator for Congressional and Legislative Affairs. Effective April 11, 1984.

One Special Assistant to the Regional Administrator in Dallas, Texas. Effective April 16, 1984.

One Special Assistant to the Regional Administrator in Philadelphia, Pennsylvania. Effective April 24, 1984.

One Special Assistant to the Regional Administrator in Philadelphia, Pennsylvania. Effective April 24, 1984.

One Special Assistant to the Regional Administrator in San Francisco, California. Effective April 26, 1984.

Office of Personnel Management.

Donald J. Devine,

Director.

[FR Doc. 84-13659 Filed 5-21-84; 8:45 am]

BILLING CODE 6325-01-M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 23308; (70-6855)]

Allegheny Power System, Inc.; Proposed Issuance and Sale of Common Stock Pursuant to Dividend Reinvestment and Stock Purchase Plan and Employee Stock Ownership and Savings Plan

May 16, 1984

Allegheny Power System, Inc. ("APS"), 320 Park Ave., New York, New York 10022, a registered holding company, has filed with this Commission a post-effective amendment to the declaration in this proceeding pursuant to sections 6(a) and 7 of the Public Utility Holding Company Act of 1935 ("Act") and Rule 50(a)(5) promulgated thereunder.

The proposed transaction involves the issuance from time to time by APA of not more than 3,000,000 shares of its authorized and unissued common stock, par value $2.50 per share ("Additional Common Stock") pursuant to its Dividend Reinvestment and Stock Purchasing Plan ("Dividend Plan") and its Employe Stock Ownership and Savings Plan ("ESOSP"). The ESOSP was formerly called the Tax Reduction Act Employee Stock Ownership Plan "TRASOP") and the Tax Credit Employee Stock Ownership Plan ("PAYSOP"). By order in this proceeding dated June 23, 1983 (HCAR No. 22985), APS was authorized to issue and sell an aggregate of 3,000,000 shares under the Dividend Plan and under the PAYSOP, of which 729,890 shares have been issued pursuant to the Dividend Plan and none pursuant to the PAYSOP as of March 31, 1984, the last date on which shares were issued under either of the Plans.

The post-effective amendment states that the PAYSOP, effective July 1, 1984, will become the ESOSP and will be comprised of a Stock Ownership Plan and a Savings Plan. The Stock Ownership Plan will be substantially identical in form and function to the PAYSOP. The savings Plan is entirely new and is intended to permit employees to provide for their future through tax deferred pre-tax contributions (which are partially matched by employer contributions of APS common stock) and post-tax contributions.

Under the Stock Ownership Plan, APS proposes to issue and sell the Additional Common stock to a trust created for the benefit of qualified employees of all system companies pursuant to the requirements of the Tax Reduction Act of 1975, as amended by the Tax Reform Act of 1976, the Economic Recovery Tax Act of 1981, and the Tax Equity and Fiscal Responsibility Act of 1982. The amount of employer contributions which may be made to the trust (and hence the value of shares of Additional Common Stock so issued) is determined by the applicable provisions of the Internal Revenue Code. In brief, contributions in respect of Plan years or portions thereof after December 31, 1982, are equal to varying percentages of Compensation (as defined) paid to Plan members less certain recaptured tax credits. Under the Savings Plan, APS proposes to issue and sell Additional Common Stock to the trust (or cash which shall be used to purchase APS common stock) at least quarterly in an amount equal in value to fifty percent of the members' pre-tax contributions under the Savings Plan. A member's pre-tax contributions are limited to no more than six percent of such member's Compensation (as defined), and such contributions and all employer contributions are further limited by Internal Revenue Code regulations. All costs of administration of the ESOSP, in excess of those allowed to be paid from contributions to the trust, will be paid by the APS companies. With respect to both plans, the shares of APS stock will be valued at a daily average of the closing prices published in the Wall Street Journal.

The amended declaration and any further amendments thereto are available for public inspection through the Commission's Office of Public Reference. Interested persons wishing to comment or request a hearing should submit their views in writing by June 13, 1984, to the Secretary, Securities and Exchange Commission, Washington, D.C. 20549, and serve a copy on the declarant at the address specified above. Proof of service (by affidavit or, in case of an attorney at law, by certificate) should be filed with the request. Any request for a hearing shall identify specifically the issues of fact or law that are disputed. A person who so requests will be notified of any hearing, if ordered, and will receive a copy of any notice or order issued in this matter. After said date, the declaration, as now amended or as it may be further amended, may be permitted to become effective.

For the Commission, by the Office of Public Utility Regulation, pursuant to delegated authority.

George A. Fitzsimmons,

Secretary.

[FR Doc. 84-13738 Filed 5-21-84; 8:45 am]

BILLING CODE 8010-01-M

[Release No. 13945; (812-5004)]

Hutton Investment Series Inc.; Application for an Order Pursuant to Section 6(c) of the Act Amending an Existing Order Granting Exemptions From the Provisions of Sections 2(a)(32), 2(a)(35), 2(a)(41), 22(c), and 22(d) of the Act, and Rules 2a-4 and 22c-1 Thereunder

May 16, 1984.

Notice is hereby given that Hutton Investment Series Inc. ("Applicant"), One Battery Park Plaza, New York, New York 10004, registered under the Investment Company Act of 1940 ("Act") as an open-end, diversified, management investment company of the series type, filed an application on March 20, 1984, for an order pursuant to section 6(c) of Act, granting additional relief from section 22(d) of the Act by amending an existing order of the Commission which, as amended, exempts Applicant, pursuant to section 6(c) of the Act, from the provisions of sections 2(a)(32), 2(a)(35), 2(a)(41), 22(c), and 22(d) of the Act, and Rules 2a-4 and 22c-1 thereunder, and thereby permits Applicant (1) to value the assets of its Short Term Investment Series (Applicant presently issues shares in six series—the Short Term Investment Series, the Growth Series, the Bond and Income Series, the Emerging Growth Series, the Option Income Series and the Government Securities Series) (individually, "Series") pursuant to the amortized cost method of valuation, and (2) to impose a contingent deferred sales charge upon redemption of its shares under certain circumstances and subject to certain waiver provisions. All interested persons are referred to the application on file with the Commission for a statement of the representations contained therein, which are summarized below, and to the Act for the text of the applicable statutory provisions.

Applicant's general operations, its use of amortized cost valuation, its distribution financing plan established pursuant to Rule 12b-1 under the Act, and the contingent deferred sales charges imposed upon its shares at redemption, are described in Investment Company Act Release No. 12079 (December 4, 1981), and permitted by an order issued January 4, 1982 (Investment Company Act Release No. 12135). These provisions were modified pursuant to an order issued November 9, 1982 (Investment Company Act Release No. 12798), which permitted Applicant to waive contingent deferred sales charges with respect to redemption of its shares following the death or disability (as defined in section 72(m)(7) of the Internal Revenue Code of 1954 of a shareholder, or accompanying certain distributions from an individual retirement account or other tax-qualified retirement plan (for a further description of these modifications, see Investment Company Act Release No. 12729, October 13, 1982).

Applicant requests an order amending the aforesaid existing order and extending its exemption from section 22(d) of the Act to the extent necessary to permit an additional waiver of contingent deferred sales charges in respect of periodic redemption payments pursuant to a Systematic Withdrawal Plan ("Plan") which Applicant proposes to offer its shareholders. Applicant believes that many of its shareholders would be attracted by the opportunity to receive automatic redemption payments on a regularly scheduled basis. Applicant notes that a substantial number of competing mutual funds offer some form of systematic withdrawal plan.

Applicant states that because contingent deferred sales charges apply to redemptions which reduce the value of the shareholder's account below his aggregate purchase payments (within the last six years), a shareholder may, in effect, redeem any increases in value (through reinvestment of income or capital gain dividends, or increases in per share net asset value), as well as the entire amount of purchases made more than six years previously, without paying any contingent deferred sales charge. However, a sharholder wishing to receive regular payments from Applicant without paying contingent deferred sales charges could elect to receive cash dividends (which are not subject to the charge but which are paid only at quarterly intervals (annually, in the case of Applicant's Emerging Growth Series), and/or monitor fluctuations in the value of his account—and periodically redeem amounts reflecting any increases in the value of his account. The disadvantage of this alternative would be, Applicant states, that, due to usual fluctuations in Applicant's shares, specific amounts could not be redeemed at regular intervals with certainty that contingent deferred sales charges would not be imposed with respect to certain redemptions. In order to remove this uncertainty, and to provide the convenience of automatic redemptions, Applicant proposes to establish its Systematic Withdrawal Plan, pursuant to which contingent deferred sales charges would be waived in respect of all redemptions pursuant to the Plan.

In accordance with the Plan as proposed, a shareholder having an account of a value of $10,000 or more could elect to receive periodic redemption payments, either to himself or a designated payee, on a monthly, quarterly, or annual basis. Such payments normally would be made within the first seven days of each month. The minimum rate of withdrawal would be $100 per month and the maximum annual withdrawal would be 12% of current account value as of the date the shareholder's participation in the Plan begins (minus the amount of any subsequent redemptions outside the Plan or exchange out of a particular series). A participant in the Plan would be required to reinvest all income and capital gain distributions, and would not be eligible to continue to participate if he redeems shares other than pursuant to the Plan, or exchanges to a different Series, in an amount which causes his account value in the Series from which the redemption or exchange is made to fall below $10,000. Applicant could amend or terminate the Plan, and a shareholder could terminate participation in the Plan at any time. Applicant proposes that any contingent deferred sales charges which might otherwise be applicable to redemptions made in accordance with the Plan be waived. However, any contingent deferred sales charges otherwise applicable would be imposed as to any redemptions outside the Plan, and for that purpose, Plan redemptions would be deemed to have been made from the most recent purchase payments.

In support of the relief requested, Applicant asserts that in the case of the more common "up-front" sales charges which are deducted from investment company share purchases prior to investment of the net amount, the Commission has adopted rules and issued orders granting individual exemptions to permit elimination of or reductions in the sales load on the basis of differences in costs and services, or considerations of basic fairness, national economic policy, or sound business practice.

Applicant asserts that the Plan has been structured so that, over time, the aggregate amounts redeemed without charge pursuant to the Plan should not exceed amounts which could have been

redeemed directly without charge, were it not for usual fluctuations in investment performance (Applicant further states that because of performance fluctuation, no assurance can be given that Applicant's projections as to redemption experience pursuant to the Plan will materialize). However, to the extent amounts redeemed pursuant to the Plan do not exceed increases in account value over time, Applicant contends that there would be no difference in treatment between shareholders electing to participate in the Plan and those not participating. In addition, all shareholders meeting minimum account requirements would be eligible to participate in the Plan. It is further asserted that operation of the Plan would not impose additional costs on Applicant or its shareholders; for example, there would be no transfer agent charges relating to the Plan (the Plan bears such incidental costs—postage, for example—as it would bear with respect to any redemptions).

Thus, Applicant contends that the proposed waiver of contingent deferred sales charges on redemptions made pursuant to the Plan would be consistent with sound business practice, fair, and consistent with the best interests of its shareholders. Waiver of contingent deferred sales charges under the Plan would not harm Applicant, or non-participating shareholders, or unfairly discriminate among shareholders or investors, Applicant concludes. In light of the foregoing, Applicant submits that amendment of the above-described existing exemptive order, to provide additional relief from the provisions of section 22(d) of the Act to permit Applicant to waive contingent deferred sales charges in connection with its proposed Systematic Withdrawal Plan would be appropriate and in the public interest, and consistent with the protection of investors, and consistent with the purposes fairly intended by the policy and provisions of the Act.

Notice is further given that any interested person wishing to request a hearing on the application may, not later than June 11, 1984, at 5:30 p.m., do so by submitting a written request setting forth the nature of his/her interest, the reasons for the 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 address stated above. Proof of service (by affidavit or, in the case of an attorney-at-law, by certificate) shall be filed with the request. 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. 84-13739 Filed 5-21-84; 8:45 am]

BILLING CODE 8010-01-M

[Release No. 13946; (812-5801)]

Sears Fixed Income Investment Trust (and Subsequent Trusts and Similar Series of Trusts) and Dean Witter Reynolds, Inc.; Filing of Application Pursuant to Section 45(a) of the Act for an Order Granting Confidential Treatment

Notice is hereby given that Sears Fixed Income Investment Trust ("Sears"), registered under the Investment Company Act of 1940 (the "Act"), as a unit investment trust, and all subsequent series and similar series of trusts, and their sponsor, Dean Witter Reynolds, Inc., Unit Investment Trust Department, 5 World Trade Center, New York, NY 10048, ("Sponsor," collectively with Sears, the "Applicants") filed an application on March 20, 1984, for an order, pursuant to section 45(a) of the Act, granting confidential treatment for profit and loss statements of the Sponsor filed with the Commission from time to time in connection with registration statements of Sears and all subsequent series and similar series of trusts. All interested persons are referred to the application on file with the Commission for a statement of the representations contained therein, which are summarized below, and to the Act and the rules thereunder for the provisions thereof which are relevant to a consideration of the application.

The order requested will apply to Sears and subsequent series and similar series of trusts sponsored by the Sponsor (collectively, the "Trust"). According to the application, "subsequent trusts" will meet the description of the Trusts in the application, whereas "similar trusts" will be structured the same but may contain different types or maturities of debt obligations and, in some cases, units of previously issued series of trusts. Applicants state that the Trusts will be governed by a trust indenture and a Standard Terms and Conditions of Trust for that Trust (the "Trust Agreement") under which the Sponsor will act as depositor, United States Trust Company of New York will act as trustee, and Interactive Data Services, Inc., will act as evaluator.

According to the application, the Trust Agreement for each Trust will incorporate standard terms and conditions of trust common to all Trusts. Pursuant to the Trust Agreement, when the portfolio for the Trust has been acquired, the Sponsor will deposit with the Trustee interest-bearing bonds, notes, debentures, certificates of deposit, commercial paper, and other obligations of the United States, its agencies or instrumentalities, foreign or domestic corporations, and other entities and, in some cases, previously issued series of Trusts (collectively, "Portfolio Securities"). Simultaneously with such deposit, the Trustee will deliver to the Sponsor registered certificates for the requisite number of units that will represent the entire beneficial ownership of the Trust at the date of deposit. The Portfolio Securities will not be pledged or be in any other way subjected to any debt at any time after the Portfolio Securities are deposited in the Trust. The Sponsor will accumulate the Portfolio Securities for deposit in Sears and will follow a similar procedure for each future trust. In selecting the Portfolio Securities, the following factors are considered: (1) a rating of no less than "A" from a nationally recognized rating organization or, if unrated, comparable characteristics; (2) maturities or mandatory payment dates consistent with the life of the Trust; (3) prices of the Securities relative to other securities of comparable quality and maturity; and (4) diversification of the Securities as to purpose and location of the issuer.

Applicants state that the portfolio of each Trust will consist of the Portfolio Securities, together with accrued and undistributed interest and principal and undistributed cash realized from the sale, redemption, prepayment, maturity or other disposition of the Portfolio Securities. Applicants state that the Sponsor may, under the Trust Agreement, direct the trustee to sell or liquidate any of the Securities only upon the happening of specific events including, among others, (i) default in the payment of principal or interest; (ii) institution of legal proceedings involving such Portfolio Securities; (iii) a breach of covenant or warranty which could adversely affect the payment of debt service on the Portfolio Securities; and (iv) default in the payment of principal or interest on any other outstanding obligations of the same issuer. Applicants represent that the proceeds from the disposition of Portfolio

Securities will not be reinvested but will be distributed to unitholders unless the Trust has elected to qualify as a regulated investment company under the Internal Revenue Code.

Applicants represent that each unit in a particular Trust will represent a fractional undivided interest in the principal amount of Portfolio Securities in the Trust. The numerator of the fractional interest represented by each unit will be 1 and the denominator equal to the number of units of the Trust then outstanding. Units of each Trust will be redeemable. In the event that any units shall be redeemed, the denominator of the fraction will be reduced and the fractional undivided interest represented by such unit decreased. Units will remain outstanding until redeemed or until the termination of the Trust Agreement as provided therein. The Trust Agreement may be terminated (i) by the written consent of 51% of unitholders of the Trust, (ii), in the event that the last of the Portfolio Securities then currently in the portfolio of the Trust has matured or has been redeemed or sold upon direction of the Sponsor to the Trustee, or (iii) automatically on a date specified in the Trust Agreement, not to exceed 50 years after the date of deposit. In addition, the Trust may be terminated, upon written instruction of the Sponsor, if the value of the Trust falls below a percentage of the par value of the Portfolio Securities initially deposited in the portfolio, as specified in the Trust Agreement.

According to the application, following the deposit of Portfolio Securities for each Trust by the Sponsor with the trustee, and following the declaration of effectiveness of the registration statement of that Trust under the Securities Act of 1933 and clearance by the securities authorities of various states, the Sponsor will offer the units of that Trust to the public at the public offering price set forth in its prospectus, plus accrued interest. Applicants represent that, while not obligated to do so, the Sponsor intends to maintain a market for the units of each series of Sears and subsequent series and similar series of Trusts, and to continually offer to purchase such units at prices, subject to change at any time, based on the aggregate of the then current offering prices of the Portfolio Securities in the Trust as computed by the evaluator.

According to Applicants, if the supply of units exceeds demand, or for other business reasons, the Sponsor may discontinue purchases of units at prices based on the offering prices of the Portfolio Securities. In such event the Sponsor may discontinue purchases of units at prices based on the offering prices of the Portfolio Securities. In such event the Sponsor may nonetheless purchase units, as a service to unitholders, at a price based on the then current redemption value of those units. In no event will the price offered by the Sponsor for repurchase of units be less than the current redemption value. If the Sponsor purchases any units at the current redemption value as set forth above, it may not resell such units or re-offer such units, but may tender such units to the Trustee for redemption. Upon completion of the initial public offering of units, the Sponsor from time to time, for its own account, may offer units acquired by it in the over-the-counter market or otherwise, at a public offering price determined as of the close of business on the last business day of the preceding week as of the evaluation time as set forth in the Trust Agreement.

Applicants request confidential treatment of the Sponsor's profit and loss statements pursuant to section 45(a) of the Act. Applicants assert that public disclosure of these profit and loss statements is neither necessary nor appropriate in the public interest or for the protection of investors. According to the application, investors in the Trust are not offered an opportunity to acquire any interest in the Sponsor. Apart from the Sponsor's obligation under the Trust Agreement to recommend the disposition of underlying Portfolio Securities for the reasons set forth above (which obligations may be performed by the trustee or successor Sponsor if not performed by the current Sponsor), the Sponsor functions solely as an underwriter of the Trusts. Applicants state that there is no legitimate interest on the part of the investors in the public disclosure of the profit and loss statements of the underwriters from whom the units are purchased. Applicants further state that, to the extent that the Sponsor's solvency may be relevant to the maintenance of the secondary market in the units of the Trusts, the Sponsor's statement of financial condition which is filed with the Commission and various stock exchanges and is readily available to the public contains fully adequate information in this regard. Applicants also state that there is adequate disclosure in the Trusts' prospectuses of the Sponsor's right to terminate secondary market activities in a particular Trust. Unitholders are nevertheless fully protected by their right under the Trust Agreement to redeem their units upon presentation of such units properly endorsed to the trustee. According to Applicants, the unitholders will receive the redemption value of the units computed on the underlying assets of the particular Trust.

Notice is further given that any interested person wishing to request a hearing on the application may, not later than June 11, 1984, at 5:30 p.m., do so by submitting a written request setting forth the nature 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 address stated above. Proof of service (by affidavit or, in the case of an attorney-at-law, by certificate) shall be filed with the request. 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. 84-13740 Filed 5-21-84; 8:45 am]

BILLING CODE 8010-01-M

[Release No. 20962; (File No. SR-CBOE-84-10)]

Chicago Board Options Exchange, Inc.; Order Approving Proposed Rule Change

May 15, 1984.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act"), 15 U.S.C. 78s(b)(1), and Rule 19b-4 thereunder, the Chicago Board Options Exchange, Incorporated ("CBOE") LaSalle at Van Buren, Chicago, IL 60605, submitted on March 12, 1984, a proposed rule change to adopt new CBOE Rule 3.23, authorizing CBOE to implement an Integrated Billing System ("IBS").[1] Under the new rule, CBOE members would be required to designate an Options Clearing Corportation ("OCC") member for the payment of monthly Exchange invoices through the IBS. The Commission solicited comments on this proposal, but received none.

Currently, CBOE Exchange members pay their monthly Exchange invoices individually. Under CBOE's new Rule 3.23, the designated clearing member

[1] Notice of the terms of substance of the proposed rule change were published in Securities Exchange Act Release No. 20810 (April 2, 1984), 49 FR 13933 (April 9, 1984).

would pay the Exchange member's monthly undisputed bills to the Exchange with funds from the clearing member's account with OCC. The clearing member would submit a check to the Exchange after the Exchange informs the clearing member of the total amount that the clearing members, as designee for certain Exchange members, owes the Exchange. As stated in the new rule, OCC would not incur liability in connection with the clearing member's responsibility to forward monthly checks to CBOE in the amount the Exchange represents is owed to it by the clearing member. New CBOE Rule 3.23 is intended to streamline CBOE's monthly billing and collection procedures by reducing the number or organizations involved in the collection process.

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to national securities exchanges. In particular, the Commission finds that the proposal is consistent with section 6(b)(4) of the Act, which requires that the rules of the Exchange provide for the equitable allocation of reasonable dues, fees, and other charges among its members.

It is therefore ordered, pursuant to section 19(b)(2) of the Act, that the above-mentioned proposed rule change be, and hereby is, approved.

For the Commission, by the Division of Market Regulation pursuant to delegated authority.

George A. Fitzimmons,

Secretary.

[FR Doc. 84-13736 Filed 5-21-84; 8:45 am]

BILLING CODE 8010-01-M

[Release No. 20963; (SR-CBOE-80-16)]

Chicago Board Options Exchange, Inc.; Order Extending Partial Approval of Proposed Rule Change on a Summary and Temporary Basis

May 15, 1984.

I. Introduction

On June 9, 1980, the Chicago Board Options Exchange, Incorporated ("CBOE"), LaSalle at Van Buren, Chicago, IL 60605, filed with the Commission, pursuant to the Securities Exchange Act of 1934 (the "Act") and Rule 19b-4 thereunder, copies of a proposed rule change to modify its operations and procedures relating to options market makers. Among other things, the proposed rule change created a single class of market makers by eliminating supplemental appointments, increased the number of options classes in which market makers were permitted to have appointments, and established a new Exchange committee responsible for evaluating the performance of and taking disciplinary action against market makers. The proposed rule change also prescribed minimum requirements concerning the extent to which a market maker's trading activity must be conducted in person.[1] The rule change was approved by the Commission on February 12, 1981,[2] but the 1981 approval order was vacated on April 5, 1982, by the United States Court of Appeals for the Seventh Circuit in *Clement* v. *Securities and Exchange Commission*, an action challenging the minimum requirement for in-person market maker transactions, and the matter was remanded to the Commission.[3]

On May 11, 1982, with extensions thereafter effective until April 13, 1984, the Commission reviewed the rule filing and summarily and temporarily approved those portions of the proposed rule change not addressed in *Clement*.[4] During this interval, the Commission awaited certain amendments to the proposal and additional information from CBOE.[5] The Commission also solicited and evaluated public comment upon the proposed rule change.[6]

Further information has been received from the CBOE concerning the impact of CBOE's previous in-person requirement prior to that requirement's elimination by *Clement* v. *Securities and Exchange Commission*.[7] The Commission expects to act soon with respect to the proposed in-person rule. In the interim, it will be necessary for the Commission to extend for an additional 30 days its summary and temporary approval of those portions of the proposed rule change not at issue in *Clement*.[8]

Copies of the original submission, all subsequent amendments, allwritten 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 persons, other than those which may be withheld from the public in accordance with the provisions of 5 U.S.C. § 552, wil 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 CBOE.

It is therefore ordered, that the proposed rule change referenced above, and to the extent indicated above, be, and it hereby is, approved until June 14, 1984.

For the Commission, by the Division of Market Regulations pursuant to delegated authority.

George A. Fitzsimmons,

Secretary.

[FR Doc. 84-13735 Filed 5-21-84; 8:45 am]

BILLING CODE 8010-01-M

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[1] Notice of the proposed rule change was published in Securities Exchange Act Release No. 16919 (June 24, 1980), 45 FR 43914 (1980). Subsequently, on July 9, 1980, the CBOE filed an amendment to the proposed rule change excluding certain closing transactions from the calculations of transactions required to be executed in person by market makers and requiring the recording of additional information on market maker orders. Notice of the amendment to the proposed rule change was published in Securities Exchange Act Release No. 17012 (July 25, 1980), 45 FR 51325 (1980).

[2] Securities Exchange Act Release No. 17535 (February 12, 1981), 46 FR 13055 (1981) ("1981 Approval Order").

[3] *Clement* v. *Securities and Exchange Commission*, 674 F.2d 641 (7th Cir. 1982).

[4] *See* Securities Exchange Act Release Nos. 18727 (May 11, 1982), 47 FR 21169 (1982); 18963 (August 18, 1982), 47 FR 37020 (1982); 19203 (November 1, 1982), 47 FR 50790 (1982); 19386 (December 30, 1982), 48 FR 915 (1983); 19641 (March 29, 1983), 48 FR 14795 (1983); and 19923 (June 28, 1983), 48 FR 31133 (1983); 20082 (August 12, 1983), 48 FR 3775 (1983); 20228 (September 23, 1983), 48 FR 44962 (1983); and 20362 (November 10, 1983), 48 FR 52529 (1983); 20475 (December 13, 1983), 48 FR 56291 (1983); 20552 (January 12, 1984), 49 FR 2176 (1984); 20637 (February 9, 1984), 49 FR 6062 (1984); 20754 (March 14, 1984), 49 10605 (March 21, 1984); 20858 (April 13, 1984), 49 FR 16913 (April 20, 1984).

[5] CBOE filed a substantive amendment to the proposed rule change on October 19, 1982. *See* Securities Exchange Act Release No. 19203 (November 1, 1982), 47 FR 50790 (1982). The Commission also received a letter from CBOE requesting approval of its proposed "in-person" rule on a pilot basis. *See* letter of May 10, 1983, from Anne Taylor, Secretary and Associate General Counsel, CBOE, to Richard Chase, Division of Market Regulation, Securities and Exchange Commission. File No. SR-CBOE-80-16.

[6] The public comments received since the beginning of November 1982 are discussed in Securities Exchange Act Release Nos. 19386 (December 30, 1982), 48 FR 915 (1983); 19641 (March 29, 1983), FR 14795 (1983); and 20082; (August 12, 1983), 48 FR 37755 (1983), and are available for public inspection in File No. SR-CBOE-80-16. A further letter from CBOE, noted in the preceding footnote, is discussed in Securities Exchange Act Release No. 19923 (June 28, 1983), FR 48 31133 (1983). Further letters are discussed below.

[7] *See* letter of Anne Taylor, Secretary and Associate General Counsel, CBOE, to Kevin Fogarty, Division of Market Regulation, Securities and Exchange Commission, September 22, 1983. The Chicago Board of Trade also submitted its interpretation of the data provided in this CBOE letter. *See* letter of January 10, 1984, from Thomas R. Donovan, President, Chicago Board of Trade, to George A. Fitzsimmons, Secretary. File No. SR-CBOR-80-16.

[8] CBOE has consented to this extension of partial approval.

[Release No. 20964; (SR-CBOE-84-18)]

Chicago Board Options Exchange, Inc.; Filing and Order Granting Accelerated Approval of Proposed Rule Change

May 15, 1984.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 934 (the "Act"), 15 U.S.C. 78s(b)(1), notice is hereby given that on May 4, 1984, the Chicago Board Options Exchange, Incorporated ("CBOE") LaSalle at Van Buren, Chicago, IL 60605, 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 CBOE proposes to extend until May 22, 1984, its pilot program under which CBOE member firms may use CBOE's Order Support System ("OSS") to route electronically to CBOE's limit order book any public customer limit orders for Standard and Poor's ("S&P") Telecommunications Industry Index options.[1] Currently, limit orders for other options may be electronically routed to CBOE's limit order book (thus bypassing the floor brokers) only if they are at a limit price that is above or below the current bid or ask by specified amounts ("parameters") The extension of CBOE's pilot program would eliminate these parameters for S&P Telecommunications Index options on an experimental basis until May 22, 1984. CBOE states that the statutory basis for this proposed rule change is section 6(b)(5) of the Act.

Interested persons are invited to submit written data, views and arguments concerning the submission within 21 days from 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, NW., Washington, DC 20549. Reference should be made to File No. SR-CBOE-84-18.

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 at the principal office of the CBOE.

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange and, in particular, the requirements of Section 6 and the rules and regulations thereunder.

The Commission finds good cause for approving the proposed rule change prior to the thirtieth day after the date of publication of notice of filing thereof in that the proposed rule change would simply extend until May 22, 1984 an existing pilot program that allows the experimental expansion of CBOE's automated order routing system for a limited class of orders in one index option.

It is therefore ordered, pursuant to section 19(b)(2) of the Act, that the proposed rule change is approved.

For the Commission, by the Division of Market Regulation pursuant to delegated authority.

George A. Fitzsimmons,

Secretary.

[FR Doc. 84-13637 Filed 5-21-84; 8:45 am]

BILLING CODE 8010-01-M

[1] The original pilot program, which expired on April 20, 1984, was approved on April 2, 1984 (Securities Exchange Act Release No. 20811, April 2, 1984; 49 FR 13923, April 9, 1984).

[Release No. 20968; File No. SR-MSTC-84-4]

Filing of Proposed Rule Change By the Midwest Securities Trust Company

May 16, 1984.

The Midwest Securities Trust Company ("MSTC") submitted to the Commission on May 16, 1984, a proposed rule change pursuant to Rule 19b-4 under the Securities Exchange Act of 1934 (the "Act") that would amend MSTC's By-laws to increase the number of MSTC's directors. The proposed By-law amendment would authorize MSTC to increase its Board of Directors from seventeen to eighteen individuals.

In its filing, MSTC states that the proposed rule change would permit MSTC to add to its Board of Directors a qualified individual from the business community. MSTC believes that this change is consistent with the Act because it provides for fair representation of participants in the selection of MSTC's directors.

In order to assist the Commission in determining whether to approve the proposed rule change or institute proceedings to determine whether the proposed rule change should be disapproved, 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, D.C. 20549. Reference should be made to File No. SR-MSTC-84-4.

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 persons, 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, 450 Fifth Street, N.W., Washington, D.C. 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. 84-13734 Filed 5-21-84; 8:45 am]

BILLING CODE 8010-01-M

SMALL BUSINESS ADMINISTRATION

Reporting and Recordkeeping Requirements Under OMB Review

ACTION: Notice of reporting requirements submitted for OMB review.

SUMMARY: Under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35), agencies are required to submit proposed reporting and recordkeeping requirements to OMB for review and approval, and to publish a notice in the **Federal Register** notifying the public that the agency has made such submission.

DATE: Comments must be received on or before June 25, 1984. If you anticipate commenting on a submission but find that time to prepare will prevent you from submitting comments promptly, you should advise the OMB reviewer and the agency clearance officer of your intent as early as possible.

Copies: Copies of the proposed survey the requests for clearance (S.F. 83), supporting statements, instructions, transmittal letter, and other documents submitted to OMB for review may be obtained from the Agency Clearance Officer. Comments on the items listed should be submitted to the Agency Clearance Officer and the OMB Reviewer.

FOR FURTHER INFORMATION CONTACT:

Agency Clearance Officer: Elizabeth M. Zaic, Small Business Administration, 1441 L Street, NW., Room 200, Washington, D.C. 20416. Telephone: (202) 653–8538

OMB Reviewer: J. Timothy Sprehe, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 3235, New Executive Office Building, Washington, D.C. 20503, Telephone: (202) 395–4814.

Information Collection Submitted for Review

Title: Survey of Business School Alumni to Assess Entrepreneurship and Effect of Veteran Status

Frequency: One time, nonrecurring

Description of Respondents: Alumni from business schools

Annual Responses: 8,000

Annual Burden Hours: 2,667

Type of Request: New collection.

Richard Vizachero,

Acting Chief, Information Resources Management Branch, Small Business Administration.

[FR Doc. 84–13643 Filed 5–21–84; 8:45 am]

BILLING CODE 8025–01–M

[Declaration of Disaster Loan Area No. 2133]

Georgia; Declaration of Disaster Loan Area

Bulloch, Toombs and the adjacent counties of Montgomery and Tattnall in the State of Georgia constitute a disaster area because of damage caused by a series of tornadoes, high winds, heavy rains, hail, and flooding which occurred on May 3–4, 1984. Applications for loans for physical damage may be filed until the close of business on July 16, 1984, and for economic injury until the close of business on February 15, 1985, at the address listed below: Disaster Area 2 Office, Small Business Administration, Richard B. Russell Federal Bldg., 75 Spring Street, SW., Suite 822, Atlanta, Georgia 30303, or other locally announced locations.

Interest rates are:

	Percent
Homeowners with credit available elsewhere	8.000
Homeowners without credit available elsewhere	4.000
Businesses with credit available elsewhere	8.000
Businesses without credit available elsewhere	4.000
Businesses (EIDL) without credit available elsewhere	4.000
Other (non-profit organizations including charitable and religious organizations)	10.500

The number assigned to this disaster is 213306 for physical damage and for economic injury the number is 616800.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008).

Dated May 15, 1984.

Heriberto Herrera,

Acting Administrator.

[FR Doc 84–13644 Filed 5–21–84; 8:45 am]

BILLING CODE 8025–01–M

[Declaration of Disaster Loan Area No. 2132]

Texas; Declaration of Disaster Loan Area

Motley County in the State of Texas constitutes a disaster area because of damage caused by a series of tornadoes on May 1, 1984. Applications for loans for physical damage may be filed until the close of business on July 13, 1984, and for economic injury until the close of business on February 14, 1985, at the address listed below: Disaster Area 3 Office, Small Business Administration, 2306 Oak Lane, Suite 110, Grand Prairie, Texas 75051, or other locally announced locations.

Interested rates are:

	Percent
Homeowners with credit available elsewhere	8.000
Homeowners without credit available elsewhere	4.000
Businesses with credit available elsewhere	8.000
Businesses without credit available elsewhere	4.000
Businesses (EIDL) without credit available elsewhere	4.000
Other (Non-profit organizations including charitable and religious organizations)	10.500

The number assigned to this disaster is 213212 for physical damage and for economic injury the number is 616700.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008)

Dated May 14, 1984.

James C. Sanders,

Administrator.

[FR Doc 84–13642 Filed 5–21–84; 8:45 am]

BILLING CODE 8025–01–M

Sunshine Act Meetings

Federal Register
Vol. 49, No. 100
Tuesday, May 22, 1984

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).

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1

CONSUMER PRODUCT SAFETY COMMISSION

TIME AND DATE: 10:00 a.m., Wednesday, May 23, 1984.

LOCATION: Third Floor Hearing Room, 1111—18th Street, NW., Washington, D.C.

STATUS: Open to the Public.

MATTERS TO BE CONSIDERED:

1. Residential Swimming Pool Hazard: Status Report

The staff will brief the Commission on issues related to the risk of drowning to children under five years of age in residential pools and spas.

2. Unvented Gas-Fired Space Heaters: Final Revocation

The staff will brief the Commission on comments received on a proposed revocation of the Commission's mandatory standard requiring the oxygen depletion sensor on unvented gas-fired space heaters (16 CFR Part 1212).

Closed to the Public

3. FOIA Appeal OS #5379

The Commission will consider FOIA Appeal S #308046.

For a recorded message containing the latest agenda information, call: 301—492–5709.

CONTACT PERSON FOR ADDITIONAL INFORMATION: Sheldon D. Butts, Office of the Secretary, 5401 Westbard Ave. Bethesda, Md. 20207 301—492–6800.

Dated: May 17, 1984.

Sheldon D. Butts,

Deputy Secretary.

[FR Doc. 84–13742, Filed 5–18–84; 4:43 pm]

BILLING CODE 6355–01–M

2

FEDERAL COMMUNICATIONS COMMISSION

May 17, 1984.

The Federal Communications Commission will hold an Open Meeting on the subjects listed below on Thursday, May 24, 1984, which is scheduled to commence at 9:30 A.M. in Room 856, at 1919 M Street, NW., Washington, D.C.

Agenda, Item No., and *Subject*

General—1—Title: *Report and Order:* In the Matter of Inquiry into Enforcement of Prohibitions Against the Use of Common Carriers For the Transmission of Obscene Materials. Summary: The Commission will consider whether or not to adopt a *Report and Order* which proposes to restrict access by minors to obscene or indecent telephonic communications.

Common Carrier—1—Title: Second Further Notice of Proposed Rulemaking proposing a framework for the acquisition of customer premises equipment (CPE) by federal agencies for national security and emergency preparedness (NSEP) communications purposes; CC Dkt. No. 81–893. Summary: The Commission will consider whether to adopt a notice of proposed rulemaking which: (1) Proposes mechanisms for the provision of CPE by carriers to government agencies under the Computer II Rules; and (2) proposes rules for the detariffing of embedded CPE owned by the Independent telephone companies and currently tariffed at the federal level.

Common Carrier—2—Title: Order modifying the effective date for the application of the Computer II Rules to certain customer premises equipment (CPE) owned by American Telephone and Telegraph Company (AT&T) and used in designated national security and emergency preparedness (NSEP) communications systems; CC Dkt. No. 81–893. Summary: The Commission will consider whether to: (1) Delay the June 1, 1984, effective date for the application of Computer II Rules to CPE supplied by AT&T to the government for NSEP purposes; and (2) extend the May 31, 1984, termination date to certain waivers which have been established regarding the furnishing of this equipment by AT&T.

Common Carrier—3—Title: Applications for authority to: (1) Construct eighth transatlantic cable ("TAT–8"); and (2) land cable in the U.S. by AT&T, FTCC, Hawaiian Telephone Co., ITT, RCA, Western Union, WUI, and TRT. Summary: Consideration of Applications in File Nos. L–T–C–072 and S–C–L–84–001 to construct, land, and operate eighth transatlantic cable ("TAT–8") for the provision of digital, fiber optic capacity between the United States and both France and the United Kingdom.

Common Carrier—4—Title: Petitions for Reconsideration of an Order in Policy and Rules Concerning the Furnishing of Customer Premises Equipment, Enhanced Services and Cellular Communications Services by the Bell Operating Companies. Summary: The Commission will consider petitions for reconsideration of the requirements it adopted for the provision of enhanced services and customer premises equipment by the Regional Bell Operating Companies.

Mass Media—1—Title: Application for Review filed by Voy Cheyovich, President, Serbian National Defense Council of America, of the Bureau's ruling of February 1, 1984. Summary: The Commission will consider whether or not to reverse the Bureau's ruling with respect to the Fairness Doctrine.

Mass Media—2—Title: Amendment of the AM Broadcast Station Rules with Respect to Signal Coverage Requirements over Community Business and Factory Areas (MM Docket No. 83–15). Summary: The Commission considers deleting premium coverage requirements over business and factory areas within the community of license of AM stations. Also under consideration is the requirement that permittees of directional AM facilities take field strength measurements in connection with their covering license applications.

Mass Media—3—Title: (a) "Petition for Favorable Action on Applications for Assignments of License" filed March 13, 1984 by Metroplex Communications of Florida, Inc. (b) Application for voluntary assignment of AM Station WORL, Eatonville, Florida from Sudbrink Broadcasting of Central Florida, Inc. to Metroplex Communications of Florida, Inc. (BAPL–840124EG). (c) Application for voluntary assignment of FM Station WJYO–FM, Mt. Dora, Florida from CKK Broadcasting Company, Inc. to Metroplex Communications of Florida, Inc. (BALH–840124GH). Summary: The Commission will consider whether to grant the petition for favorable action on the applications for assignment of license of WORL and WJYO–FM and grant these applications for voluntary assignment.

This meeting may be continued the following work day to allow the Commission to complete appropriate action.

Additional information concerning this meeting may be obained from Sally Lawrence, FCC Pubic Affairs Office, telephone number (202) 254–7674.

William J. Tricarico,

Secretary, Federal Communications Commission.

[FR Doc. 84–13757 Filed 5–18–84; 9:57 am]

BILLING CODE 6712–01–M

3

FEDERAL COMMUNICATIONS COMMISSION

May 17, 1984.

The Federal Communications Commission will hold a Closed Meeting on the subjects listed below on Thursday, May 24, 1984 following the Open Meeting, which is scheduled to commence at 9:30 A.M. in Room 856, at 1919 M Street, NW., Washington, D.C.

Agenda, Item No., and Subject

Hearing—1—Application for review in the GAF Broadcasting Company, Inc., New York, New York, FM radio comparative renewal proceeding (BC Docket Nos. 82–371–72).

Hearing—2—Petitions for Reconsideration and stay of Commission Orders rejecting claims of attorney-client privilege and the attorney-work-product doctrine in the A.S.D. Answer Service, Inc., DPLMRS proceeding (Docket Nos. 82–587–90).

These items are closed to the public because they concern Adjudicatory Matters (See 47 CFR 0.603(j)).

The following persons are expected to attend:

Commissioners and their assistants
Managing Director and members of his staff
General Counsel and members of his staff
Chief, Office of Public Affairs and members of his staff

Action by the Commission May 16, 1984. Commissioners Fowler, Chairman; Quello, Dawson, Rivera and Patrick voting to consider these items in Closed Session.

This meeting may be continued the following work day to allow the Commission to complete appropriate action.

Additional information concerning this meeting may be obtained from Sally Lawrence, FCC Public Affairs Office, telephone number (202) 254–7674.

William J. Tricarico,

Secretary, Federal Communications Commission.

[FR Doc. 84–13758 Filed 5–18–84; 9:57 am]

BILLING CODE 6712–01–M

4

FEDERAL MINE SAFETY AND HEALTH REVIEW COMMISSION

May 17, 1984.

TIME AND DATE: 10:00 a.m., Wednesday, May 23, 1984.

PLACE: Room 600, 1730 K Street, NW., Washington, D.C.

STATUS: Closed (Pursuant to 5 U.S.C. 552b(c)(10)).

MATTERS TO BE CONSIDERED: In addition to the previously announced items to be discussed after oral argument, the Commission will consider the following:

2. Secretary of Labor, MSHA v. Pontiki Coal Corp., Docket Nos. KENT 83–181–R, etc.
3. Secretary of Labor, MSHA v. Belcher Mine, Inc., Docket No. SE 84–4–M.

It was determined by a unanimous vote of Commissioners that Commission business required that a meeting be held on these items, and a majority vote of Commissioners voted that the meeting be closed. No earlier announcement of the addition was possible. 5 U.S.C. § 552b(e)(1)

CONTACT PERSON FOR MORE INFORMATION: Jean Ellen, (202) 653–5632.

Jean Ellen,

Agenda Clerk.

[FR Doc. 84–13769 Filed 5–18–84; 10:30 am]

BILLING CODE 6735–01–M

5

FEDERAL RESERVE SYSTEM

TIME AND DATE: 11:00 a.m., Tuesday, May 29, 1984.

PLACE: 20th Street and Constitution Avenue, NW., Washington, D.C. 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.
2. Any items carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board; (202) 452–3204.

Dated: May 18, 1984.

James McAfee,

Associate Secretary of the Board.

[FR Doc. 84–13832 Filed 5–18–84; 3:45 pm]

BILLING CODE 6210–01–M

6

FEDERAL TRADE COMMISSION

TIME AND DATE: 2:00 p.m., Tuesday, June 19, 1984.

PLACE: Room 432, Federal Trade Commission Building, 6th Street and Pennsylvania Avenue, NW., Washington, D.C. 20580.

STATUS: Open.

MATTER TO BE CONSIDERED: Consideration of recommendation of Bureau of Consumer Protection and Bureau of Economics that the Commission publish the attached notice of proposed rulemakings in the "Eyeglasses II" investigation.

CONTACT PERSON FOR MORE INFORMATION: Susan B. Ticknor, Office of Public Affairs: (202) 532–1892
Recorded Message: (202) 523–3806

Benjamin I. Berman,

Acting Secretary.

[FR Doc. 84–13793 Filed 5–18–84; 3:58 pm]

BILLING CODE 6750–01–M

7

FEDERAL TRADE COMMISSION

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT: FR 49, May 9, 1984, page No. 19766.

PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING: 2:00 p.m., June 7, 1984.

CHANGES IN THE TIME AND DATE OF MEETING: The Federal Trade Commission has changed the date and time of its previously announced open meeting from June 7, 1984, 2:00 p.m. to June 19, 1984, 10:30 a.m.

CONTACT PERSON FOR MORE INFORMATION: Susan B. Ticknor, Office of Public Affairs: (202) 532–1892

Benjamin I. Berman,

Acting Secretary.

[FR Doc. 84–13794 Filed 5–18–84; 12:45 pm]

BILLING CODE 6750–01–M

federal register

Tuesday
May 22, 1984

Part II

Office of Science and Technology Policy

Chemical Carcinogens; Notice of Review of the Science and Its Associated Principles

OFFICE OF SCIENCE AND TECHNOLOGY POLICY

Chemical Carcinogens; Review of the Science and Its Associated Principles, May, 1984

AGENCY: Executive Office of the President, Office of Science and Technology Policy.

ACTION: Notice.

SUMMARY: The Office of Science and Technology Policy has prepared this draft document to be used as a framework for regulatory agencies in assessing cancer risks from chemicals. The document does not attempt to formulate policy or develop standardized methods of risk assessment. It tries to define principles, based upon current scientific information, to serve as guidelines in certain matters when considering carcinogens. The present document is the culmination of drafts extensively reviewed by governmental and non-governmental scientists. The public is now invited to review and comment on this document prior to final publication.

DATE: Comments must be received on or before August 1, 1984.

ADDRESS: Send comments to: Ronald W. Hart, Ph.D., Director, NCTR, Chairman, OSTP Interagency Staff Group, National Center for Toxicological Research, Jefferson, AR 72079; Telephone: 501–541–4000.

Dated: May 10, 1984

Jerry D. Jennings,

Executive Director, Office of Science and Technology Policy.

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INTRODUCTION

I. Background

Over the years, agencies and programs have been established to deal with the problems of cancer. Congress has enacted legislation and appropriated funds to address various aspects of hazardous substances (Table 1). A detailed analysis of the legislative acts concerning toxic substances reveals an evolution of thought in that each reflects the scientific views that existed at the time of enactment. Consequently, these acts are not uniform in their view of the disease, the role chemical substances might play in its incidence, and what ought to be done about potential toxic substances and potential carcinogens.

TABLE 1.—FEDERAL LAWS RELATED TO EXPOSURES TO TOXIC SUBSTANCES

Legislation	Agency	Area of concern
Food, Drug and Cosmetics Act (1906, 1938, amended 1958, 1960, 1962, 1968, 1976).	FDA	Food, drugs, cosmetics, food additives, color additives, new drugs, animal and feed additives, and medical devices.
Federal Insecticide, Fungicide and Rodenticide Act (1948, amended 1972, 1975, 1978).	EPA	Pesticides.
Dangerous Cargo Act (1952)	DOT, USCG	Water shipment of toxic materials.
Atomic Energy Act (1954)	NRC	Radioactive substances.
Federal Hazardous Substances Act (1960, amended 1981)	CPSC	Toxic household products.
Federal Meat Inspection Act (1967)	USDA	Food, feed, color additives, and pesticide residues.
Poultry Products Inspection Act (1968)		
Egg Products Inspection Act (1970)		
Occupational Safety and Health Act (1970)	OSHA, NIOSH	Workplace toxic chemicals.
Poison Prevention Packaging Act (1970, amended 1981)	CPSC	Packaging of hazardous household products.
Clean Air Act (1970, amended 1974, 1977)	EPA	Air pollutants.
Hazardous Materials Transportation Act (1972)	DOT	Transport of hazardous materials.
Clean Water Act (formerly Federal Water Control Act) (1972, amended 1977, 1978)	EPA	Water pollutants.
Marine Protection, Research and Sanctuaries Act (1972)	EPA	Ocean dumping.
Consumer Product Safety Act (1972, amended 1981)	CPSC	Hazardous consumer products.
Lead-Based Paint Poison Prevention Act (1973, amended 1978)	CPSC, HEW (HHS), HUD.	Use of lead paint in federally assisted housing.
Safe Drinking Water Act (1974, amended 1977)	EPA	Drinking water contaminants.
Resource Conservation and Recovery Act (1976)	EPA	Solid waste, including hazardous wastes.
Toxic Substances Control Act (1976)	EPA	Hazardous chemicals not covered by other laws, includes pre-market review
Federal Mine Safety and Health Act (1977)	DOL, NIOSH	Toxic substances in coal and other mines.
Comprehensive Environmental Response, Compensation, and Liability Act (1981)	EPA	Hazardous substances, pollutants and contaminants.

Most abbreviations are same as below. Additional ones are:

DOL—Department of Labor;
DOT—Department of Transportation;
HEW (HHS)—Department of Health, Education and Welfare (many functions assumed by HHS—Department of Health and Human Services);
HUD—Department of Housing and Urban Development;
NIOSH—National Institute of Occupational Safety and Health;
NRC—Nuclear Regulatory Commission;
USCG—United States Coast Guard.

II. The Purpose of This Report

The purpose of this document is to: (1) Articulate a view of carcinogenesis that scientists generally hold in common today (Part II); and (2) draw upon this understanding to compose, as was done here by senior scientists from a number of Federal agencies, a series of general principles that can be used to establish specific guidelines for assessing carcinogenic risk (Part I). Because of present gaps in understanding, the principles contain statements of what is generally accepted as fact as well as judgmental (science policy) decisions on unresolved issues, and there has been, however, an attempt to clearly distinguish between the different types of information presented. These principles also provide to all interested parties specific reference to the analysis upon which they are based. They can serve as the basis for consistent regulatory cancer guidelines that the Federal agencies can tailor to meet the requirements of the legislative acts they are charged to implement. Similar documents, with varying degrees of specificity, have been produced in the past, *e.g.*, in the late 1970s and early 1980s several agencies of the Federal government produced statements directed toward providing a consistent basis for a general Federal cancer policy. This document should be seen, in the broad view, as part of an ongoing process, on behalf of the Federal government, that strives to periodically update and review current understanding of carcinogenesis and the scientific process of how this understanding is utilized.

This document is the result of the combined efforts of senior scientists from the following Federal health-related units, operating in the Interagency Staff Group, under the direction of the Office of Science and Technology Policy (OSTP):

Bureau of Foods (B.F.), Food and Drug Administration (FDA)
Consumer Product Safety Commission (CPSC)
Environmental Protection Agency (EPA)
Office of the Commissioner (OC), FDA
Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA)

National Cancer Institute (NCI), National Institutes of Health (NIH)
National Center for Toxicological Research (NCTR), FDA
National Institute of Environmental Health Sciences (NIEHS), NIH
National Toxicology Program (NTP)
Occupational Safety and Health Administration (OSHA)

III. The Context of This Report

This document is written in light of a decision-making process used by many of the regulatory agencies, which involves the assessment of carcinogenic risks posed by chemical substances. The scientific inputs to these evaluations can be best appreciated by examining the decision-making process in some detail.

Risk can be conceived of as being composed of two aspects, each of which can be addressed by science: Hazard* and exposure. Although other definitions have been used historically, this document conforms to present usage and "hazard" generally refers to the inherent toxicity of the substance (for some toxic endpoint) and is deduced from a wide array of data including: epidemiological evaluations, long-term animal studies, short-term tests, information on mechanisms, and the results of structure/activity relationships. "Exposure" generally refers to the amount of the substance that people come in contact with. The "risk", in a quantitative risk assessment, is estimated by coupling the results of the exposure and hazard assessments. As either the hazard or exposure approaches zero, the risk also approaches zero.

As a first step in assessing the cancer risk associated with the use of a particular chemical substance, the qualitative evidence that a given chemical substance is likely to be a human carcinogen must be evaluated. In this step, as in the whole process, a number of assumptions and approximations must be made in order to deal with inherent limitations found in the existing data bases. Then, estimates of human exposure, and distribution of exposures likely to be encountered in the population are made. Next, one or more methods for estimating the dose-response relationship at doses below those generally used experimentally must also be evaluated. Finally, the exposure assessment is combined with the dose-response relationship to generate an estimate of risk. The various ways in which these steps are conducted and combined and their attendant uncertainties treated constitute what is generally referred to as "cancer risk assessment", although an assessment can be terminated at different stages to estimate risk for different purposes.

Some legislation calls for action in the presence of any risk. Other forms of legislation use the concept of unreasonable risk, defined, in some acts, as a condition in which the risks outweight the benefits; *e.g.*, the Toxic Substances Control Act (TSCA) and the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). A spectrum of approved responses, from simply informing the public of a risk through restricted use to a complete ban, may be available to bring the risks and benefits into appropriate balance.

This document does not perform a risk assessment nor does it suggest that one method of cancer risk assessment is better than another; but, rather, it attempts to review the science of chemical carcinogenesis and develops from this review a set of general principles. It is not a comprehensive treatise; nor a document written for the lay public but is rather a semi-technical review which tries to evaluate the impact of scientific findings of the last decade on general assumptions or principles important to risk assessment. This is based upon the inherent belief of the group that elucidation of the basic mechanisms underlying cancer and the identification of cancer-causing agents and conditions, when coupled to research aimed at identifying and evaluating the problems created by such agents, should provide the optimal adminstrative bases for making sound and reasonable judgments.These overlapping approaches to evaluating the problems of cancer, we believe, should form one of the strongest foundations upon which a technologically based society could base its decisions.

IV. The Content of This Report

This document is composed of two parts. Part I presents a set of general principles that may be used by regulatory agencies as they review their own specific guidelines for performing cancer risk assessments. Part II addresses the current state-of-the-science concerning carcinogenesis and cancer risk assessment and forms the underlying scientific basis of Part I.

The general principles in Part I, as has been suggested for similar guidelines in the National Academy of Sciences report on Risk Assessment in the Federal government**, can be useful despite an inherent tendency toward over simplification and the mixing of scientific knowledge with risk assessment science policy. Many components of the risk assessment process lack definitive scientific bases. Often a choice must be made among several different scientifically plausible options. The above cited report identified over 50 components where the uncertainty in the science requires, in part, scientific judgements and science policy decisions to go from one component to another to reach a decision. This document attempts to leave the majority of these necessary scientific inferences to the scientific regulatory agencies. However, some are so important and fundamental to all cancer risk assessment procedures, regardless of the source of hazard or the different statutory provisions of the agencies, that they are included in some of the principles. Where this has occurred, we have attempted to indicate, both in Part II and the wording of the principle itself, that a public health science policy decision is embodied in it. For example, Principle 8 makes the point that an animal carcinogen should be considered a suspect human carcinogen. Many scientists would agree that, while there is a significant amount of evidence to support qualitative animal to human extrapolation for carcinogenesis, the evidence falls short of establishing this proposition as a scientific fact (when determining the response of different species to chemcials, many chemicals appear to be carcinogenic in one species or strain and not in another, even when only rodents are being compared). Nonetheless, this principle has been accepted by all health and regulatory agencies and is regarded widely by scientists in industry and academia as a justifiable and necessary inference. It is not possible to draw a sharp distinction in every instance between principles which are based solely on science and those which embody a choice based also on science policy. However, several of the principles clearly reflect certain aspects of science policy, *e.g.* Principles 8, 11 and 26.

Part II of this document is divided into six separate chapters, each discussing the current information in an area of science used in the cancer risk assessment process.

Chapter 1 highlights some of the recent advances in our understanding of

*The European community uses the term "risk" where we have used the term "hazard" and vice versa.

** Managing the Process: Risk Assessment in the Federal Government, National Academy of Sciences, Washington, D.C., 1983.

the mechanisms of carcinogenesis. A general consensus has evolved which describes cancer as a multi-stage process involving a variety of events which can include metabolic conversion, initiation, promotion, and proliferation. The chapter highlights some advances in our understanding that have implications in the way we assess cancer risk. At the same time, the chapter also identifies some of the vast amount of information that remains to be collected and analyzed.

Chapter 2 examines short-term testing and the relationship between genetic toxicity and carcinogenicity. Tests for gene mutation, chromosomal aberration, DNA damage and repair, and cellular (morphologic) transformation have provided valuable information on the potential for chemical substances to cause cancer. This field is currently characterized by a great deal of activity, and the data generated must be carefully analyzed and verified before use in cancer risk assessment.

The third chapter contains an evaluation of long-term animal tests, which have been a major factor in past assessments of cancer risk. A review of the usefulness in cancer risk assessment of the data developed via this approach to chemical evaluation is made, and potential limitations and pitfalls of such data relative to extrapolation to human populations are discussed.

The fourth chapter examines the current state of epidemiological knowledge relating to human cancer. Data collected during the past 50 years permit the analysis of trends in cancer incidence/mortality and provide information related to the various etiologies of cancer. Recent developments in cancer epidemiology are highlighted and their potential impact on risk assessment pointed out. Much of the discussion concentrates on the methods to be used in such studies in attempting to overcome past, often cited, limitations of this approach.

In addition to these chapters which examine factors associated with hazard assessment, part II also contains a discussion of exposure assessment. As Chapter 5 points out, the field of exposure assessment has been marked by significant progress in the areas of monitoring data, computer modeling, transformation and transport of chemicals, and laboratory approaches to determining the behavior of chemicals in the environment. At the same time uncertainties remain, and any risk assessment will necessarily be affected by these limitations.

Chapter 6 concludes Part II of the document and discusses how the hazard and exposure elements of the preceding five chapters are used as inputs into the qualitative and quantitative cancer risk assessment processes. This chapter depends heavily on all the other chapters of this volume and attempts to make clear the various approaches that are used in risk assessments, noting both the limitations and advantages of each. Common themes within each chapter are the uncertainty, the gaps in data, and the questions of interpretation associated with some aspects of the scientific information used in the risk assessment process. A critical evaluation of this information comprises Part II of the document and led to the principles listed in Part I. These general principles were developed to provide interim guidance in areas of uncertainty until such time that additional scientific experimentation provides the required information needed to improve estimations of risk in human populations. As a note of caution, it should be recognized that the chapters of Part II, taken *in toto*, provide the underlying support for the principles articulated in Part I. To read Part I without a full appreciation of the material in Part II is to invite oversimplification and misinterpretation.

Finally, a note is needed, chiefly addressed to specialists on the various topics that are briefly discussed in Part II. If reports of a broad nature are to be written at all, and general reports are often necessary to present organized thought on subjects of vital interest, it is inevitable that those who write them must spend less time on a topic than someone who concentrates almost exclusively on one specific interest. Therefore, there are certain to be areas which some authorities think are not discussed enough, others which some feel go on *ad infinitum*. Also, since the chapters in Part II of this document is an attempt to provide a balanced account of what is generally accepted, derived from a vast amount of information involving the work of thousands of individuals, citing relatively few, some must be slighted. Both problems are inevitable in a work of this type. Hopefully, deficiencies in the choice of topic for emphasis or failures to acknowledge contributions have not been egregious.

PART I—PRINCIPLES

Preface

The principles contained within this segment of the OSTP carcinogen document were derived by the authors of the various chapters, from the information detailed in Part II, in cooperation with all members of the Interagency Staff Group. This section attempts to provide, in a non-technical form, some important general statements relevant to the evaluation of the role of chemicals in carcinogenesis. These statements are intended to serve as a bridge connecting the basic science as expounded in Part II and the multifaceted process of risk assessment.

Since there are gaps in the information available, differences in evaluations and in scientific opinion may exist about certain of the points highlighted as prinicples. However, these principles derive from a *weltanschauung* utilizing a balanced approach with an appreciation of all elements of the problem, from hazard identification and estimation, through exposure and risk assessment. It is clearly understood that new information and newly emerging concepts may modify some of these statements, however, for the time being, as a result of an ardous cooperative effort these statements, we believe, represent an up-to-date summary on a number of important topics.

I. Principles Derived From the Mechanisms of Carcinogenesis

1. Carcinogenesis is a multistage phenomenon that may involve the genome both directly and indirectly. These stages of carcinogenesis may be, to varying degrees, influenced by a number of variables such as age at exposure, diet, hormonal status, intra- and inter-species variability, which should be considered when trying to predict human response to potentially carcinogenic agents (Chapter 1, Section VI).

2. Appropriate *in vitro* and *in vivo* tests can indicate that an agent has a certain action such as genetic toxicity or promotion. Such information may be useful in evaluating mechanism(s) of cancer induction. However, in evaluation of human risk, the attribution of observed findings of carcinogenicity to a particular biological effect must rest upon sound evidence that the effect is responsible for the cancer induction. It must be kept in mind that a chemical may contribute to carcinogenesis in multiple ways (Chapter 1, Section VI).

3. At the present stage of knowledge, mechanistic considerations, such as DNA repair and other biological responses, in general do not prove the existence of, the lack of existence of, or the location of, a threshold for carcinogenesis. The presence or absence of a threshold for one step of the carcinogenic process does not necessarily determine the presence or absence of a threshold for the whole

process. For example, there is strong evidence that the existence of DNA repair will not result in a threshold for the accumulation of DNA damage (Chapter 1, Section V, Part A); however, the consequences of this for a threshold for carcinogenesis is unclear.

4. The carcinogenic effects of agents may be influenced by non-physiological responses induced in the model systems. Testing regimens inducing these responses, such as extensive organ damage, saturation of metabolic pathways, saturation of DNA repair with functional loss of the system, should be evaluated for their relevance to the human response to the agent (Chapter 1, Section V, Part B) and evidence from such a study, whether positive or negative, must be carefully reviewed.

II. Principles for Tests of Cancer Induction

A. Short-Term Tests

5. Short-term tests, such as assays for point mutations, chromosomal aberrations, DNA damage, and *in vitro* transformation are useful in: (1) Screening for potential carcinogens; (2) supporting a judgment on the carcinogenicity of a chemical; and (3) providing information on carcinogenic mechanisms (Chapter 2, Section IV, Part B).

6. At the present, short-term tests are limited in their ability to predict carcinogenicity and cannot supplant data from epidemiological investigations or long-term animal studies since the tests do not necessarily screen for all potential means of cancer induction and do not necessarily mimic all reactions that would occur *in vivo*. Additional research is required to improve existing tests and develop ones that identify chemicals which act by genetic mechanisms not yet detected or which act by other, non-genetic, mechanisms (Chapter 2, Section IV, Part C).

7. Short-term tests should be carefully selected to ensure they have been adequately validated. Several tests with different endpoints may be required to characterize a chemical's spectrum of response (Chapter 2, Section IV, Parts A and B).

B. Long-Term Animal Tests

8. In the context of the result from a long-term test, the term carcinogen should be used in a broad sense, *i.e.* a substance or process capable of increasing the incidence of neoplasms (combining benign and malignant when scientifically defensible) or decreasing the time it takes for them to develop. Agents found carcinogenic in animal studies, subject to the considerations discussed in Principles 4 and 14, are considered suspect human carginogens (Chapter 3, Section II, Part A).

9. Some experimental animal models normally have high incidences of certain tumors. The evaluation of tumor data from such animals can pose special problems. For example, the interpretation of cancer incidence in some strains of rats with testicular or mammary tumors, or in some strains of mice with lung or liver tumors must be approached carefully in the light of other biological evidence bearing on potential carcinogenicity (Chapter 3, Section II, Part C).

10. Protocols for long-term tests should be designed to achieve an appropriate balance between the two essential characteristics of a biological assay: Adequate biological and statistical sensitivity (a low false negative rate) and adequate biological and statistical specificity (a low false positive rate) (Chapter 3, Part II, Section D, Number 2). The absence of biases in selection and allocation of animals between control and treatment groups as regards diet, husbandry, necropsy and pathology is crucial (Chapter 3, Part I, Section B, Number 2).

11. It is appropriate to use test doses that generally exceed human exposure levels in order to overcome the inherent insensitivity of the traditional design of the long-term animal test. The highest dose should be selected after an adequate prechronic study and after evaluating other relevant information, *e.g.* pharmacokinetic data, as necessary to determine the highest dose consistent with predicted minimal target organ toxicity and normal lifespan, except as a consequence of the possible induction of cancer (Chapter 3, Section I, Part B, Number 4 and Section II, Part B, Number 1).

12. The diagnosis of pathologic lesions is complicated and requires judgment and appropriate experience. Diagnoses can differ depending on the tissue and species involved and can change with time as techniques improve and data on bioassays accumulate. Accurate interpretation of tumor data is contingent upon careful attention to gross observation, tissue sampling, slide preparation and histologic examination. Diagnosis of tumors should be guided by evidence of their histogenic origin and stage of progression (Chapter 3, Section II, Part C).

13. Appropriate statistical analysis should be performed on data from long-term studies to help determine whether the effects are treatment related or possibly due to chance. These should include a statistical test for trend and a test based on pairwise comparisons, including appropriate correction for differences in survival. The weight to be given to the level of statistical significance (the p-value) and to other available pieces of information is a matter of overall scientific judgment (Chapter 3, Section II, Part D).

14. Decisions on the carcinogenicity of chemicals in animals should be based on consideration of relevant biological and biochemical data (Chapter 3, Section II, Part B, Number 3), including the following (Chapter 3, Part II):

(a) Use of background or recent historical control incidence of tissue specific tumors can be an aid in the evaluation of tumor data. Care should be exercised when combining different control groups to avoid inappropriate combinations of such groups.

(b) Evidence of probable reproducibility is important. This evidence can consist of independent confirmation of the original findings or may be derived from intergroup comparisons of tumor incidence data, between dose groups, sexes, strains or species.

(c) Evidence of dose response increases confidence that the effect is treatment related; similarly the lack of an observed dose-response may reduce the likelihood that the effect is associated with the treatment.

(d) Confidence is increased when: (1) The incidence of tumors is markedly elevated in the treated groups compared to controls, particularly when the tumors in controls are infrequent; (2) tumor incidence is significantly increased at multiple anatomical sites; and (3) tumor latency is reduced.

(e) In addition to tumor incidence at specific tumor sites, the stage in the development of neoplasia should be evaluated. For example, the finding that the majority of neoplastic lesions at a specific tissue site is more advanced in a treated group compared to its control may provide additional evidence of a treatment related effect. Conversely, the finding that the control group lesions are more advanced might argue that a marginal elevation of tumor incidence is not treatment related.

(f) The incidence of preneoplastic lesions in treatment or control groups may, in certain instances, provide evidence for the biological plausibility of a neoplastic response and contribute to the interpretation of a bioassay.

(g) Identification from prechronic studies, or other toxicity studies of effects in the target organ(s), can assist in evaluating whether or not differences in tumor incidences are treatment related.

(h) Information on the activity of chemicals at the physiological, cellular and molecular level may be important to the evaluation of carcinogenicity data on a case-by-case basis.

III. Principles for Epidemiology

15. The strength of the epidemiological method is that it is the only means of assessing directly the carcinogenic risk of environmental agents in humans; however, because of the limitations of the available information, *e.g.*, the elements discussed in Principle 18 as well as the paucity of data, primary reliance is often placed on animal testing (Chapter 4, Section II, Part A).

16. Descriptive epidemiological studies (based on the measurement of disease rates for various populations), including correlational studies (in which the rate of disease in a population is compared with the spatial or temporal distribution of suspected risk factors), are useful to generate and refine hypotheses, or provide supporting evidence in evaluating relationships detected by other means, but rarely, if ever, provide information allowing a practical causal inference (Chapter 4, Section IV, Part A).

17. Well designed, conducted and evaluated analytic epidemiological investigations of either case-control or cohort variety can provide the basis for practical casual inferences especially useful for public health decisions (Chapter 4, Section IV, Part B).

18. Elements in interpreting the likely practical causality of epidemiological observations include the magnitude of the risk estimates (strength of the associations); the possibility of their being due to chance (statistical significance); the rigor of the study design to avoid various kinds of bias, including those related to selection, confounding, classification and measurement; dose-response relationships; the temporal relationships between exposure and disease; the specificity of the associations; their biological plausibility; and the reproducibility of the findings (Chapter 4, Section III).

19. A high quality negative epidemiological study, while useful, cannot prove the absence of an association between chemical exposure and human cancer. Within the scope of the study, specifically for the populations studied (including concomitant exposures), for the levels and durations of exposure to the agent evaluated and for the time assessed following exposure, likely upper bounds on the estimates of risk can be made and the statistical likelihood of the study to detect an effect can be assessed (Chapter 4, Section VI).

IV. Principles for Exposure Assessment

20. It is desirable that exposure routes employed in animal health effects studies are comparable to human exposure routes both for the simplification of risk assessment and because there may be important route-dependent differences in molecular, biochemical and physical parameters in organs (Chapter 1, Sections II and III).

21. At present, a single generally applicable procedure for a complete exposure assessment does not exist. Therefore, in the near term, it is expected that integrated exposure assessments (utilizing monitoring data, results from physical and chemical models, and consideration of all routes of exposure through all media) will be conducted on a case-by-case basis (Chapter 5, Section II).

22. The depth and accuracy of an exposure assessment should be tailored to provide the degree of knowledge required to support analytical needs. A preliminary assessment using available crude data can often shed light on the upper or lower bounds of potential risks (Chapter 5, Section II, Part D).

23. An exposure assessment should describe the strengths, limitations and uncertainties of the available data and should indicate the assumptions made to derive the exposure estimates (Chapter 5, Section III, Part F).

24. In general, an array or range of exposure values is preferable to a single numerical estimate (Chapter 5, Section III, Part F).

V. Principles for Risk Assessment

25. Decisions on the carcinogenicity of chemicals in humans should be based on considerations of relevant data, whether they are indicative of a positive or negative response and should use sound biological and statistical principles. This weight of evidence approach can include consideration of the following factors and should give appropriate weight to each on a case-by-case basis (Chapter 6, Section II, Part A):

(a) Findings from long-term animal studies (See Principle 14);

(b) Results from epidemiological studies (see Principles 16–18);

(c) *In vivo* and *In vitro* short-term tests;

(d) Structure-activity relationships of chemicals.

(e) Known metabolic differences between animals and humans.

26. No single mathematical procedure is recognized as the most appropriate for low dose extrapolation in carcinogenesis. When relevant biological evidence on mechanism of action (*e.g.*, pharmacokinetics) exists, the models or procedures employed should be consistent with the evidence. However, when data and information are limited, as is the usual case, and when much uncertainty exists regarding the mechanism of carcinogenic action, models or procedures which incoporate low-dose linearity are preferred (Chapter 6, Section II, Part C).

27. The quantification of the various sources of uncertainty involved in cancer risk assessment can be as important as the projection of the risk estimate itself. The sources that might be addressed include:

(a) The statistical uncertainty associated with the given risk estimate;

(b) The variability introduced by the selection of a particular low-dose extrapolation procedure;

(c) When risk estimation is based on laboratory generated data, the biological variability associated with the use of a particular test organism and its scaling or extrapolation to man (Chapter 6, Section II, Part D).

28. An estimate of cancer risk for humans exposed to an agent can be no more accurate than an exposure assessment that it utilizes. Lack of adequate exposure data is frequently a major limiting factor in evaluation of carcinogenic risks for humans (chapter 6, Section II, Part B).

29. While several considerations often enter the risk assessment process, it is important to try to maintain a clear distinction among facts (statements supported by data), consensus (statements generally held in the scientific community), assumptions (statements made to fill data gaps), and science policy decisions (statements made to resolve points of current controversy) (Chapter 6, Section II, Part D).

30. Differences in human susceptibility, and variable and extreme exposures to chemicals suggest the likelihood that there are subpopulations that are at greater than average risk. (Chapter 1, Section III, Part C, and Chapter 5, Section II, Part C). Increased consideration should be given to the identification of high risk populations.

31. Because of the uncertainties associated with risk assessment, a full evaluation of risk to humans should include a qualitative consideration of the basic strengths and weaknesses of the available hazard and exposure data in addition to any numerical estimations that are made (Chapter 6, Section II, Part D).

PART II—STATE-OF-THE-SCIENCE

Preface

This segment of the OSTP carcinogen document contains the details about the topics emphasized in Part I, and, as such, is a summary of the current science in a number of fields important to adequate risk assessment. Special emphasis has been placed on those areas considered to be particularly relevant to estimation of hazard and risk.

This section of the document is composed of six chapters. A chapter on the mechanisms of cancer induction is followed by two on testing, one each for short-term and long-term testing. These methods of hazard evaluation are complemented by a chapter summarizing a number of aspects of epidemiology, which estimates human hazard. There is a chapter on exposure assessment, a critical problem in assessing human risk, followed by a chapter, that draws on the others, which discusses risk assessment as a whole. It is clear that the limited space available in this review does not allow a totally comprehensive treatise on the various subjects involved, and specialists in the various fields may disagree with the importance of certain aspects of the discussion. The focus has been on a balanced presentation of what is consensus in the various fields discussed as they intersect with the need to understand the effects of chemical agents.

Chapter 1—Current Views on the Mechanisms of Carcinogenesis

I. INTRODUCTION

A. Philosophical Perspectives

Underlying the study of mechanisms is the search for causality in biological phenomena. Since science is continually advancing, our understanding of such relationships must be periodically re-evaluated in light of new, generally agreed upon findings. Such a review is especially important in rapidly advancing, highly specialized and interdisciplinary areas that are of significance to public health. The mechanisms underlying induction of cancer represent such an area and, therefore, are re-examined here in light of the findings of the last few years.

This disussion first places our understanding of the mechanisms of cancer induction in a historical perspective and provides a synopsis of some current commonly held beliefs. The bulk of the discussion in the text focuses on the interaction of cancer-related agents with factors both external and internal to an organism and the consequences of such interactions at the molecular, cellular, tissue and organismic levels relative to the development of cancer. The sequence of events presented is not written to advance any specific mechanism of cancer induction, but to indicate the response of various levels of biological organization to cancer-related agents. It should also be appreciated that the data presented have been obtained from studies using various research model systems (e.g. cell-free, cellular, whole animal) to isolate various components of the process derived from various strains and species treated under a great variety of experimental conditions. This approach to the study of cancer is generally accepted for many reasons, primarily the belief that, while biological systems vary, the degree of similarity at the level of their basic processes is greater than at higher levels of integration.

B. Historical Perspectives

Studies in paleopathology have indicated that while cancers occurred in pre-historic times (*1*), their incidence may be increasing concurrent with an increase in mean life span and the development of complex societies (*2*). The study of carcinogenesis is at least 300 years old. During the first 200 years, the studies were primarily descriptive. The involvement of life-styles in cancer occurrence was first observed by Ramazzini (1700) who noted that nuns exhibited a higher frequency of breast cancer than other women (*3*). Subsequently, Hill (1761) associated the use of tobacco snuff with cancer of the nasal passage (*4*) and Pott (1775) noted the occurrence of scrotal cancer with occupational exposure to soot in chimney sweeps (*5*). In the latter half of the nineteenth century, Rehn (1895) published evidence that aromatic amines were associated with bladder cancer (*6*), Unna (1894) and Dubreuilh (1896) associated sunlight exposure with skin cancer (*7, 8*), and Weismann (1881) suggested an association between the "germplasm" (the reproductive or life principle) and cancer (*9*). Over the next 50 years, with the development of appropriate models, numerous agents were found to induce cancer in experimental animals. Over the last 30 years, there has been an increased emphasis on understanding the mechanisms of carcinogenesis and, recently, on the role of factors such as personal habits in the enhancement or inhibition of tumor formation (*10, 11, 12*). Consequently, in the last decade, more progress has been made in understanding the overall mechanisms of carcinogenesis than at any other time in history.

C. Current Beliefs

From the mass of data on carcinogenesis, a consensus has emerged on a number of important scientific issues:

First, cancer can be induced by radiation, biological, "physical" and/or chemical agents.

Second, on a biochemical and molecular level, there are important similarities among mammalian species.

Third, an estimate of the potency of carcinogens may never be exact and may vary with life style, habits, age, sex, individual genetic differences, ethnic background, test strain and/or species, diet, dose rate, route of administration, vehicle or solvent used (if any) as well as the presence or absence of other agents, and the environmental conditions prior to, during, or after exposure.

Fourth, cancer development is a multi-stage process that may involve the genome, both indirectly (frequently termed epigenetic events) and directly, which may include the participation of chemicals or viruses, and which may be modulated by higher order functions, *i.e.* at the organ and organismic level.

Fifth, numerous factors may alter the frequency of cancer induction by altering one or more of these stages.

Sixth, the genesis of a cancer appears to require an alteration in the ability of a cell to elaborate its appropriate genetic program *i.e.* in its information processing capacity, with the subsequent fixation and propagation of that alteration.

Seventh, we still lack an in-depth understanding of the mechanisms and stages of cancer induction and expression.

Eighth, only by understanding the stages of tumorigenesis and carcinogenesis, the substances and processes which modulate them, and how these may differ among cells, organs, individuals, strains and species will we ultimately understand the role of substances, radiations, viruses and/or life-style factors in human cancer.

II. PREABSORPTION MODIFICATION OF CARCINOGENS

Natural exposure to carcinogens occurs by dermal contact, inhalation, ingestion, or a combination of these routes of exposure. Alterations of an agent can occur as a result of interaction with factors that are in association with, but not actually part of, the organism. Examples of these factors are solar radiation interacting with an agent on the surface of the skin, (*13*), interaction with cellular secretions, as in the case of certain inhaled carcinogens (*14*), or metabolic conversions by gut microflora, as may occur after ingestion (*15–24*). An illustration of the impact that these factors can have is exemplified by the role of the gut microflora in the

metabolism of xenobiotics. It has been suggested that the potential for metabolism in the gastrointestinal tract is similar to that of the liver (*20*). However, hepatic metabolism of non-nutrients is predominantly oxidative and synthetic (conjugations), while reactions by intestinal microflora are mostly of a hydrolytic and reductive nature (*20*). It also appears that intestinal microbial metabolism is most important for polar compounds that are not well absorbed from the gut and for those that are excreted, free or conjugated, in the bile (*20*). Examples of this include the metabolism of cycasin to a carcinogenic aglycone (*19*) and enzymatic reduction of a number of azo dyes by numerous genera of anaerobic gut bacteria (*24*). Intestinal microfloral metabolism can give rise to competition or cooperation between mammalian and microbial enzyme systems in sequential reactions in the cells and in the enterohepatic circulation.

Intra- and interspecies comparisons of microfloral metabolism of xenobiotics have been rare. In one study, rat, monkey and human intestinal microflora exhibited the capacity to reduce several benzidine and benzidine-congener based dyes to potentially carcinogenic aromatic amines under test conditions (*15*). Since there is a similarity between the biological effects of these dyes and the effects of benzidine on humans (*25*), this study suggested that, for these dyes at least, gut microflora may play a significant role in the etiology of urinary bladder cancer. Diet composition has also been shown to effect microbial metabolism. Diets with high pectin content can alter the metabolic activities of bacteria in the gut, as well as directly effect hepatic covalent binding of carcinogens (*26*). Further studies in this area, especially in regard to the relation between gut microflora in animals with different feeding habits, *e.g.* carnivore, herbivore and omnivore, and their susceptibility to certain classes of carcinogens would be of interest. Species and individual differences in microflora composition could quantitatively and qualitatively alter the nature of the agent to which the animal is ultimately exposed and, thus, the biological response.

III. ORGANISMIC AND CELLULAR METABOLISM

A. Activation, Detoxification and Reactivation

Carcinogens include biological agents, such as some viruses (*27*), radiations, such as X-rays and ultraviolet light (*28*), "physical agents", such as plastic surfaces and wounding (*29*), chemical agents, both organic and inorganic (*30*), and combinations thereof. Chemical carcinogens occur in a number of chemical classes including polycyclic aromatic hydrocarbons and their derivatives, aromatic amines, azo dyes, nitrosamines, nitrosamides, halogenated hydrocarbons, alkylating agents and metals, as well as in plant and microbial products (*30*). Ordinarily, not all chemicals belonging to any class are carcinogenic, nor are all those compounds within a class which exhibit carcinogenicity equally potent. Carcinogens may be naturally occurring (*31, 32*) (*e.g.* in food (*33*)), result from industrial processes (*32, 34, 35*), or represent the consequences of social activities (*36*). With the exception of a few direct acting agents, the organic carcinogens (*37*) and, possibly, some of the inorganic metal complexes (*38*) require metabolic activation in order to exert their cancer-inducing properties. In general, by whatever route chemicals enter the body, the enzymes involved in biotranformation of a chemical to carcinogenically active (as well as to a number of carcinogenically inactive) metabolites as part of the same mechanisms responsible for detoxication of drugs. Included in this interpretation of the detoxication mechanism is the partitioning of a compound and its metabolites into various body compartments and the effects of differing physiology (blood pH, blood flow to various organs, etc.) on the distribution of the compound and its metabolites. For example, the prolonged retention of acidic urine in dog and man, compared to the rat, can result in very different profile or aromatic amine metabolites than in the rat, due to the effect of a lower urine pH over a longer time on N-hydroxyarylamine conjugates (*39*). Also included in this approach is the total metabolic potential of the organism. For instance, nasal epithelium can activate chemical carcinogens (*40*), a consideration especially important to understanding the effects of exposure by inhalation.

The enzyme systems involved in biotransformation can be divided for convenience into two groups that convert a compound into either a phase 1 or phase 2 metabolite. Phase 1 metabolites are primary oxidation or reduction products, which are usually more water soluble than the parent compound and thus may generally be more easily eliminated from the body. These metabolites may be then conjugated with various soluble intracellular constitutents, forming glucuronides or sulfates, to become even more water soluble and available for excretion from the body. These conjugated metabolites constitute the phase 2 metabolites (*41*), which are usually excreted. However, deconjugation prior to excretion may release an active carcinogen at a site distant from the site of conjugation (*42*).

The reactions that occur in the formation of either phase 1 or phase 2 metabolites require specific enzymes for their conversion (some of the better characterized of which are listed in Table 2). Interactions between a chemical carcinogen and these metabolizing systems may form a large spectrum of phase 1 and phase 2 metabolites. A generally accepted mechanism for the reaction of metabolically activated agents with the cell has been proposed by Miller and Miller (*37*) namely that the ultimate carcinogenic forms of organic chemical carcinogens are electrophilic (electron deficient) reactants that bind with target intracellular nucleophilic (electron-rich) macromolecules such as DNA and proteins. The reactive metabolites formed may also react with other nucleophiles such as glutathione or water (*43, 44*). Through these latter processes, the effects of agents can be neutralized by forming less biologically reactive metabolites that are very polar and may be more easily excreted. The efficiency of this is an important factor in tumor induction. For example, if detoxification by glutathione is efficient, the effective local concentration of the active metabolites of the agent is reduced, which results in decreased binding to macromolecules. However, the electrophilic properties of some chemicals may be enhanced by glutathione conjugation (*45*) although this is usually not the case. Thus, determining the details of chemical biotransformation is desirable when assessing the impact of a chemical.

Table 2—Some Enzymes Needed for Phase 1 and Phase 2 Reactions

Phase 1

(1) Enzyme systems containing cytochrome P-450 and the FAD-containing mono-oxygenase catalyze epoxidation of aromatic rings or olefinic double bonds, produce hydroxylation of aromatic rings or alkly chains, perform oxidative dealkylation, and N-oxidation (44). This system occurs mainly in the endoplasmic reticulum of liver, Kidney, lung and intestine. The enxymes may occur in multiple forms and exhibit different or overlapping substrate-specificity (44).

(2) Epoxide hydrolase catalyzes the hydrolysis of arene oxides and alkene oxides into *trans*-dihydrodiols.

(3) Dehydrogenases, flavin-containing cytochrome-450 reductases and xanthine oxidase catalyze the reduction of nitroaromatics to nitrosoarenes, N-

hydroxyarylamines, and arylamines, and the reduction of azo compounds to amines.

Phase 2

(1) Glutathione S-transferases catalyze the conjugation reaction between glutathione and a variety of electrophilic compounds such as arene oxides. These enzymes exist in multiple forms (44).

(2) UDP-glucuronyltransferases catalyze the conjugation reactions between glucuronic acid with substrates such as phenol and bilirubin. These enzymes are also found in multiple forms (44).

(3) Sulfotransferases catalyzes sulfate ester formation.

(4) N-Acyltransferases and N,O-acyltranferases catalyze N-acetylation and N,O-acyltransfer of aromatic amines and arylhydroxamic acids.

Understanding the metabolism of chemical carciongens is often complicated by the diversity of the enzymatic reactions. For example, for aromatic amines and related compounds, the N-hydroxy derivatives may be the only phase 1 metabolites needed to generate the nitrenium ion-species that bind with target intracellular macromolecules (*39, 46*). Alternatively, the common metabolic activation of nitrosamines and nitrosamides occurs via the formation of diazo intermediates, which subsequently decompose to molecular nitrogen and active alkyl carbonium ions (*30*). To illustrate the complexity of metabolism of a chemical carcinogen, most of the known metabolic pathways and the phase 1 metabolites formed from benzo(a)pyrene, one of the most ubiquitous of environmental compounds known to be a carcinogen in animals, are shown in Figure 1. In this system, many of these metabolites can be converted to different conjugates by phase 2 enzymes. The enzymes cytochrome p-450 and epoxide hydrolase exhibit high selectivity for a particular molecular region and its local conformation (*47*). This results in arene oxides, *trans*-dihydrodiols and *trans*-dihydrodiol-epoxides being formed as specific optically active isomers (enantiomers). These enantiomers exhibit markedly different biological activities (*48*).

Simply knowing the identity of the major matobolites of a compound may not always allow prediction of its hazard. For example, metabolism of polycyclic aromatic hydrocarbons to *trans*-dihydrodiols was long known, but thought to be a pure detoxification process (*49*). However, identification of the *anti*-isomer of the dihydrodiol-epoxide of benzo (a)pyrene, which is derived from the *trans*-7,8-dihydrodiol (Figure 1), as the electrophilic metabolite of benzo(a)pyrene which binds DNA (ultimate carcinogen) has proven that some *trans*-dihydrodiol metabolites can be enzymatically activated (*50, 51*). Additionally, detoxified metabolites formed in the liver may be reactivated in other organs, *e.g.* the bladder (*39*). The metabolic fate of a compound is a function of three processes occurring together (activation, deactivation, and reactivation), whose dynamic interaction results in the local concentration and life time of the active metabolite(s). The combination of whole animal, organ and cellular processes results in a local variable dose-rate of active species with time. These changes may be significant factors in producing the biological effects seen with a particular agent.

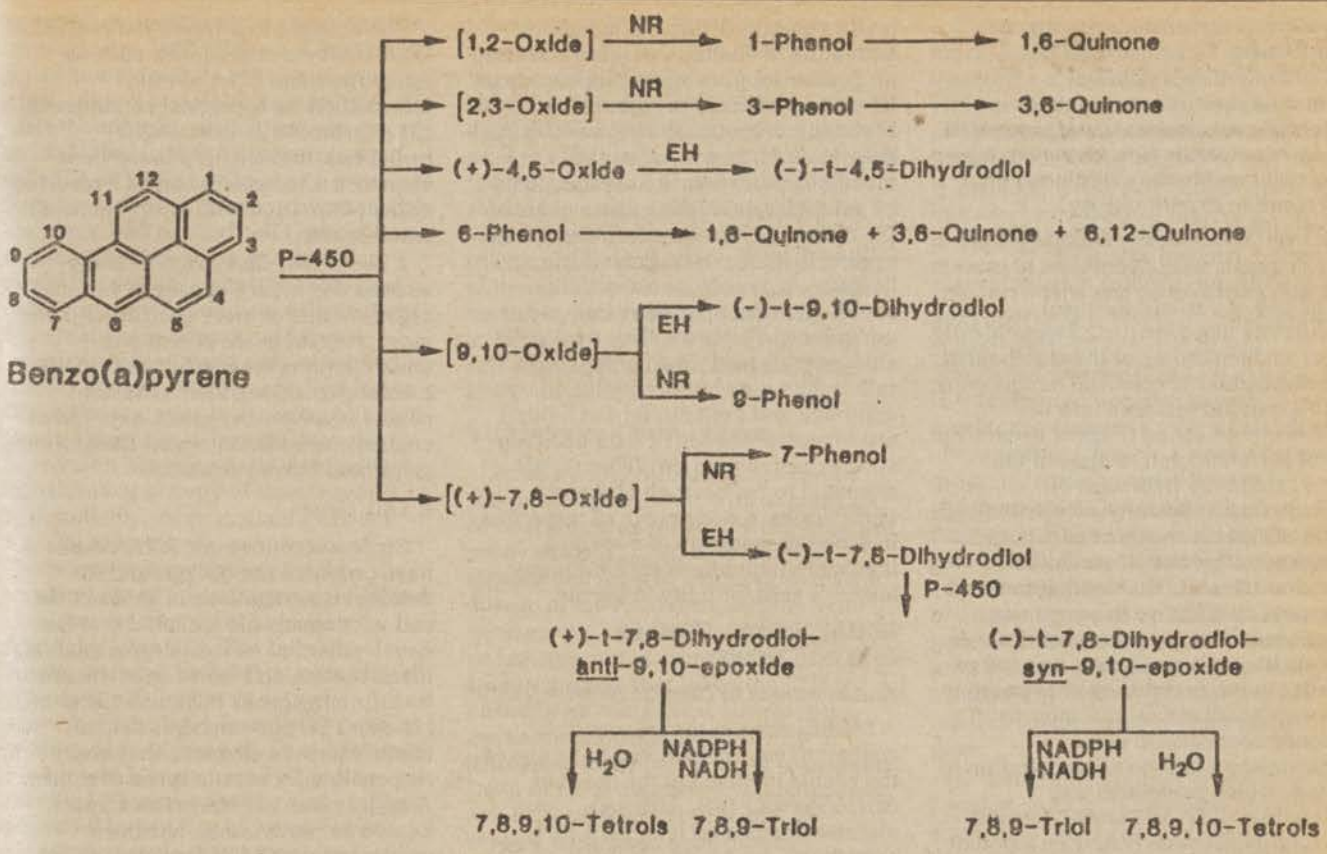

Figure 1. Metabolic pathways and metabolites of benzo(a)pyrene obtained from metabolism by rat liver microsomes. Abbreviations: P-450, Cytochrome P-450 containing enzymes together with cofactors; EH, Epoxide hydrolase; NR, Non-enzymatic rearrangement; t, *trans*.

B. Modulation of Metabolism

Compound metabolism is a function of the three processes in tissues described above, in combination with the cellular, organ and whole animal distribution and excretory processes. This dynamic interaction can be modulated by a number of factors. Such factors include enzyme inhibitors, enzyme inducers, metabolite scavengers (see below), starvation, age, sex, stress,, tissue ablations, nutritional factors, individual genetic differences, and hormonal status (*44, 52*). Various synthetic chemical agents have been shown to act as inhibitors, inducers, or scavengers (*53*) and this diversity of effects has been suggested as well for some commonly eaten foods, which contain naturally-occurring inhibitors or inducers, and which also appear to modulate metabolism (*11, 33*). Briefly, there are three general mechanisms accounting for the modulation of metabolism by inhibitors or inducers (*53*): (1) Stimulation of cellular metabolism which results in an increased deactivation and/or activation. For example, a wide range of compounds including polycyclic aromatic hydrocarbons, phenobarbital, flavones, halogenated hydrocarbons, and indoles induce an increase in mono-oxygenase activity and changes in the relative proportions of the different isozymes. Other enzymes, such as glutathione S-transferases may simultaneously be enhanced. Affinity constants may be altered. As a consequence of any and all these changes, the relative proportions of various metabolites may change, thereby influencing the ratio of metabolic activation to deactivation (*54*). (2) Interference with enzymatic activation of chemical carcinogens to form the ultimate carcinogenic metabolite(s). For example, disulfiram is thought to inhibit dimethylhydrazine-induced neoplasia of the large bowel by directly reducing the rate of conversion of the agent into a reactive metabolite (*53*). (3) Alteration of scavenging (neutralization) of the reactive metabolites by nucleophiles, such as glutathione, or other defense systems, such as superoxide dismutase. For example, starvation, other nutritional imbalances, or compounds such as butylated hydroxyanisole may drastically alter glutathione levels (*55,56*). Decreases in glutathione levels may lead to a decreased proportion of the reactive metabolite being detoxified. Conversely, the increased levels of glutathione and glutathione transferase produced by butylated hydroxyanisole may indicate greater detoxification of a reactive metabolite, provided that the glutathione conjugate products are not reactivated.

However, it is the balance between the activation and detoxification systems for a chemical carcinogen, and their interaction over time, rather than the change in one of these processes *per se*, which is important. If mono-oxygenase activity has been stimulated, resulting in increased reactive metabolite formation, a greater proportion of biologically available carcinogen will result only if the

detoxification mechanisms can not compensate. As an example of compensation, low doses of acetaminophen, whose reactive metabolite reacts with glutathione, will not be hepatotoxic (*57*). However, larger does will deplete the glutathione pool and result in hepatotoxicity. Alternatively, if glutathione levels are decreased, concentrations of electrophilic metabolites may increase.

The use of various chemical modulators has contributed significantly to our understanding of the metabolism and disposition of chemical carcinogens. With extended research into the mechanism of action of these agents, the use of such modulators may, in the future, aid in the treatment of individuals accidentally exposed to high doses of certain chemical carcinogens. However, at present, it would be premature to state that modulators will be generally effective in preventing cancer induction by some chemicals or that such agents could ever be used as an alternative to reducing or preventing exposure to identified carcinogens. An indication for caution is the demonstration that co-administration of aspirin, which modulates the metabolism of N-[4-(5 nitro-2-furyl)-2-thiazolyl]formamide (FANFT), a potent rat urinary bladder carcinogen, will decrease the number of bladder tumors induced by FANFT, at the time however increasing the number of forestomach tumors produced (*58*).

C. Organ and Species Differences

Because the total enzyme level and substrate specificity of the phase 1 and phase 2 metabolizing enzymes exhibit organ, individual, and species differences (*52*), the metabolic patterns of both activation and deactivation of a particular agent could also differ markedly. An example of this is the differences in the monooxygenase activities in nasal epithelium in different species (*59*). Also, there exist multiple forms of cytochrome P-450 enzymes, each of which exhibits its own specificity toward the substrate metabolized (*44*). Since glutathione S-transferases and UDP-glucuronyltransferases also occur in multiple forms (*44*), their particular form in different tissues, strains, individuals or species may also vary. Moreover, the activity of each metabolizing enzyme in a specific tissue of the same strain could vary widely depending on age, sex, nutritional factors, hormonal status, or other factors (*32*). for these reasons, unless one knows the rates of the activation-deactivation processes and the participating isozymes responsible for these reactions, it is impossible to predict quantitatively the metabolic activation of chemical carcinogens from an *in vitro* to an *in vivo* system, or from laboratory animals to humans. Metabolic comparisons between animal species and humans, when the metabolic pathways are similar, could be useful for qualitative asessments of the relevance of a specific animal test system to human risk. Presently, however, a paucity of comparative metabolism data on either induced or noninduced systems exists since most studies are based on an ontogenetic rather than a molecular-evolutionary approach and are therefore of limited use for extrapolation of data between species and organs (*60*). There is also expected to be, because of these variabilities, a wide range of responses in different members of a species, leading to individuals with different levels of susceptibility to agents.

IV. MACROMOLECULAR INTERACTIONS

A. Alterations in Genetic Information

Modification of the information content of cells is believed to be one of the events involved in the onset of carcinogenesis (*61*). Although macromolecules such as RNA (*37*), protein (*62*), and lipid-containing membranes (*63*) will be altered by many carcinogens, and may be important at different stages in carcinogenesis, it is believed that the primary initial site for cancer induction is the DNA. The evidence for this hypothesis rests on a number of observations: (1) The great majority of biological carcinogens that have been examined interact with the DNA of the host cell (*64*); (2) many, but not all, radiations and chemical carcinogens are mutagens and mutations result from alterations in the DNA (*65*); (3) individuals with certain genetic diseases which are characterized by defective DNA repair, such as xeroderma pigmentosum, are prone to cancer at a number of sites and cells from these individuals have increased sensitivity to several radiations and chemical mutagens (*66–68*); (4) ultraviolet (254 nm) light-induced tumor formation in the gynogenetic fish, *Poecilia formosa*, is directly related to the amount of DNA damage remaining after different levels of photoreactivation repair of the DNA (*69*). Agents which by themselves do not induce cancer but influence the expression of cancer cells may or may not act on the DNA. These agents will be referred to throughout the text, but especially in the subsequent sections on promotion, progression and multiple agents.

The changes in information content of DNA can take many forms such as integration into DNA of viral information for biological carcinogens, chromosomal alterations with radiations, and changes in the base sequence after replication as a result of adduct formation with many chemical carcinogens.

1. Biological Carcinogens. Many viruses will induce cancer in various organs of one or more species (*70*). The most progress made recently in understanding the mechanisms of viral carcinogenesis relevant to human cancer involves *onc* genes, expression control elements, dominant transforming genes and human viruses.

a. Onc Genes

Studies on oncogenic RNA viruses have provided the background for detailed investigations of genes in the cell with oncogenic potential and for development of methodologies enabling identification and isolation of dominant transforming genes in human tumor cells (*71–84*). This approach has helped identify genetic elements that may be responsible for certain types of cancer. A major class of RNA tumor viruses, known as retroviruses, has been particularly useful in providing new insight into the cancer process. Retroviruses are unique among animal viruses in their mode of transmission and their intimate assocation with a wide variety of vertebrate species (*85*), factors which may have allowed them to become oncogenic in a number of species. Certain members of this group, the acute transforming retroviruses, appear to have arisen by recombination of the viral genome with cellular genes. The acquisition by these viruses of cellular genes, termed *onc* (for oncogenic) genes (*86*), is associated with the ability of these viruses to induce rapid neoplastic disease in newborn animals and to transform cells, an *in vitro* model for carcinogenesis, in culture. More than two dozen such viruses have been isolated and characterized, and more than 18 *onc* genes have been identified in both avian and mamalian species (*87, 88*). These RNA tumor viruses can be thought of as vectors that carry isolated cellular genes critical for malignant neoplastic disease. These isolated *onc* genes can then be used to make probes for examining human cancer cells for active oncogenic sequences.

The *onc* genes appear to have been derived from the normal genome of a cell which the virus had once infected. These genes are representatives of a gene family that is highly conserved in

vertebrates (and, in some cases, even in invertebrates [*87*]). There are human genes homologous to retrovirus *onc* genes (*88–93*) and RNA transcripts corresponding to specific *onc* genes can be identified in certain human cancer cells (*94, 95*). Most cellular *onc* genes are found in low or single copy number and are expressed in most cell types at low levels (*93*). Also, some *onc* genes are rarely expressed, some are expressed chiefly in specific kinds of cells derived from malignant tumors, and some appear to be expresed only in cells of certain lineage or differentiation states. When the *onc* gene is expressed at high levels, the increase in gene dosage or expression has been correlated with the transforming activity of the virus (*89*). Alternatively, there is some evidence that the removal of a suppressor or regulatory gene, with the possible involvement of an oncogene as a second step, may be important in human retinoblastoma (*96*). The cellular functions coded by most *onc* genes are unknown, although a variety of activities have been found. The gene product of one family of oncogenes, *src*, is a protein kinase, usually tyrosine specific (*97*), similar to the kinase often activated by binding of a number of growth factors to their receptors. Sometimes, only pieces of a receptor are coded, *e.g., erb-b* codes for the integral membrane and large interior portions of the epidermal growth factor receptor (*98*) and *fgr* seems to produce a hybrid protein resulting from the recombination of actin and part of a tyrosine specific gene kinase (*99*). Interestingly, phorbal tetradeconate acetate (TPA) (an important model compound in tumor promotion), (see below), also activates a tyrosine specific protein kinase (*100*), which phosphorylates insulin and somatomedin receptors (*101*). The *onc* gene of simian saroma virus was probably derived from genetic material encoding platelet-derived growth factor (PDGF), which is a growth factor in the type of tissue which bones becomes cancerous as a result of this virus (*102*). Beyond the receptor level, an early effect of PDGF is to stimulate *myc* (*103*), an oncogene that codes for a nuclear protein (*104*). This is especially interesting in that it has been shown that at least two oncogenes working together, *ras* and *myc*, are necessary to transform primary fibroblasts in culture (*105*). Altogether, these data suggest that there is a two part model for oncogene involvement in transformation, one part centering around the stimulation of some growth factor, and the other, around an alteration in the cell nucleus. The first part, as suggested by the data concerning PDGF (*102*) may involve the interaction of a cell with other cells, and the second part may be an intrinsic change in the cell itself. Although this is a speculation, and there are important gaps to information, a general picture of the mechanism of viral carcinogenesis is starting to emerge which also may be very important in understanding chemical carcinogenesis. An indication of this is the evidence that each of nine mammary carcinomas induced by a single injection of nitroso-methylurea in rats contained an activated *ras* gene (*106*).

b. Expression Control Elements

Some normal cell *onc* genes can be activated when linked with expression control elements (ECE) derived from the retroviruses (*71, 107, 108*). The ECE regulate the level of expression or gene dosage of the retrovirus genome in an infected cell and can be used to "switch on" expression of other genes. Recent studies suggest that when the ECE is linked to an *onc* gene it activates the gene's transforming potential by increasing the gene's level of expression (*107*). *In vivo*, the same two factors, *onc* and ECE, which appear to link by chance, have been shown to be responsible for oncogenesis in animals infected with certain retroviruses (*107*).

The viruses from which the acute transforming retroviruses seem to have originated, the leukemia retroviruses, usually cause leukemias or lymphomas, but can also cause a variety of other neoplastic diseases in animals after long latent periods (*85*). When these viruses infect a large population of cells, viral genetic information can integrate at many loci in the host genome. The stable integrated form of the virus (called the provirus) is bracketed by the same ECE described above. These ECE are virus specific and are generated during the integration process (*109*). During the past two years, it has been demonstrated that, in some instances, these viruses will integrate at loci in the host chromosome adjacent to cellular *onc* genes and will cause neoplastic disease (*87, 88*). Similar to the situation described above for the acute transforming retroviruses, this specific integration results in elevated levels of expression of a specific cellular *onc* gene which becomes regulated by the viral ECE. The long latent period required for neoplastic disease induced by these viruses may be associated with the frequency of or time to specific integration in the host chromosome adjacent to a cellular *onc* gene of the viral ECE.

Some radiations and chemical carcinogens might enhance either the frequency of initial integration of the virus or subsequent rearrangement of viral material by inducing chromosomal translocations. For example, in Burkitt's lymphoma, a characteristic portion of human chromosome 8 (carrying c-*myc*) is translocated to chromosome 14, and the site of immunoglobulin heavy chains (*109–111*). This *onc* gene is the same one activated by a retrovirus transcription control element in avian bursal lymphoma disease (*112,113*). Also, c-*abl* is translocated in patients with chronic myelocytic leukemia with a Philadelphia chromosome which is a translocation of the gene from chromosome 9 to chromosome 22 adjacent to an immunoglobulin light chain cluster of genes (*114*). Such translocations might conceivably result in the juxtaposition of an *onc* gene and an ECE, altering *onc* gene expression. The same result might arise from direct genetic insult (via some carcinogen) to the ECE which normally regulates expression of the cellular *onc* gene.

Considerable study is now being focused on ECE. It has been known for some time that certain nucleotide sequences which bracket structural genes are associated with the initiation and termination of gene expression (*115*). However, it was first shown with transforming genes that a region termed "enhancer" must be present in order for these start and stop signals to be recognized (*71,107,116,117*). Although it is not yet known how enhancers function, apparently they can be located in a number of different positions surrounding the structural gene. Moreover, even though the few that have been examined bear no sequence homology, the enhancer sequences from retroviruses have been shown to function and allow expression of a DNA tumor virus, SV40 (*117*). Also, the sequences seem to be utilized in normal differentiation, as shown by the evidence that immunoglobulin heavy-chain class switching in a pre-B cell line is accompanied by gene rearrangement (*118*), and, in the development of Burkitt's lymphoma, the activation of the translocated c-*myc* gene seems to occur by an enhancer in the heavy-chain immunoglobulin locus (*119*). It is possible that translocation into a region controlled by an enhancer or mutations in gene enhancer or activator sequences of cellular *onc* genes could participate in expression of a transforming phenotype.

c. Dominant Transforming Genes. Another area of considerable study during the past two years has been the direct isolation of dominant tranforming genes from human tumor cell lines (*82–84*). This technology is a direct result of studies of viruses and cancer. A biological assay referred to as transfection was used early in tumor virology to demonstrate that host genomic DNA containing dominant viral *onc* genes could be transferred to normal cells (*85*). The early studies were developed and refined using cells transformed with acute transforming retroviruses; they demonstrated clearly that the integrated provirus could be transferred as part of the cellular genomic DNA into specific cell lines capable of assimilating foreign DNA into their chromosomes. By using this technology it has been possible to transfer dominant transforming genes from a variety of tumor cell lines from different species, including human. These include genes from human lung cancer, colon cancer, bladder cancer, and breast cancer cell lines (*82–84–120–122*). Utilizing techniques of recombinant DNA, it has also been possible to identify and isolate (in certain instances) these dominant transforming genes from the transformed recipient cell and to show that these isolated genes are of human origin (*82–84*). In the molecular cloned state, the genes have high oncogenic potential. It is of particular importance that some of these genes (for example, genes associated with human bladder, lung, and colon cancers) are related to a specific family of one of the acute transforming retroviral *onc* genes (*123–125*). In the case of a human bladder cancer gene, it has recenty been shown by three investigative teams that a single base change in a normal human gene results in expression of the oncogenic potential (*126–127*). Also, in the case of chemically-induced tumors, there is suggestive evidence that the activation of an oncogene occurs by a single base change (*106*). The study of RNA tumor viruses has provided an initial understanding of how viral *onc* genes cause cellular transformation. The correlation with human *onc* enes provides an enormous leap in our understanding of causal factors in human neoplastic disease.

d. Human Viruses

Recently, retroviruses of the kind that cause leukemia in animals have been isolated from humans. These human leukemia viruses (HTLV) are known to be associated with several types of T-cell leukemias in man (*129–130*). When they are transmitted to normal human T-cells, they induce a morphology, behavior, and phenotype similar to those naturally occurring in transformed cells isolated from individuals with T-cell leukemia and lymphomas (*131*). This virus, the presence of which correlates with clusters of the disease, thus may represent a true human cancer virus (*132–133*). However, other viruses, such as herpes viruses, especially Epstein-Barr virus (EBV), hepatitis B virus, and papilloma viruses, have also been associated with human cancers (*134*). Although these viruses do not fit all the presently recognized criteria for a true human tumor virus, they may nonetheless influence the development of certain human cancers. Thus, EBV appears to be a stimulus for proliferation of B-cells which may be an early event in the development of African Burkitt lymphoma (*135*). Herpes simplex, a DNA virus, is associated with cervical cancer (*136*), and hepatitis B virus to liver cancer (*137*). Papilloma viruses cause bening skin growths (warts) and some strains have recently been shown to be associated with squamous cell carcinoma (*138*). Much current work is focused on a possible similar role for papilloma viruses in cancers of the genital tract and accessory organs (*139–140*). How, and even whether, these and other viruses play a rule in various types of cancer or interact with various "physical" and chemical carcinogens is poorly understood; but the belief that DNA is a critical target for the biological carcinogens is strongly supported by current studies. New methodology to prepare antibody—using chemically synthesized peptides from nucleic acid sequences—make it possible to generate antibodies against several different *onc* gene products (*141*) and to characterize the molecular properties of the transforming proteins in transformed cells. This method should aid in developing a better understanding of how chemicals and viruses interact with one another.

2. Radiation. Radiations, both ionizing (the corpuscular radiations and X and gamma-ray photons) and non-ionizing (ultraviolet light [UV]), have been shown to act as carcinogens (*28*). Ionizing radiations are ubiquitous, with cosmic rays and naturally occuring radioisotope decay being examples of major sources of background radiation. UV is also ubiquitous, being a component of sunlight.

Carcinogenesis by ionizing radiations is generally related to the special distributions within cells of the ionizations they produce (*28*) as well as total dose, dose rate and fractionation, and target tissue (*142*). The deposition of energy which results from the interaction of radiation with biological media creates ions, free radicals and excited molecules (*142*). The free radicals are thought to be most important product since: (1) Hydroxyl free radicals are involved in some of the biological effects of radiation (*143*); (2) chemicals that are cellular free radical scavengers inhibit the ability of ionizing radiations to transform cells in vitro (*144*); and (3) chemicals involved in protection from free radicals, such as selenium which is important in the action of glutathione peroxidase (an endogenous scavenger), inhibit radiation induced transformation (*142*). Presumably, these data also indicate a role for modulators of metabolism in radiation induced carcinogenesis. Free radicals will react with many cellular macromolecules, but the production of single-strand breaks, double-strand breaks, chromosomal aberrations, and the production of mutations by ionizing radiation, argue that the DNA is the critical cellular target for the biological effects (although the relationship of any of these phenomena with carcinogenesis is not definitive) (*142*). Although experimental dosimetry is much better defined for radiation compared to most chemical agents, the molecular lesion(s) significant for carcinogenesis is (are) unknown and may be different for different radiations. The absence of "radiolabelled adducts," common for many chemical agents, has hampered analysis. One example of a possibly significant lesion is the reaction of the hydroxyl radical with the deoxyribose in DNA, which results in DNA strand breakage (*125*), although many other lesions are formed.

UV photocarcinogenesis is wavelength dependent with UVB (photons with a wavelength of 280–320 nm) being most effective on mouse skin (*146*). Although the photoproducts produced by UV irradiation in cells are myriad (*147*), reaction with the DNA has been shown to be the critical factor in carcinogenesis. There are a number of lines of evidence which suggest this: (1) In patients with actinic keratoses (a premalignant condition) the DNA repair capacity for UV induced damage (UV excision repair) in lymphocytes was found to be less than in matched controls (*148*); (2) individuals with xeroderma pigementosum, who exhibit a predisposition for sunlight-related cutaneous malignancies, although having seven genetic complementation groups, were all found to be deficient in the ability to repair damage induced by UV(*67*); (3) by use of antibodies, DNA

has been shown to be altered immediately and directly by UV irradiation (*149*); (4) the persistence of UV photoproducts after photoreactivation, a repair mechanism which specifically corrects pyrimidine dimers in the DNA induced by UV, is directly correlated with the capacity of UV irradiated tissue to develop into tumors (*69*); (5) the action spectrum (relationship of intensity of a biological response to frequency) of UVB photons is the same for their carcinogenic action and the production pyrimidine dimers in mouse skin (*150*).

It is important when making estimations of risk for chemical agents that we realize what are the origins of many of the tenets upon which these estimations are made. For example, the hypothesized mechanisms of the action of radiation, while not the primary concern of this document, have served, and continue to serve, as the basis for some of the primary models for chemical carcinogenesis (*151, 152*). Much evidence that damage to the cellular DNA is a step in the induction of tumors comes from studies using radiation. Similarly, various models for high-dose to low-dose extrapolation have their origins in studies using radiation and the best data for these models have been obtained from such studies.

3. Chemical Carcinogens. The interaction of chemical electrophiles with DNA, as discussed in the section on metabolism, may lead to covalently bound adducts, intercalations, strand breaks, phosphotriesters, crosslinks, apurinic sites, apyrimidinic sites, deaminations, and/or hydrations, all of which are forms of DNA damage that may alter genetic information (*53, 153–165*). Studies of chemical carcinogenesis have focussed on covalent adducts. Examples of this are the observations that: (1) Simple alkylating agents can methylate or ethylate any of the nitrogens or oxygens in either of the four bases in the DNA as well as the sugar residues and phosphate backbone of the DNA (166); (2) the epoxide derivatives of aflatoxin can attack the N–7 position of guanine (167) (as well as other sites); (3) activated aromatic amines attack the C–8 and N–2 position of guanine (*168, 169*); and (4) the dihydrodiol-epoxide derivatives of benzo(a)pyrene and certain other polynuclear aromatic hydrocarbons attack the N–2 position of guanine and, to a lesser extent, form adducts with adenine and cytosine (*170, 171*). Activated derivatives of these and other carcinogens form similar lesions in the DNA of a number of diverse tissues and species (*171, 172*).

The biological significance of these alterations in the DNA is not always clear, and different alterations may have very different biological effects. Some alterations may cause mutations (*173, 174*). For example, modification of the 0–6 position of guanine will cause this base to be misread, during DNA replication, as adenine (*175*). Also, the major guanine adduct of benzo(a)pyrene, through a transversion, may be misread as a cytosine or thymine in replication (*176, 17*). Alterations in the control of DNA are possible. The amount of methylation of DNA, which may be used in the control of genetic expression (178), can be altered by some agents. Some of the carcinogenic metals may work through alteration of the enzyme that replicates DNA (DNA polymerase) to cause alterations in the genome through miscoding of DNA bases after replication (this will be discussed in detail in the section on fidelity/infidelity of replication).

4. "Physical" Carcinogens. This class of carcinogens encompasses a number of very diverse phenomena including skin abrasion, scar formation, implantation of non-reactive materials (foreign bodies), schistosomiasis, etc. (the term physical carcinogen is also sometimes used to describe radiation, *i.e.* a physical agent). Common factors of this class seem to be: (1) The need for the development of a chronic fibrosis, or at least an inflammatory response; and (2) any chemical properties, *e.g.* of a foreign body, are not important (*29*). An interesting mechanism, with a number of steps, proposed for foreign body carcinogenesis may be relevant to the whole class. During tumor induction, there is an acute inflammatory response with an outgrowth of capillaries as cells adhere to the surface of the foreign body. This response is induced by a number of substances (including mitotic stimuli similar in some ways to growth factors), elaborated by cells in the vicinity of the foreign body. Fibroblasts increase in number, which leads to tissue deposition of collagen (fibrosis). After a latent period, uncontrolled proliferation begins (*179*). The initiation event seems to occur away from the foreign body surface, inducing an initiated cell through changing the environment of the cells in the vicinity of the foreign body (*29*). However, the inflammatory response results in an active cellular proliferation of a number of vascular-derived cells. This step can also occur in the inflammatory response generated by the other "physical" carcinogens. By its presence, the foreign body causes the macrophages to become quiescent and the reactive tissue to develop into a chronic fibrotic state, so that there is surface-in-dependent maturation of the initiated cell (*29*). Asbestos, which is frequently considered a member of this class, may induce cancer by a different pathway. Unlike other "foreign bodies" fragments of asbestos fiber are incorporated into and activate macrophages (*180*). However, the end result is a fibrosis, *i.e.* asbestosis, which, though more diffuse, is similar in many ways to fibrosis induced by the foreign bodies (*29*). The size of the asbestos fiber and the possibility of chemical effects because of fiber dissolution of adsorbed molecules make direct comparison with foreign body cancers difficult.

It is not clear how, if at all, this class of carcinogens interacts with the genome. The range of speculations include: (1) No interaction with the genome, with the recruitment of omnipresent previously initiated cells by a proliferative stimulus into neoplasia; (2) the environment of the inflammatory response, especially the production of free radicals by macrophages, causes chromosomal damage and rearrangement resulting in transformation; (3) a stimulation of proliferation may result in mutation as a result of infidelity of replication (see below); however there is little information in the area.

5. General Statements. The interaction of electrophiles, or the products of irradiation, with DNA can play a role in the induction of a tumorigenic phenotype through either of two mechanisms: (1) Directly by altering genetic material through a somatic mutation (*173*); or (2) indirectly by altering gene expression (*178*). For example, in the former case, somatic mutation can arise from the direct interaction of DNA with electrophiles, free radicals derived from carcinogens, or with activated oxygen produced by metabolism of the agent. In the latter case, the alteration of gene expression can arise from either: (1) A direct mutational event in a regulatory gene controlling expression (*e.g.* base transition) (*173, 181*); (2) changes in gene expression resulting from an increased rate of abnormal base incorporation due to enhanced DNA synthesis, or abnormal methylation of nucleic acid bases (*178*); or (3) induction of genetic transpositions or gaps in the DNA leading to an alteration in gene expression (higher order alterations) (*12*). Direct alterations in the informational content of cells seem to be common for many, but not all, carcinogens. The potential involvement

of an *onc* gene with either direct or indirect alteration of the genome has been discussed in a previous section.

Understanding the significance of these changes may now be possible with the recent development of new methods to determine the structural alterations caused in DNA by chemical carcinogens and radiation (*183*). This has occurred as a result of recent advances in spectroscopic and spectrometric instrumentation, especially in the areas of nuclear magnetic resonance spectroscopy and mass spectrometry. Significant progress has also been made in understanding the effect of carcinogens upon DNA's secondary structure (*184–186*). For example, recent studies have demonstrated that while methylating and ethylating agents do not induce major steric changes in DNA, aromatic amines induce "base displacement" (*187*). Additionally, 2-acetylaminofluorene appears to induce a flip from the conventional right-handed B-helix of DNA to the left-handed Z form (*170, 187*). Such changes, while not induced by all chemical carcinogens could, if they occur *in vivo*, suggest mechanisms by which chemicals induce major steric alterations in the structure of DNA. The biological consequences of such changes, however, are uncertain. Even newer techniques are being developed, such as radioimmunoassays using monoclonal antibodies against specific forms of DNA damage (*188*) and reversed labeling methods that are able to detect a single damage base per cell (*189*), that may eventually allow routine estimation of DNA in humans.

V. MODULATION OF ALTERED GENETIC INFORMATION

For many carcinogens, it is necessary for cellular proliferation to occur before the damage induced by a given agent is expressed. For instance, a cell replication must occur within 48 hours to express X-ray induced transformation in culture (*190*). Replication must also occur *in vivo* in liver (*191*). One way to think about the process is that a cell is first "primed" for alteration by interaction with a carcinogen; cell replication then results in at least one daughter initiated cell, *i.e.* a cell irreversibly altered so that it can interact with the proper stimulus to form a malignant cell.

The alteration of genetic information that produces the initiated cell is modulated by a number of factors. Two of the most important are: (1) The amount of DNA damage (adducts, strand-breaks, etc.) that is removed from the "primed" cell and its daughters (DNA repair); and (2) the accuracy of DNA synthesis (fidelity/infidelity of replication), both as a result of damage to the genome and as a result of changes in cellular parameters (ion concentrations, etc.).

A. DNA Repair.

The processes of DNA repair (Table 3) are believed to be some of the primary modulators of physical and chemical carcinogenesis. The bulk of evidence for this assertion comes from studies implicating UV and ionizing radiation as etiologic agents in cancer (*193*). For example, as discussed above, individuals with xeroderma pigmentosum who are defective in repair of UV-induced and some forms of chemically induced DNA damage (*67*) exhibit a high incidence of light-related cancers (*194*).

Table 3—Mammalian DNA Repair Mechanisms

1. Nucleotide excision repair—a mechanism that removes bulky, noncoding lesions from the DNA in a manner similar to, but not identical with, bacterial nucleotide excision repair (163, 197–203).

2. Base excision repair—a mechanism that permits reinsertion of the proper base into the gap left in the DNA by the action of enzymes that effect the excision of inappropriate bases from DNA as the free base (DNA glycosylases), avoiding scission of the DNA backbone (204–207) as well as a system similar to the bacterial one requiring strand scission (208–213). Included as part of this form of repair, following Setlow (214), are direct demethylation by transfer of a methyl group to an acceptor protein (215, 216) and AP site repair (direct repair of a removed base) 205–207, 217).

3. Strand break repair—the process by which single and double-strand breaks are rejoined with the addition of a few or no additional nucleotides through the action of a sealing enzyme (218–223).

4. Photoreactivation—a light activated enzymatic mechanism specific for the breakage of the UV induced covalent bond attaching two pyrimidines in a cyclobutane-type ring (224–230).

5. Recombination repair (post-replication repair)—a system once believed to occur in mammalian system, although now controversial, by which bulky, noncoding lesions were transferred to DNA synthesized after damage (231–234).

6. Replication bypass (post-replication repair)—a process that may function in mammalian cells as an alternative to recombination repair in which the bulky lesions are bypassed and the gap created filled (235–236).

7. Inducible DNA repair systems—the most recently described and still speculative (for mammalian systems) repair system in which DNA damage triggers the induction of enzyme systems to remove the damage (237–243).

More generally, the available data are equivocal as to whether there is an increased risk of development of cancer of the internal organs (*68, 195*). Problems with interpretation of these observations include: (1) Chemically-induced and UV-induced damage may induce cancer by different means; (2) organ specific differences exist for cancer induction; and (3) the time to tumor may differ significantly between organs and death of the individual due to complications arising from the skin tumor prior to the onset of cancer in an internal organ or tissue. It is also possible, however, that the data bases were too small to support any conclusion and that a larger study should be conducted.

Because of the importance of DNA damage, a number of short term bioassay systems that measure it, directly or indirectly, have been developed to screen for potential carcinogens (see Chapter 2, this volume). One modulator of the amount of DNA damage an agent causes, DNA repair, has been studied in numerous *in vitro* and *in vivo* biological systems (*196*).

From these studies, various pathways for repair of numerous forms of DNA damage have been identified (Table 3) (*197–243*). Many of the processes of repair in mammalian cells are similar to those described in bacteria and thus it is assumed that these systems have been conserved during the course of evolution. It has been speculated that the primary role of these systems in evolution was to protect the genetic information of the species from both endogenous and naturally-occurring exogenous DNA damaging agents, especially long enough for the organism to replicate (*244*). All species examined thus far possess at least one form of DNA repair (214).

Since the nature of DNA lesions formed by agents which are genetically toxic, and the methods of their repair, are so similar across species, the use of prokaryotes to screen for this particular form of genotoxicity seems reasonable. However, the greater complexity of the mammalian systems require that care must be exercised in the interpretation of bacterial data. For example, chromatin structure in mammalian cells appears to make some regions of the DNA more accessible, and others less accessible, to adduct formation and repair (*245–247*). Furthemore, significant differences in the repair efficencies between tissues (*248*) and species (*249-260*) have been observed. In terms of general understanding of the signficance of these differences, it is known that among the placetal mammals there is a good correlation between the maximum achievable lifespan of a species and the ability of primary fibroblast cell cultures

from these species to perform unscheduled DNA synthesis following UV exposure (*260*), though some details of the correlation are controversial (*257*). It is not known whether there is any such relationship for DNA damage induced by chemical electrophiles. Also, in animals, the organization of cells into tissues presents other complicating factors. One example, based on tissue interactions, involves the complex effects of xenobiotic liver metabolism on the activated agent concentration in other tissues. Another involves tissues that are less active mitotically than others. The longer cells are given to perform DNA repair prior to DNA replication, the less likely it is that a transformation event will occur (*194, 256*). Still another example may be the maintenance of many cells in stationary phase (G_0) in a tissue. Those cells could be triggered into DNA replication, and run the risk of mutagenesis, by an agent delivered in a dose sufficently high to induce cell killing (see below, section on hyperplasia) (*261*). Since the latter possibility has been used to explain the apparent threshold effects seen in various long term low-dose vs. high-dose carcinogensis experiments using nitrosamines, by presuming that the high dose induces cell killing and resultant division leading to effects that are only seen with a high dose (*261*), understanding factors such as those are important in assessing risk. Other complicating whole animal effects include diet, age, and hormonal status, all of which impact DNA repair (*262-264*).

Many biochemical mechanisms are involved in the repair of DNA damage, and many factors may modify their effectiveness. One mechanism is a nuclear enzyme system which polymerizes activated ADP-ribose residues to form poly(ADP-ribose) (*265*). The biological function of ADP-ribosylation is not clear, however there is a relationship between it, DNA damage and DNA repair, which may involve the capacity of the system, demonstrated *in vitro*, to utilized damaged DNA (*266*). This system also seems to influence the production of sister chromatid exchanges (*267*) and has some relationship to mutagenesis and carcinogenesis, although not a simple one (*266*). Another mechanism, recently brought to light by the identification of a series of enzymes, collectively referred to as the DNA glycosylases (*209-213,268-274*), active in base excision repair (Table 3), has indicated that there is much greater specificity for the various kinds of DNA damage than was previously thought. Over a dozen of these enzymes have been isolated from bacterial and mammalian systems, each involved in the repair of a specific form of DNA damage. The apparent lack of nonspecific DNA damage recognition enzymes in adult mammalian tissues and the high degree of specificity of those repair systems that have been studied suggest that a series of enzymes can recognize many forms of DNA damage, including those induced by man-made substances. Another mechanism recently discovered involves an inducible antimutagenesis repair system in bacteria (*275*). An inducible system, considered part of post-replication repair, was also found in mammalian cells (*238, but see 239*). Los doses of certain mutagenic agents appear to induce a response in the liver that enhances the repair of damage subsequently induced by those agents. For example, in rat liver, an inducible protein transfers the intact methyl group, added to the uanine base by the potent carcinogen dimethylnitrosamine, from the DNA to a cysteine residue. Pre-stimulation of the animal with small doses of the compound can enhance this inducible repair system by as much as 3-fold (*216*).

As an example of the relation between knowledge of mechanisms and resolution of policy questions, one can consider the relationship of DNA repair systems and a threshold phenomena in carcinogenesis. In simple terms, the threshold concept maintains that there is a level of exposure to an agent below which there is either no observable effect and/or *no* adverse biological effect, as a result of some reserve (*e.g, see 276*). The practical manifestation of this concept is a dose-response cure which does not appreciably differ from zero risk at some non-zero dose. The concept is used to evaluate many toxic phenomena, but has been a source of controversy in the evaluation of carcinogenicity.The existence of DNA repair systems has been used by some authors to support speculation that a threshold exists for the biological effects of chemical carcinogens. Such a speculation is not supported by present data, as is shown below. The following analysis will concentrate on the question of a threshold for DNA damage and it must clearly be recognized that DNA damage is probably only one part of a complex chain of events leading to carcinogenesis. A threshold, or lack of threshold, for DNA damage may be a different matter than a threshold, or lack of threshold, for carcinogenesis.

First, no DNA repair system reduces DNA damage to zero. Consistent with this observation is the observation that DNA damage accumulates in postmitotic tissue, as a function of age even in the absence of known chemical exposure (*277*). The repair proficient systems found in dividing *Escherichia coli*, when fully induced, can reduce mutagenesis by up to 5,000-fold, but the mutation rate in exposed cultures is still 10 times that which is produced spontaneously (*278*). The fragmentary data from mammalian cells suggests that there may be an inducible system (*278*), but it would be unreasonable to assume that replicating eukaryotic cells would be at less risk than prokaryotic cells from low doses of a mutagen. Second, not all DNA repair systems are error-free. While the data on inducible error-prone bypass mechanisms in mammalian systems are meager (*278*), virus reactivation, which is likened to a mutagenic effect, has been well established in eukaryotes (*240, 278*). This suggests that mammalian cells also possess an error-prone bypass system. Third, major variations in DNA repair efficiency occur between cells, tissues, strains and species exposed to similar doses of the same carcinogen (*249–264*). This heterogeneity limits generalizations about the effectiveness of repair systems, constitutive or inducible, relative to the completeness of repair or the notion of a "safe" threshold. Tissue differences in repair might result in a dose response relationship indicating a threshold for repair in one tissue, but a relationship indicating no threshold for repair in another, thereby providing little hope for uniform protection within an organism. In tissue or cell culture, repair appears to vary between cells. Thus, even if biochemical analyses, which normally measure the average repair capacity of a heterogenous population of cells, demonstrate that a tissue or cell culture is repair proficient, the possibility of repair deficient subpopulations cannot be disregarded.

It is clear that DNA repair will not produce a threshold for DNA damage. However, it is not clear what the significance is of the DNA damage which results from exposure to exogenus agents. Since some damage results from normal metabolism and, probably, exposure to chemicals in foodstuffs (*33*) over the life of the animal, the importance of the additional burden induced by a carcinogen above this backround is hard to determine. As noted above, since DNA damage is only a part of the complex process leading to the production of cancer, this determination probably can only be made when a clear understanding of the

mechanism(s) of carcinogenesis is achieved.

B. Fidelity/Infidelity of DNA Replication.

Another modulator of the alteration of genetic information is the fidelity of DNA replication. Although it is not proven that the role of DNA replication in initiation is to stabilize incorporation of the effects of DNA damage in the genome ("fixation") (*279*), it remains the most attractive possibility, since the fidelity of replication (*280*) will help determine the integrity of genetic information in the initiated cell.

Before one considers the ways fidelity can be altered, it is important to understand the consequences of error accumulation in DNA in nondividing somatic cells (*244*). In dividing cells, one is concerned with replicative error propagation; that is, the transmission of mistakes from one generation to the next. Mechanisms that enhance the frequency of such mistakes could involve alterations in the DNA synthetic apparatus and have been referred to as intrinsic mutagenesis (*281*). In non-dividing cells, one is concerned about the effect of accumulated unrepaired DNA damage on cell function. When considering mechanisms in carcinogenesis, attention is normally limited to either dividing cells or to resting cells destined to undergo at least one further division cycle. With our present understanding, a cell which fails to undergo further division is not usually considerd pivotal with respect to neoplasia. However if amitotic cells become, through some mechanism, able to divide, or if non-dividing cells are involved in the control of dividing cell populations, the accumulation of damage in them can be significant. For instance, non-dividing neurons control the level of thyroxine, and it has been shown that this hormone is an important factor in X-ray transformation of cells (*282*). Therefore, although usually not appreciated, the effects of agents on non-dividing cells should not be ignored.

In dividing cells, a repaired or inadequately repaired DNA lesion, such as an adduct, when present on the DNA template at the time of replication, could result in a genetic alteration, e.g. base substitution, such as replacing a guanine with a cytosine. However, damaged DNA need not always cause significant base substitutions during DNA replication. First, parental cells containing the damaged DNA may fail to divide and thus be progressively diluted during cellular proliferation. Second, due to the redundancy of the genetic code, as well as other factors, approximately 25% of incorrect base substitutions may not result in amino acid substitutions. However, a number of modification of the DNA template or of the DNA polymerases have been shown to cause incorrect substitutions during copying by DNA polymerases *in vitro* (*283, 284*). If these modifications are not corrected by subsequent DNA repair, it is a reasonable expectation that the unrepaired lesions will in time result in either mutations or cessation of cell reproduction (*283, 284*). If these modifications are not corrected by subsequent DNA repair, it is a reasonable expectation that the unrepaired lesions will in time result in either mutations or cessation of cell reproduction (*258*). Alkylating agents and carcinogens have been shown to induce mis-incorporation *in vitro* by modification of DNA templates and by removal of purines from the DNA (*285–290*). Also, the induction of an error-prone repair pathway (SOS) may cause problems since the underlying concept of this repair pathway is that it can alleviate potentially lethal damage only at the expense of inducing mutations (*275*).

Even if the templates is undamaged, other factors which can be altered by carcinogens both directly and/or indirectly, may cause the template to be copied incorrectly. Table 4 lists some factors that have been found to diminish the fidelity of DNA synthesis *in vitro* in two different systems, (*285*) and may have to be considered *in vivo*. During replication, the fidelity of DNA synthesis is altered by only a few types of changes in the reaction conditions. The error rate of mammalian DNA polymerases *in vitro* has been shown to be dependent on the ratio of correct to incorrect nucleotides with polynucleotide and natural DNA templates (*291, 292*). There is evidence that alterations in cellular nucleotide pool sizes and content are mutagenic (*293–295*), and the cellular homeostatic mechanisms for precise maintenance of deoxyribonucleotide concentrations may be altered by various chemical agents. Furthermore, agents may directly alter some of the nucleotides in the pools available for replication, leading to possible misincorporation (*296, 297*).

Table 4—Changing Reaction Conditions That Diminish the Fidelity of DNA Synthesis

1. Ratio of incorrect to correct nucleotide substrates (291–297).
2. Type of incorrect nucleotide substrates (293–297).
3. Different metal activators for DNA polymerase (285, 288, 292).
4. Nonactivating metal mutagens and/or carcinogens (285).
5. Depurination of template (290).

Lindahl and Nyberg (*298*) estimated that the *in vivo* rate constant for thermal depurination is approximately 3×10^{-11} sec^{-1} suggesting that as many as 10,00 purines may be lost from the genome of a mammalian cell per generation time (20 hours). Furthermore, this rate consfant may be significantly increased after alteration of bases by alkylating agents (*298*). The intensity of this damage formation suggests that during replication, the cellular mechanisms for correcting depurinated sites on DNA might not be able to repair every site before the polymerase complex involved in replication encounters a damage site. Thus, replication over a damaged site may be a secondary result of cellular interaction with a carcinogen. Lastly, mutagenic/carcinogenic metals, not reacting directly with DNA, have been shown to affect the fidelity of DNA synthesis *in vitro* (*285*). Thus, various agents that do not damage DNA directly or enhance the production of metabolites that can induce such damage may exert their effect by alltering the fidelity of DNA replication. Methods to assess or screen for such agents in mammalian cells are generally lacking. The end result of these processes is that a daughter cell can have an irreversible alteration in genetic information (*279*) even though the apparent cell which interacts directly with agent does not. This altered cell may be similar to normal cells in many respects, but may be capable of giving rise to a cancer, *i.e.* be initiated, and may lead to carcinogenesis if, during the lifespan of the animal, it encounters an appropriate stimulus, *e.g.* perhaps a "physical carcinogen".

As previously noted, it is not clear what role DNA synthesis has in intiation though it has been shown that manipulation of the rate of cellular proliferation under some conditions may modify tumor incidence. This has been demonstrated in : (1) Partial hepatectomy in animals treated with methylnitrosourea, dimethylnitrosamine (*279*), benzo(a)pyrene and radioactive particles that localize in the liver (*299*); (2) chemical treatment combined with diet changes, drugs or natural physiological agents such as hormones or bile acids (*279*), and (3) the stimulated hyperplasia resulting from the toxic effect of carbon tetrochloride (*300*); and (4) regeneration in skin (*301*). Much of these data are hard to evaluate however since some of the treatments induce a chronic inflammatory response, especially the skin regeneration work which utilizes skin abrasion, and it is not clear whether one is studying the effects of proliferation or the

inflammatory response, which is probably an important factor in carcinogenesis by "physical agents". On the other hand, retinoids, which stabilize the differentiated nondividing state of epithelial cells among their other biological effects, have been used to inhibit mammary and colon carcinogenesis (*302, 303*).

The doses of agent used to produce cancer experimentally may be much lower than those doses which cause frank cytotoxicity for a number of reasons. One is that a cytotoxicity could be a stimulus for cellular proliferation which could result in hyperplasia (*304*) (usually termed restorative or reactive hyperplasia). This replication may act to "fix" changes in cells previously "primed" by some unknown stimuls or it may result in replication errors through some of the mechanisms suggested above. An example of this hyperplasia is the effect of carbon tetrachloride in mice (*300, 305*). This agent has no or only minimally detectable genetic toxicity in most bacterial tests, but induces tumors while causing substantial necrosis in the target tissues of mice. Another example may be foreign body carcinogenesis, as discussed in Section IV.A.4., which may induce some necrosis at a site.

The possibility that hyperplasia can lead to carcinogenesis has led to speculation that a cytotoxic mechanism is important in the carcinogenic effect of all carcinogens which do not act directly on the DNA that are tested at a high dose (*306*). This hypothesis overlooks the obvious problem that although cytotoxicity can induce certain changes in cells, it is by no means the only way an agent can alter either replication or gene expression. For example, certain compounds can stimulate hyperplasia without significant cytotoxicity (*307*). Furthermore, it has been shown many times that neither the induced hyperplasia (*308*) nor the irritant properties resulting from promoters such as PMA (*309*) are sufficient to explain carcinogenic effect. Thus, a cytotoxic action should be considered simply as an additional possible mechanism of carcinogenesis and not equated to an explanation for carcinogenesis for all non-directly-genotoxic agents tested at high dose.

Whatever mechanism(s) is (are) important in the formation of initiated cells, it is clear that cells irreversibly altered in a heritable fashion are induced during this process and that these are the progenitors of further new cell populations during the carcinogenic process. The properties of these cell populations are discussed in the next section.

VI. CANCER FORMATION

How initiated cells with altered genetic information result in a cancer seems to be the least understood area of carcinogenesis. The process can be divided into two operational stages, promotion and progression. Promotion will be used to describe the process(es), usually initially reversible in test systems, but later irreversible (*310*), that results in cellular proliferation and terminates when one or more neoplastic cells, *i.e.* cells with the ability to grow autonomously, is (are) formed. Neoplastic progression will refer to the next step(s) in which cells become able to form tumors and become malignant with some potential to metastasize.

A. Promotion.

1. Promoter action. A promoter is experimentally defined as an agent which results in an increase in cancer induction after long-term application subsequent to treatment of an animal with an initiator. Under otherwise identical conditions, neither initiator nor promoter alone induces many tumors, nor does a regiment with reversed order (treatment with promoter followed by an initiator) (*308*). At a particular dose level and treatment schedule, a carcinogen that does not require supplemental promoter activity is termed complete. Many or all complete carcinogens act as both an initiator and promoter in their interaction with the organism and some act as initiator or promoter for different tissues in the same organism at the same time (*311, 312*). Also, the promoter action of a complete carcinogen may not act by the same mechanism as promoters used in initiator-promoter paradigms (*309*). Separation of these two aspects of carcinogenic action is frequently difficult. However the term remains a convenient description for one part of an experimentally isolated complex process. For the most part, the phenomenon of tumor promotion has been most carefully delineated in skin and liver carcinogenesis. It remains to be established more firmly with cancer at other sites though there is suggestive work in colon, breast, kidney, central nervous system (*279*) and bladder (*307,313*) carcinogenesis. At present, given the lack of information on mechanisms of carcinogenesis in humans and the myriad interactions of tissue and the biological effects of promoters demonstrated in experimental systems, it is premature to designate agents as acting through only a promotion-type mechanism although there are suggestions of promotion by a number of agents.

This experimental definition will not clearly differentiate between promotion and progression since is measures only the production of a malignant tumor. In practice, however, laboratory studies of promoter action are usually ended after a focal mass of cells (*e.g.* papilloma, nodule) is observed (*307*). The appearance of the first neoplastic cells after the formation of these focal masses has been proposed as a definition of the end of promotion (*279*). This definition is useful since it emphasizes the frequently seen reversible effects of promotion, *i.e.* regression of the direct results of a promoter (*e.g.* papilloma) with termination of its use, while clearly indicating that the role a promoter has in carcinogenesis is to induce a presumably irreversible event, a neoplastic cell. A similar definition is suggested by the separation of promotion into 2 stages, based on work in skin promotion in mouse (*310*). Stage one is partially reversible, while stage 2, which requires cell proliferation, is initially reversible and then becomes irreversible. Many of the focal masses induced by promotion are reversible, especially in skin and liver (*279*). How these non-neoplastic masses originate is not completely known, but they seem to arise through the differential stimulation of cells altered by the initiator to respond to the promoter (*279*). Of the persistent masses, in all systems studied, almost all do not become neoplastic *i.e.* acquire growth autonomy (*192*).

Promoters are usually thought of as exogenous compounds. Many of them are plant products (*307, 314*) such as certain of the phorbol esters (*e.g.* 12-0-tetradecanoylphorbol-13-acetate [TPA] or phorbal tetradeconate acetate [see Section IV.A.1], which is also known as phorbol myristate acetate [PMA]). However, there is also evidence that certain compounds normally present in the body (endogenous) may also be promoters (*315, 316*). Promotion by such endogenous compounds may be difficult to demonstrate since production of the compound in the body must usually be altered (which normally has many ramifications) to observe an effect, as opposed to exogenous compounds, whose levels are controlled by direct application to a tissue. Another type of interaction that seems to have promoter action occurs in foreign body tumorigenesis (*193*). Although it has been claimed that a single event determines the sarcoma which results from the implantation (*179*), it is clear that there is a step where pre-neoplastic

cells of probable vascular origin (produced in a surface-contact independent step) require a surface-contact dependent step to become neoplastic (*179*). Like other promoters, removal of a foreign body before the last step will, as a rule, prevent the sarcoma from developing. Thus some surfaces, as well as exogenous and endogenous compounds, seem to be able to act as promoters.

Despite recent progress, the mechanism of action of PMA, the model promoter, is not completely clear. There is good evidence PMA binds to a receptor (*317, 318*), that activates protein kinase C (*319*), which phosphorylates insulin, somatomedin (*99*) and a tyrosine-specific phosphorylation, similar to a number of growth factors. Other promoters interact with a cell receptor (*307, 320*). Also, estrogens, suggested to be promoters of mammary and liver tumorigenesis (*321*), are known to produce their main biological actions through receptors (*322*).

PMA produces profound biological effects *in vivo*, including edema, erythema, inflammation and cellular proliferation (a property which allows the promoter to participate in "fixation" if given within a short enough time after the initiator dose). But these same effects can be produced by agents that are not promoters (*307*). By stimulating specific separate effects of PMA in other ways, one can define at least two stages in promotion (*310, 323, 324*), supporting the hypotheses that cancer is a multistep process and that more than one aspect of PMA may be important in promotion. *In vitro*, promoters have been shown to induce an array of diverse morphological and biochemical changes (*307, 321, 325*). One of the most important seems to be the interaction of PMA and other promoters with cells to generate free radicals (*326–328*). A similar stimulation is seen with the use of either ionizing radiation or activated oxygen (*328*). The capacity to stimulate radicals seems to be correlated with promoter potency to generate tumors (*326*) and varies in a dose dependent manner for the strong promoter PMA (*329*). PMA can also: (1) Cause dedifferentiation or inhibit terminal differentiation (*330*); (2) stimulate cellular differentiation (*331*); (3) alter macrophages (*332*); (4) induce chromosomal alterations (*333*) and sister chromatid exchanges (SCE) (*334*); and (5) induce virus synthesis (*335*). It is not known which, if any, of these effects are central to the role of promoters in carcinogenesis since evidence for all models of promotion is indirect. However, the effects on chromosomes may be especially relevant.

PMA can induce chromosomal anomalies such as SCE, although the concentrations (100 ng/ml) required for this effect are quite high (*334*). The activated oxygen species produced by the promoters, perhaps through an interaction with membrane components, can induce chromosomal damage and a soluble substance which induces chromosomal abnormalities (a clastogen) in nearby cells (*333*). However, the promotional effects of PMA are reversible unless it is given for a fairly long time and a chromosomal change, such as an aberration, is almost certainly not reversible. This suggests that any chromosomal alteration would probably have to be induced by prolonged exposure to the promoter (*187, 308*). This analysis is consistent with the observation that papillomas, which emerge in a common response to promoter action in skin carcinogenesis during the stage when it is reversible, are primarily associated with a diploid karyotyed whereas malignant tumors usually have karyotypic alterations (*336, 337*). Although the selection process for cellular characteristics important to neoplasia may occur during the entire promotion process (indeed selection may be important even during initiation [*279*]), a certain type of chromosomal alteration might be the final event which results in a neoplastic cell. Also, the need for prolonged exposure, leading to a relatively large cumulated dose, may be why such high doses have to be given to observe the effect in short-term experiments *in vitro*.

Chromosomal changes, although not proven to be responsible for growth independence of neoplastic cells, are implicated in transformation (*338*). For example, SK–L7 human lymphoid cells markedly increase their cloning efficiency in soft agar and decrease their doubling time from 30 hours to 14 hours upon introduction of an additional chromosome 15 (*339–341*). More directly, a clastogenic effect is produced by cells from an individual with Bloom's syndrome, a clinical entity in which there is usually a high cancer incidence (*333*). Specific chromosomal transpositions, as seen in the case of the lymphoma, can be associated with changes in the regulation of gene expression and also could be associated with phenotypic changes such as differences in antigenic expression and unresponsiveness to regulator of cell growth.

The hypothesis that a chromosomal change is a causal factor in cancer induced by promoters is attractive, especialy when viewed with the evidence concerning the effects of transposition in oncogenes (see Section IV.A.1); however, few data directly support this contention (*195*). Although there is a lack of methods to measure such changes readily in vertebrates, this hypothesis is interesting since such genetic alterations: (1) Are much more drastic than localized changes in base sequences; (2) may be either site-specific or non-site-specific; (3) do occur at different frequencies; (4) appear to affect the stability of neighboring genes; and (5) are vitrually irreversible. In rapidly multiplying bacterial cells, conventional mutagens do not enhance the frequency of transposition (*342*); however, factors that trigger transpositions or govern their rate of movement are not yet understood well enough to determine whether mutagens enhance transposition in mammalian cells *in vivo*. Large-scale changes, such as rearrangements and deletions, rather than the small changes repairable by excision repair that can be detected in the usual tests for mutagenicity may be important components in humam cancer (*195*). While it appears that localized lesions in DNA can be carcinogenic (*54, 343*), it is not clear whether such lesions might either independently or through the direct or indirect induction of major genetic alterations (*344*). Furthermore, this analysis is limited since one is drawing general conclusions about malignancy from the pathogenesis of a rare disease in persons with a limited life span.

Evidence is starting to accumulate that both oncogene activation and treatment by some promoters have some aspects in common, *i.e.* the activation of some growth factor-like stimulus. For some cases, this stimulus seems to need some second factor, another oncogene involving a nuclear protein in the case of oncogenes, or Phase II promoters, involving replication, to cause transformation. In this light, chromosomal changes might be seen as merely a possible, but not obligatory, method to accomplish the same end, with the final, chromosomal change equivalent to the second oncogene activation or the effect of proliferation and other changes in the case of the PMA stimulation.

Cancers in humans from causes such as exposure to cigarette smoke or exposure to benzidine in the workplace have a very long latent period. It is not clear whether this long period is the time from exposure to the production of a neoplastic cell (promotion) or the time necessary to go from a neoplastic cell to a malignant tumor (progression).

Evidence that the carcinogenic risk of cigarette smoking declines with the length of time after smoking stops (*345*), suggests that most of the latent period is partially "reversible" and therefore probably occupied by a phenomenon similar to promotion.

This is also suggested by a recent model for the development of Burkitt's lymphoma, which seems to be a virally produced cancer (*346*). According to this model: (a) A lymphoma clone develops in one or more steps from B lymphocytes that have acquired neoplastic characteristics due to EBV transformation, and (b) the fully malignant phenotype occurs only when the lymphoblastoid cells acquire a specific chromosomal translocation that involves the immunoglobin locus. The long latency period seen in the disease has been suggested to arise from the need for a promoter-like stimulus that may cause proliferation and interfere with the differentiation of the long-lived initiated B cells (*337*).

Since neither initiator nor promoter alone is sufficient to cause tumors and since promotion appears to be involved in the carcinogenic process, especially in time to tumor induction, low-level exposure to certain carcinogens may only become significant after subsequent exposure to promoters. This bears on the question of a threshold for tumor promoters. Although it has been stated that promoters have a threshold (*306*), there is no good evidence for this. Studies of the dose-response curves for promoters (e.g. PMA [*347*]) have clearly been inadequate for the purpose of defining a threshold, as is usually acknowledged by the authors involved. There is a recent suggestion that promoters may be much more important for low doses of initiators than high doses and may expand the risk associated with the initiators (*348*). Important factors in tumor promotion such as dose, dosing schedule, tissue specificity, etc. create substantial uncertainty about any general statements regarding thresholds. Generally, animal bioassay studies, because of their design and the conditions under which they are conducted, fail to distinguish between initiating or promoting activity or between a direct or indirect action by the agent on the genome. Although it may be useful to group compounds with some criteria, *e.g.* mutagenic in a particular strain, or having a particular biological effect on a particular strain, one should be careful about implying that something is known about the mechanism of action. The grouping, since it is not based on knowledge of carcinogenic mechanism *in vivo*, may have no relationship to the multiple routes by which carcinogenesis could be induced in a particular instance. It is difficult to be clear about what is the target of a particular agent, when the mechanism of effect of any agent is still unknown. However, it is still important to define the kinds of promoters and to examine the patterns of exposure to them to help elucidate mechanism.

2. Specificity/Antipromotion. Tumor promoters often display tissue specificity, having primary effects on only one or a limited number of tissues in a particular species. For example, estrogens seem to be promoters in breast (*315*) and liver (*316*) in animal models. Mouse skin and bladder are also specifically responsive to certain promoters (*307*). An interesting sidelight to this aspect of promotion is that the PDGF-like material stimulated by the *sis* oncogene is active specifically for the tissue which develops the sarcoma produced by the virus (*102*). Since some promoters seem to be simulating growth factors, and many growth factors tend to be fairly tissue specific, this may be the source of the specificity seen.

The potential for any tissue to give rise to a tumor after initiation may be partly determined by inherent biological processes; treatment to prevent disease may be designed to interfere with those processes, especially with endogenous tumor promotion. Such inherent processes may be altered by diet, stress, or other conditions such as individual genetic differences or altering physiological function. For example, a number of experimental animal studies suggest that a high fat diet can promote carcinogenesis in breast and colon, while epidemiological studies show a positive relationship between dietary fat and breast cancer in some populations (*348*). However, to confirm that a low fat diet will decrease these types of cancer (*11*), additional studies need to be conducted in countries with a wide genetic diversity where a high proportion of the population's caloric intake comes from fats. It must be kept in mind that the total carcinogenic response should be considered. For instance, there are certain populations, with certain lifestyles and diets, such as the Japanese, which have a low incidence of one cancer. However, they frequently have a high incidence of some other type of cancer which has a low incidence in other populations (*349*).

Studies have also revealed several compounds, called antipromoters, that inhibit responses to PMA *in vitro* (*144*) and prevent tumor promotion *in vitro* (*350*). Antipromoters are effective during different phases of the multistep process of promotion. Although "pure" promotion has not been conclusively demonstrated in humans, the existence of antipromoters in other systems has been used to suggest that it may be possible to design cancer prevention methodology based on the interference of promotion with a putative antipromoter in humans. Clinical studies are currently underway to test the therapeutic efficacy of some compounds, including synthetic retinoids (*351*) which are known antipromoters.

While cell culture methods offer possibilities for screening for tumor promoters and antipromoters, it will first be necessary to determine which functions altered *in vitro* by promoters are critical to the promotion process and which are secondary. The species and tissue specificity of tumor promoters make it likely that a number of different cell types will be required for any screening procedure.

B. Neoplastic Progression

The progression of a neoplastic cell into a malignant tumor, which does not occur to every neoplastic cell, is the last major stage of cancer formation and is probably accomplished through a number of steps. Many cancers have more than the normal numbers of chromosomes and exhibit poorly controlled and sometimes higher rates of growth, invasiveness and anaerobic glycolysis, factors that may be important to their survival in the animal.

The route by which a neoplastic cell becomes a cancer may entail a sequence of interactions between tumor cells and both specific and nonspecific host defenses (*352*), as well as a series of events that result in the cell acquiring more of the characteristics of cells in a malignant neoplasm (*279*). These selection processes are non-exclusive of each other and may involve karyotypic changes (*353*). The factors that are important in neoplastic progression, especially in the pre-malignant stage after neoplastic cells emerge and before a malignant neoplasm is formed, may be similar to those in tumor dormancy, a phenomenon in which tumor cells reappear many years after apparently successful treatment. The major mechanisms of tumor dormancy seem to be: (1) Inhibition of cell division; and (2) cell division accompanied by cell lysis. Mitotic control can be exercised by macrophages (*354*), soluble factors such as lumphokines (*356*), nutrient depletion (*357*), or a hormonal requirement for growth (*358*). Continuing cell division in a tumor, the major characteristic of a neoplasm, can continue without much

effect if daughter cells are lysed about as fast as they are produced. This can result from immunological lysis, nutritional deprivation or very slow tumor cell production. Any or all these factors may lose their effectiveness during the selection processes for malignancy described above, perhaps in a number of steps.

An interesting model for the progression of a neoplasm to malignancy is the one proposed by Gersten, Fidler and Hart (354. 359). After a primary tumor is established, there is tumor vascularization, by an angiogenic factor (*357*), with invasion of surrounding tissue and blood vessels. This invasion seems to be accomplished throught tissue damage by a number of different enzymes, such as collagenase (*360*) and cathepsin B (*361*), and the role of tumor cell motility is not clear (*359*). The widespread dissemination of cancer cells occurs by the lymphatic (carcinomas) and hematogenous (mesenchymal tumors) routes. During lymphatic spread, the regional lymph node is involved in the host immune responses to neoplasia (*362*). During hematogenous spread, release of tumor emboli in the bloodstream results in most tumor cells being destroyed by interaction with a number of blood elements (*363*). However, the more that are released, the more that survive to form metastases. Arrest and subsequent growth of circulating tumor cells or implantation in another site seem to be a function of tissue and metastasis, and there are some data that the site is selected by the membrane properties of the metastatic cells (*364*). Metastatic cells then leave the blood vessel and form micrometastases which induce blood vessel proliferation leading to metastatic growth (*359*).

Progression seems to be modulated by a number of factors. Important among these is the immunological system. Many tumors induced by physical and chemical agents are antigenically distinct (*365–367*). To overcome the immunological defenses of an immunocompetent individual, the tumor could: (1) Simply not be immunogenic, *e.g.* contain only antigens expressed normally in the body; or (2) suppress the immunological response. Lack of immnogenicity seems to be very common in spontaneous tumors in animals (*367, 368*). This also seems to be the case for humans since, at present, only cells from presumably viral tumors, such as Burkitt's lymphoma (*369*), may be considered to be truly immunogenic, although there is evidence of some specific antigens associated with cells from human tumors grown in culture (*e.g.* colorectal tumor cells [*370*]) (*371*). A tumor could also induce immunodeficiency, either general or selective. Immunosuppression could be accomplished by a variety of mechanisms, including produciton of circulating immune complexes (*372*) (to inhibit antibody respnse) or a rise n suppressor T-cells (*373*) (to inhibit T-cell response). Production of an immunodeficiency seems to be important for highly immnogenic tumors, such as UV induced tumors (which are decisively affected by suppressor T-cells in the formation of primary tumors [*373*]) and viral tumors (which are profoundly influenced by immunocompetence [*135, 374*]).The immunodeficiency associated with UV-induced tumors is a selective one, perhaps because of a UV-induced deficit in antigen processing by a macrophagelike cell that subsequently produces the T-cell response (*373*).

Clinically, immunodeficiency usually refers to a more general type of immunodeficiency that can occur during the later stages of carcinogenesis (*375*). This may be of importance mainly in metastasis since it has been shown that immunosuppressive treatments and agents greatly increase the incidence of distant metastases in rats with highly immunogenic tumors (though the effect is reversed for tumors with low immunogenicity [*376*]). Its role may be wider, however, since it has been suggested, from evidence about lymphoma in immunosuppressed individuals, that the immune system may be important in the selection of a particular chromosomal alteration, *i.e.* be involved in promotion (*135*).

Implicit in this analysis is the fact that factors that can alter modulators of progression can also alter progression. For example, factors such as stress that result in a mild immunodeficiency, may also mimic the effects of immunosuppression in production of lymphoma. A cancer is a product of a long series of events and it is a reasonable assumption that modulators may interact in a positive or negative fashion with this sequence at any point.

VII. MULTIPLE AGENTS

Since people are exposed to many different agents at the different times in different sequences, the effect of multiple agents on carcinogenesis is of major concern. However there is little information of general import in the field. The great number of permutations of possible agents and doses makes understanding interaction of multiple agents very difficult.

In general, the action of two or more agents can be additive (if the agents are given in a dose range where the biological response is a linear function of dose) or multiplicative (if the response is a simple exponential response to dose), synergistic (greater than expected) or antagonistic (less than expected) (*377*).

One obvious example of synergy is the tumor initiator-promoter interaction described above. Tumor incidence is much less when either agent is given separately than when the two agents are given in the proper order. Another possible example is the relation between cigarette smoking and asbestos exposure in carcinogenesis. The effect of both carcinogens is much greater than a simple additive model would predict and is closer to multiplicative (*378*). Although the mechanism for this phenomenon is not known, possibilities include: (1) Asbestos increases the uptake of the carcinogenic substances in cigarette smoke (as shown when benzo(a)pyrene is used as a model compound [*379*]); (2) asbestos stimulates metabolism of carcinogen(s) in smoke (which has been shown for benzo(a)pyrene, one component of smoke) (*380*); (3) asbestos works as a promoter with cigarette smoking the initiator (*381*); or (4) some combination of the above mechanisms (*382*).

One example of antagonism is the interaction of 3'-methyl-4-dimethylaminoazobenzene (an azo dye) and certain polycyclic aromatic hydrocarbons (PAH), such as 3-methylcholanthrene (MCA) (*383, 384*). Some carcinogenic PAH, by stimulating metabolism, inhibit azo dye carcinogensis. Although the study and understanding of the interaction(s) of multiple agents is not easy, it becomes much more difficult (conceptually as well as experimentally) when it is not clear whether more than one agent is involved. An example is the interaction of immunosuppresive agents and EBV. Although immunosuppresive agents are presumed not to induce tumors, their use may allow the expression of EBV induced carcinogenesis, as has been suggested for renal transplant patients who have a substantially raised incidence of tumors, especially lymphomas (*135*). Since EBV is ubiquitous, exposure to an immunosuppressive might result in an increased number of tumors in a bioassay (*i.e.* be carcinogenic) although in fact it is simply allowing expression of tumors that arise from a viral infection. Other agents may alter the modulators at any stage in carcinogenesis and result in either more intense effects of a ubiquitous agent or the expression of a tumor derived from long-lived irreversibly initiated cells.

These examples illustrate just a few of the possibilities of interaction. Some agents may stimulate metabolism, interact chemically with other agents, or be so cytotoxic that tumors induced by another agent are killed. Other agents may alter modulators of different stages of carcinogenesis or stimulate the expression of tumors that would normally not be expressed in the lifetime of the animal. At present, in the absence of a well established and comprehensive theory of carcinogenesis, the complex interaction of agents is best understood by elucidating the action of each compound. Then the effects of each compound on the organism can be evaluated and their interaction estimated.

VIII. SUMMARY

Although the study of the phenomenology of cancer was initiated many years ago, analysis of the mechanisms involved in carcinogenesis was started much more recently, and the level of activity has risen significantly in the last decade. This review has attempted to place much of the data concerning cancer into a broad perspective. Exposure to a carcinogen begins at the interface of an animal with its environment, and an agent can be modified by factors associated with an organism at that interface. An example of this is the reduction of benzidine-based aso dyes to carcinogenic benzidine by gastrointestinal microflora. Since the microflora can vary with species as well as with food habits, this provides one source of variation in the activation of agents.

There is a wide variety of processes that are involved in the activition and detoxification of most agents. The complexity of these processes is illustrated by the major products of the metabolism of benzo(a)pyrene, a carcinogen which needs activation. Lifestyle, exogenous agents, diet, age, etc. can act on several levels to alter the balance of activation and deactivation. Examples of this are the stimulation of cellular metabolism producing more reactive species, the inhibition of a particular pathway resulting in a smaller amount of reactive moiety, and the alteration of cell scavengers that absorb reactive metabolites produced by metabolism, and lower the overall concentration of reactive moiety. Activation and deactivation are functions of species, tissue, and even individuals, providing another source of variation in response to a carcinogen.

The interactions of carcinogens with DNA, which seem to be important for the carcinogenic action of many initiators and complete carcinogens, vary across the different classes of carcinogens. Biological carcinogens, such as the acute transforming retroviruses, seem to insert genetic information which allows the expression of certain cellular *onc* genes whose products are important for transformation. Some of these products seem to have effects like certain growth factors. The discovery that the dominant transforming genes of certain human cancer-derived cells are similar to certain classes of *onc* genes derived from the acute transforming retroviruses has been a breakthrough in understanding certain causal factors in human neoplasia. Radiations damage DNA, but, with the exception of ultraviolet-light (UV) irradiation, the irradiation products are not very well characterized and the role of the damage is not clear. It has been shown that a particular DNA damage is involved in the carcinogenic action of UV light, but how this occurs is also not clear. The specific damage that many chemical carcinogens produce in DNA is much better characterized, but which lesions are important in carcinogenesis and how a lesion can interact to produce a cancer are not known. "Physical" carcinogens include a number of very different agents and processes which seem to have in common the production of a chronic fibrotic reaction.

Two modulators of DNA damage are DNA repair and fidelity of replication, which help to determine the effects of a carcinogenic stimulus that survives through replication in initiated cells. Recent work on DNA repair has determined that there is a set of enzymes, the DNA glycosylases, that confer specificity in base excision repair for different types of DNA damage. Also, post-replication repair has been found to be more complex than though previously, which may help explain how a specific lesion influences DNA. Since DNA repair is modified by many factors, and is tissue and species specific, this provides another source of variation in the final response of the organism to a carcinogen. An example of how knowledge about mechanisms impacts on risk assessment is the question of how DNA repair is related to biological thresholds for effects of carcinogens. Statements that DNA repair results in a threshold for carcinogenesis are naive and cannot be substantiated.

The fidelity of DNA replication can be altered by a damaged template or, more indirectly, through changes in the reaction conditions that result in miscoding. Any of the reaction conditions could be altered by a carcinogen or by a change in physiological state induced by a carcinogen, providing a route by which the DNA could be altered without the formation of direct binding between the DNA and a carcinogen derivative.

Cancer is a phenomenon with many steps. In an experimental paradigm, two major stages can be demonstrated: Initiation, the induction of an irreversible alteration of genetic information, and promotion, a reversible process terminated by the final irreversible alterarion of initiated cells into neoplastic cells. Each stage can be subdivided. The progression of neoplastic cells into a cancer, which has not been easy to separate experimentally from promotion, is the final stage in carcinogenesis.

Promotion can occur with both exogenous and endogenous compounds (and, perhaps, certain surfaces) and is usually characterized in a number of systems by a focal proliferation of cells of which a small fraction will persist after the promoter stimulus is removed. Few focal proliferations in any experimental system will become neoplastic. Although the aspect of tumor promotion which is critical for tumorigenesis is not entirely clear, a interesting possibility is the induction of chromosomal alterations. The relationship of this process to viral carcinogenesis and the mechanisms by which alternations may lead to a neoplasm are explored. However, a causal relationship of chromosomal changes to carcinogenesis has not been proven. Tumor promoters are tissue and species specific, perhaps providing some insights into how various tissues and species are differentially affected by carcinogens.

Neoplastic progression, the process in which a neoplastic cell becomes a malignant tumor, seems to involve several steps, none of which is yet well understood. In that complex process, the role of the immunological system as one of the important modulators of progression is discussed.

Evaluation of the effect of a number of agents acting concurrently has barely begun. Models for summation, potentiation, or inhibition of effects are poorly developed, especially when considering the range of effects that agents have on a number of metabolic and physiological endpoints. Variation with species, tissue and individual at every stage in carcinogenesis produces the added uncertainty if two or more compounds interact at many levels.

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Chapter 2—Short-Term Tests for Potential Carcinogens

I. INTRODUCTION

Cancer can be induced by a variety of radiations, biological, "physical" and chemcial agents, and is manifested in a variety of phenotypes. Notwithstanding our lack of understanding of the mechanisms by which cancer is induced and expressed (See Chapter 1 of this document) there is an urgent need to identify the agents that cause and promote these diseases. The rapid identification of potential chemical carcinogens is one of the major goals of short-term testing.

The hypothesis that conversion of normal cells to neoplastic cells results from heritable genetic changes—the somatic mutation theory of cancer—was proposed early in this century (*1*) and forms a basis for the development of many short-term tests. The relationship of mutation and carcinogenesis has been stressed for some time (*2*). However, early studies relating mutagenesis and carcinogenesis were generally unsuccessful due in part to the need for metabolic activation of most carcinogens. Pioneering studies by the Millers and associates (*3*) on metabolic activation of chemicals and the coupling of metabolic activation systems and mutable targets (*4, 5*) allowed further elucidation of the possible relationship between mutagenicity and carcinogenicity. During the past 15 years, many short-term systems that detect mutagenesis and other genetic effects have been developed and attempts have been made to correlate the results of these tests with carcinogenesis. The tremendous number of chemicals that remain to be evaluated for potential hazard and the mounting cost of currently acceptable rodent carcinogenesis assays amply justify the continued effort to develop and utilize short-term tests, and to establish a mode for their application in assessing the potential of chemicals to induce cancer.

The search for tests with the capabilty to identify potential chemical carcinogens has yielded a variety of assay systems with a diversity of endpoints. The existence of such a large number of assay systems (approximatley 100 have been described [*6, 7*]) reflects both limitations and differences between assays, as well as our uncertainty about the mechanisms of induction and progression of carcinogenesis. As described in Chapter 1, the induction of cancer may have many potential mechanisms (gene or chromosomal mutation, heritable changes in DNA transcription reflected in induction or cessation of gene expression, etc.), but no causal relationship has yet been established between and mechanism of induction and any specific neoplasia. In addition, a variety of factors or conditions such as tumor promoters, hormanal levels, rate of cell proliferation, cell type specificity, genetic predisposition, etc. are known to influence the expression of neoplasia, regardless of the nature of the inducing

agent. Because of the relatively small of known human carcinogens, the predictive capability of the short-term assays is usually assessed by validation with the many more chemicals which are carcinogenic in long-term animal tests.

This chapter describes the major categories of short-term assays for chemical carcinogens, attempts to evaluate the assay systems, and recommends further studies required to define their predictive ability.

The term "genetic toxicity" in used in this chapter to indicate any effect that can be attributed to an interaction between the test agent and the genetic material of the test organism. There have been attempts to classify carcinogens on the basis of whether they show evidence of direct interaction with DMA or act by some indirect effect ("epigenetic") (*8*). However, the assay systems conventionally used to make this distinction may not detect all types of chemical-DNA interactions, nor do they adequately accomodate the tissue or cell-specific metabolism or target specificity which many carcinogens demonstrate. So it is not possible to conclusively make a clear distinction between genetically toxic and "epigenetic" on the basis of currently available in vitro tests. However, the fact that certain factors or substances do appear to induce tumors without appearing to react directly with the DNA indicates a need for development of short-term tests complementary to those which detect direct effects on the DNA if all types of chemical carcinogens are to be detected.

Many of the tests for genetic toxicity are also useful in the identification of potential germ cell mutagens; however, this represents a distinct application of the tests, and the reader is referred to the recent report of the National Academy of Sciences (*9*) for further information on this subject. In addition, screening of chemicals for genetic activity can identify agents that may be involved in the aging process or atherosclerosis (*10, 11*).

II THE SHORT-TERM TEST SYSTEMS

There have been numerous descriptions of the assays that have been developed and evaluated for their capability to detect potential carcinogens, but the details of these systems will not be discussed herein. The reader is directed to the EPA Gene-Tox Evaluations (*12–40*), the International Collaborative Program (*41*) and the review by Hollstein *et al.* (*6*) for details and further references to the individual systems. The four principal biological endpoints represented by the available tests are gene mutation, chromosomal effects, general DNA damage and neoplastic transformation. Some frequently used asays are listen in Table 5.

TABLE 5—CONVENTIONALLY USED SHORT-TERM ASSAYS

Type of assay	Endpoint	Reference
Mutation:		
(a) Microbial systems:		
Salmonella Typhimurium.	Histidine reversion	42
Escherichia coli	Tryptophane reversion	12
(b) Mammalian cell systems:		
Mouse lymphoma (L5178Y).	Thymidine kinase (Bromodeoxyuridine or Triflurothymidine [TFT] resistance).	39
Chinese hamster ovary (CHO).	Hypoxanthine guanine phosphoribosyl tranferase (6-thioguanine [6TG] resistance).	14
Chinese hamster lung (V79).	Hypoxanthine guanine phosphoribosyl transferase (6TG resistance)..	18
	Na/K ATPase (Ouabain resistance).	
Human lymphoblasts.	Thymidine kinase (TFT resistance) hypoxanthine guanine phosphoribosyl transferase (6TG resistance).	44
Chromosome effects:		
Many cell types in vitro and in vivo.	Chromosomal aberrations.	17, 19
	Sister chromatid exchanges.	
	Micronuclei	
	Chromosome gain or loss.	
	Translocation	
DNA damage:		
Unscheduled DNA synthesis (UDA).	Radioactive nucleoside incorporation.	40
Repair deficient bacteria.	Differential growth inhibition.	20
Mammalian cell transformation:		
Cellular:		
Syrian hamster embryo (SHE), Balb/c 3T3, CeH/10T½.	Altered cellular morphology and growth pattern, growth in soft agar, tumorigenicity in appropriate host.	35
Viral enhanced/mediated Syrian hamster embryo (SHE)/Simian adenovirus type 7 (SA7), Fischer rat embryo cells/Rausher leukemia virus.		35

A. Gene Mutation

Although it is possible to assay for chemically induced mutation with a variety of methods in a number of organisms and cells, the greatest amount of information on tests for potential carcinogens is derived from a relatively few systems. The system in which the largest number of chemicals has been evaluated is the Salmonella/microsome test (Ames test) (*42, 43*) where several strains of the bacterium *Salmonella typhimurium* have been genetically altered in order to provide increased sensitivity to potential mutagens. In the Ames assay, reverse mutations in the histidine locus (*i.e.* from a histidine requirement to independence) are detected. By virtue of the sensitivity, ease and relatively low cost of performance and duration of the test (48–72 hours), this assay has been used worldwide to test for chemical mutagens. Other microbial systems can also be used (Table 5) but have not been used nearly as extensively as the Salmonella assay. Cultured mammalian somatic cells (which are genetically more similar to cells as they exist in humans than to bacteria) such as the mouse lymphoma (L5178Y) (*39*), Chinese hamster ovary (CHO) (*14*), and Chinese hamster lung cells (V79) (*18*), have also been used to detect gene mutations induced by a variety of chemical agents and radiations. The various systems that have been developed are capable of detecting forward and/or reverse mutations. However, none of the specific gene loci conventionally used in the bacterial or mammalian cell mutagenesis systems (*his, tk, oau, hgprt,* etc., Table 5) appear to be related in any way to the cellular changes that occur in the induction of neoplasia. These loci are used to measure the capability of a chemical to interact with the DNA of an organism in such a way as to give rise to mutagenic effects. Although it has been widely assumed and theorized that neoplasia arises from mutation, it is known that heritable phenotypic changes also occur in mammalian cells in the process of differentiation and growth and such changes arise without the induction of gene mutation. Consequently, it is necessary to use additional biological endpoints that reflect the capacity of chemicals to cause changes through other types of interactions with the genetic material.

B. Chromosome Effects

Changes in the structure or number of chromosomes occur frequently in tumor cells (*45*) and cells from individuals exposed to radiation show evidence of chromsome damage (*46*). Cytogenetic short-term tests have demonstrated that a number of carcinogens can cause structural alterations of chromosomes (aberrations) in the bone marrow of exposed animals or in cultured cells derived from various tissues (*19*). There is increasing evidence that associates specific chromosomal rearrangements (translocations) with specific neoplastic phenotypes (*47*). Although no definitive causal associations have been defined, the use of molecular and recombinant DNA techniques promises to aid in

resolving the relationship between translocation of large segments of chromosomes and the specific DNA sequences involved. Another assay often used in conjunction with the search for chromosomal aberrations is the induction of sister chromatid exchanges (SCEs) (*48, 49*) that are believed to result from the induction of recombination by DNA damage. However, the association between an increase in the frequency of SCEs in cells *in vitro* or *in vivo* and heritable changes has not not been clearly defined.

It is also possible to identify the production of chromosome fragments (micronuclei) in reticulocytes or erythrocytes (*50*). Induction of micronuclei has been associated with chemical exposure and is also believed to be indicative of the ability of chemicals to induce chromosomal aberrations, but it is also not yet clear that the induction of micronuclei is related to heritable changes in cellular phenotypes.

A long-range potential value of tests of chromosomal effects is that they may be used to assess the comparative (trans-species) toxicity of chemicals. Since the sampling for cells is non-destructive to the exposed animal or individual, and because the assays can be conducted on cultured cells, comparisons are possible between various species and humans. However, such comparisons must be conducted with the understanding that chemical disposition (pharmacokinetics) may vary with species thus giving rise to species-dependent target cell populations. Additionally, the monitoring of human blood cells for chromosomal effects may be a valuable method to assess human exposure to hazardous chemicals (*51*).

C. DNA Damage and Repair

These tests do not measure mutation per se, but DNA damage, or the cellular repair of such damage, induced by the chemcial treatment of microbial or mammalian cells. The most extensively used method is to detect non-S phase DNA synthesis (unscheduled DNA synthesis—UDS) in hepatocytes (*40, 52*), although other cell line (*40*) have also been used. Techniques that measure DNA strand breaks (*23*) or binding of chemcials to cellular DNA *in vivo* or *in vitro* (*53*) are also used as assays for DNA damage. Other assays use strains of *E. coli* or *B. subtilis* and are based on differential growth inhibition of DNA repair proficient and deficient strains (*20, 54*).

D. Cellular Transformation

Exposure of cultured mammalian cells from a variety of tissues and species to carcinogens (biological, chemical and radiations) has been shown to result in certain heritable phenotypic changes. A variety of these change has been described (*35, 55*), but some specific morphological changes have been shown to be highly associated with the capacity of the cells to induce tumors when inoculated into appropriate recipient animals. Because of this ability of transformed cells to produce tumors in recipient hosts, these assays have been considered by some to be the short-term systems most relevant to detection of chemical carcinogens (*6, 35, 51*). A number of cellular systems derived from rodent embryos have been used to identify chemcial carcinogens (Table 5), some of which use concomitant infection with transforming or nontransforming viruses (*35, 55*). There is no clear understanding of the mechanism of *in vitro* transformation, and it is likely that the various heritable alterations can occur through one of several possible mechanisms. Recent innovative advances at the cellular and molecular level and having a major impact on our understanding of this process (*56, 57*). As the implications of studies on oncogenes and transfected transforming genes because better understood and are incorporated into methods for detecting carcinogens (See Chapter 1), there is the promise of significant improvement in the accuracy with which these systems can be used to dectect carcinogenic chemicals.

E. In Vitro Bromothion System

The existence of chemicals which appear to cause (or promote) cancer by mechanisms which may or may not directly involve the genome (See Chapter 1) has necessitated the development of short-term systems that can detect these types of chemicals. However, it should be emphasized that chemicals may have both initiating and promoting activity, and the two properties are not mutually exclusive. The V79-metabolic cooperativity assay (*58*) has been the most thoroughly studied *in vitro* system developed to detect chemicals with promoting activity. A basis for this assay has been attributed to be the interruption of cell-to-cell communication, although the exact mechanism is unknown. Further studies with this and other promotion systems are needed before they could be reliably used as test systems to detect chemicals that act as promoters of tumorigenesis.

F. In Vivo Short-Term Bioassays

Several short-term *in vitro* bioassays to detect carcinogens and/or promoters have been developed. Of these assays, the mouse skin papilloma system and the strain A mouse lung adenoma have been used for testing while the liver foci bioassay is still in developmental stage. These systems are generally viewed as intermediate in biological relevance between *in vitro* systems and the long-term animal bioassay because *in vitro* methabilism and/or chemical disposition are provided for by *in vitro* exposure. However, as the *in vitro* tests, the relevance of the endpoints measured to the development of malignant tumors remains an open question.

The mouse skin papilloma system, first reported by Berenblum (*59*), is based on a multistage (initiation and promotion) hypothesis of cancer induction and has been developed further in other laboratories (*60–64*). The system relies on the induction of benign papillomas, although carcinomas do develop in the later course of the assay. Variations in experimental test design reportedly allow chemicals to be classified as: Initiating carcinogens, promoters, complete carcinogens (chemicals with both initiating and promoting activity), co-carcinogens, and co-promoters (*64*). Several strains of mice have been used in the assay, but the SENCAR stock appears particularly sensitive (*64*). The mouse skin papilloma system is the *in vivo* system in which the greatest number of chemicals have been tested (*65*); however, many of the chemicals investigated have been polycyclic aromatic hydrocarbons, and the usefulness of the system to test other classes of chemicals, or chemicals with organ specificity other than skin, is not presently clearly known.

The strain A mouse lung adenoma system was developed by Shimkin and colleagues (*66–69*). Although lung adenomas do occur spontaneously in mice, the strain A mouse, unlike other strains, has nearly a 100% life-time incidence (*69*).Therefore, the assay appears to rely on decreasing the time-to-tumor onset by the test chemical, although Stoner and Shimkin consider the test chemcial to be inducing rather than accelerating the process (*68, 69*). A wide spectrum of chemical classes has been tested in the lung system (for review, see (*69*) and good correlations of results and the tumorigenicity of the chemicals have been reported although one study using diverse coded chemicals did not find a high correlation (*70*). The system has been criticized because the adenoma is a benign growth and an

analogous tumor does not appear in humans.

The induction of altered foci in rat liver systems have also been studied for use as short-term *in vivo* assays for carcinogens and promoters. However, these systems are relatively new and are still in a developmental stage compared to the mouse skin papilloma and lung adenoma assays. The rodent liver systems have been used by Peraino *et al.* (*71*), Pitot *et al.* (*72*), and Solt and Farber (*73*), to study the initiation/promotion phenomena. The endpoints that have been measured include the appearance of foci in the liver which have increased gammaglutamyl transpeptidase, basophilia, or diaphorase; or foci with decreased glucose-6-phosphatase, adenosine triphosphatase or iron storage (See *74* for review). Chemicals can be tested either for initiating or promoting activity in the liver assays. Since defined protocols have not yet emerged, further development is required before the possible value of the approach in a routine testing program can be assessed. In addition the relationship of the altered liver foci to liver neoplastic nodules remains to be determined.

III. FACTORS IN TEST EVALUATION

A. Metabolic Activities

Most target cells used in short-term tests have limited endogenous metabolic capability for xenobiotics and, therefore, must be supplemented with an exogenous metabolic activation system. The metabolic activation systems employed in short-term tests may be one of the major limitations in these assay systems, because a chemical may show a different metabolic profile *in vitro* from what would occur *in vivo*. From a testing point of view, a major concern is that specific activating enzymes or pathways may be decreased or lost during preparation of the metabolic activation system, thereby giving a false negative result with the test chemical. Alternatively, enhanced activation of certain chemicals would also be possible (false positive). Essentially, three types of metabolic activation systems have been used with target organisms—host-mediated (*24, 75*), intact cells (*76, 77*), and organ homogenates (usually 9000 × g supernatants called S9 [*10,43*]). Most short-term assays have used rat liver S9 preparations because of the ease of preparation and storage, capability to activate many chemical classes, and the relative compatibility (nontoxicity) with most target organisms used in genetic toxicity testing. However, it is also known that liver S9 preparations may cause different responses *in vitro* from what would occur *in vivo* due to factors such as: organotropic differences, chemical induction of S9 preparations, and destruction of certain activation enzymes during S9 preparation, decrease in conjugation capability, etc. Therefore, the inability of S9 preparations to mimic *in vivo* activation has provided the impetus to modify S9 utilization and/or investigate other metabolic activation systems.

Intact cells are another exogenous metabolic activation system used in short-term tests (*77*). These cells can be primary cultures prepared from various organs (liver is most common), embryonic cells that have been cultured only a short time, or in certain cases, established cell lines. For such an activation system to function, the test chemical must be taken up by the activating cell, be metabolized, and the activated product be transferred to the indicator cell. Thus, a negative response with a cellular system may be a function of the uptake of the test substance and the transfer and stability of active metabolites. Since most cells lose significant metabolic capability with time in culture, certain enzyme systems may be functional at reduced levels. However, this loss of activation capability can be at least partially overcome by the use of freshly prepared primary cells.

In the host-mediated assay, the indicator organism is introduced into the peritoneal cavity or injected into the circulatory system of an intact mammal (*24, 75*). The animal is then treated with the substance under test, sacrificed, and the test organism removed and examined for mutation induction. A wide range of indicator organisms has been used (*24*). Because an organism foreign to the host is commonly used as the indicator organism, problems arise such as: (1) Interaction between the host and the indicator organism, including immunological interactions; and (2) the limited time the indicator organism can be kept in the animal. Therefore, this system is unable to detect many carcinogens and chemicals which show *in vitro* mutagenesis.

Attempts to improve metabolic activation systems are certainly worthwhile and have increased our ability to detect carcinogens using *in vitro* methods. One must accept, however, that it is not possible to mimic *in vivo* metabolism in a petri plate and that negative *in vitro* results may represent "false negatives" and positive *in vitro results* may represent "false positives." These possibly erroneous test results due to metabolic activation can sometimes be resolved through the use of short-term *in vivo* rodent assays. A testing scheme has been proposed by Ashby (*78*) whereby short-term rodent assays are employed to study further chemicals falsely identified in the *in vitro* systems.

B. Statistical Evaluation of Short-Term Test Data

The overwhelming majority of short-term test data in the literature have not been statistically evaluated. In general, decisions of "positive" and "negative" are made on a subjective basis or on the basis of simple statistical procedures. Recently, a number of statistical procedures have been proposed for the Salmonella assays (*79–81*), the mammalian cell mutation (*82*) assays, and discussions of statistical approaches appear in the respective Gene-Tox reports, but there is no consensus as to which particular procedures should be used for data evaluation.

C. Factors in the Correlation of Assays With Carcinogenesis

Because short-term tests for carcinogens employ neither the organism (humans) or the biological endpoint (cancer) of concern, there is a need for a great deal of extrapolation of test results, and hence the demand for proving the validity of the tests is great. However, after more than a decade of effort to demonstrate the utility of short-term tests in predicting carcinogenicity, it is still difficult to find sufficient test results to assess: (1) The performance of an assay within or among chemical classes; (2) the activity of a chemical in a variety of tests; or (3) the performance of a group of the tests on even a small group of chemicals. This deficiency in the existing data results largely from two factors. First, there has not been enough of an effort to evaluate systematically a large number of chemicals in a group of selected assays, and second, there is a marked deficiency of genetic toxicity results on noncarcinogens. This latter point presents an immediate obstacle to the evaluation of short-term tests for carcinogens, since in the absence of an adequate data base on noncarcinogens, it is not possible to determine the performance of a single test or group of tests in discriminating between carcinogens and non-carcinogens.

1. Definition of some terms. The reliability of a short-term test system may be defined as its ability to predict accurately a chemical's *in vivo* carcinogenicity. The standard against which short-term test results are most

often compared is the rodent cancer bioassay. A short-term test which correctly identifies, when used without bias, a high percentage of known carcinogens and noncarcinogens is assumed to be capable of predicting the carcinogenicity of chemicals of unknown activity with the same degree of accuracy. The short-term assay's performance can be expressed by three criteria: Sensitivity, specificity, and accuracy. Sensitivity is the proportion of carcinogens giving positive results; specificity is the proportion of non-carcinogens giving negative results; and accuracy is the overall proportion of correct results. Unfortunately many, if not all, previous test system evaluations, have been characterized by an inadequate number of non-carcinogens, and, hence, a determination of specificity and accuracy is severely limited. Also, the accuracy of short-term tests could be altered by the ratio of carcinogens and non-carcinogens in the test sample (*83*). Additionally, the expected accuracy of a test battery (see below) is influenced by the number of tests in the battery and the number of individual tests required to be positive before the chemical is considered to be positive in the battery (*84*).

2. Non-carcinogens and test analysis. The inadequate identification of, as well as the use of, non-carcinogens, as has been noted, is one of the key problems. Many chemicals have been identified as non-carcinogenic merely on the basis of their chemical structure or perfunctory carcinogenesis tests. To date, relatively few chemicals used as non-carcinogens in short-term tests have been tested in lifetime studies using adequate chemical exposures. A major source of information on non-carcinogens is that of the NCI/NTIP rodent bioassay where two sex/species are exposed at sufficient concentration of the chemical and for sufficient duration to insure that the chemical has been tested adequately. However, few of these non-carcinogens have been tested in most genetic toxicity assays (*85*). In addition, factors that determine a "positive" or "negative" short-term test response for a test chemical can vary from laboratory to laboratory or even experiment to experiment within a laboratory. Often parameters such as control background levels, acceptable range of positive control responses, statistical significance of test chemical response, etc., all of which are important in determining whether a chemical is "positive or "negative", can be subjective. Such uncertainties could lead to an inaccurate estimation of the sensitivity and specificity of short-term tests.

3. Test endpoints and carcinogenicity. The development of the Ames test and subsequent short-term tests were predicated on the assumption that most carcinogens were mutagens and, conversely, that mutagenic chemicals will be carcinogenic. Implicit in this reasoning is the conclusion that nonmutagens will not be carcinogenic. However, this conclusion put forth by Ames *et al. (5)* and supported by others (*86–90*), that carcinogens and mutagens and the majority of non-carcinogens are not mutagens, may be based on biased data. The majority of the data used to justify this statement comes from studies where the identitity of the chemicals and their carcinogenicity were known to the investigators before they were tested. Because the investigators knew the identity of the chemicals and their "expected" mutagenicity, the test protocols could be modified until the desired results were obtained. While these practices may lead to a true picture of the mutagenicity of a chemical, and are necessary for the assay system development, they probably tend to overestimate the carcinogenicity/mutagenicity correlations.

The correlation of other endpoints (*i.e.* UDS, cell transformation, SCE induction, etc.) with carcinogenesis also is subject to the same limitations. However, the correlations between results from these other systems and carcinogenesis are further complicated by the lack of an adequate data base on chemicals of different classes, and, in some cases, a lack of demonstrated interlaboratory reproducibility of test results.

A method which may establish more objectively the correlations between short-term test results and rodent (or human) carcinogenicity is one where chemicals, coded so their identity is unknown to the persons conducting the assay, are tested, and all the test results are judged by the same criteria. Thus, the one conducting the test does not know whether the short-term test results and conclusions are "right" or "wrong" until after a determination is made. This approach may minimize the proportion of carcinogens detected, but it also eliminates much bias from the correlations. In actual practice, however, additional testing using modified protocols can be done on chemicals whose structure would lead one to believe that the original test conditions were not appropriate. For example, some benzidine-based dyes require reducing conditions, followed by an oxidative system, rather than a strictly oxidative system for their activation. Therefore, choice of test systems should vary with chemical class or nature of the test chemical, but determinations of response should be independent of knowledge of the chemical's identity.

4. Attempts to evaluate short-term test performance. Though not definitive, there have been several systematic efforts to evaluate the short-term assays, singly or in combination, for their ability to detect or predict chemical carcinogens. The largest effort to date was conducted by the Gene-Tox program of the U. S. Environmental Protection Agency and is a multi-phased effort to review and evaluate selected bioassays for mutagenicity and related endpoints using the published literature. Initially, the literature published from 1969–1979 was reviewed to assess test system performances, to determine the chemicals tested, and the ability of the various system to discriminate between carcinogens and non-carcinogens. Reports on the individual systems have been published in Mutation Research (*12–40*). During the second phase, a computerized data base of over 2600 chemical is being analyzed to determine which tests or combination of tests may: (1) Be used for routine screening or need further development; (2) determine if specific types of genetic damage are related to chemical class; (3) discriminate between carcinogens and non-carcinogens; and (4) predict heritable mutagenic risk. To aid in evaluating system performance, the Gen-Tox Program convened a panel to review and evaluate the literature on chemicals designated as carcinogenic and to develop a list of carcinogens and non-carcinogens which could be used in determining system performance.

The International Program for the Evaluation of Short-Term Tests for Carcinogenicity (*41*) was a coordinated effort designed to determine and compare the ability of a series of short-term tests to identify carcinogens and noncarcinogens. Sixty laboratories participated, using their own laboratory protocols, to test coded samples of chemicals supplied from a common source. Test results from this collaborative study led to the following general conclusons. First, while short-term tests are useful in the assessment of potential carcinogenicity, no single test or group of tests was capable fo detecting correctly all carcinogens and noncarcinogens. Secondly, there are *in vitro* eukaryotic assays that may complement the bacterial tests by identifying carcinogens not detected in bacteria.

Following the completion of the collaborative study discussed above, a subsequent study was initiated to focus specifically on the evaluation of *in vitro* eukaryotic assays with potential for identifying carcinogens not detected, or poorly detected, in bacterial mutation tests (*91*).

Other systematic attempts to evaluate the short-term assays include an analysis of their ability to detect pesticides (*92*) and a series of reports prepared for the International Commission for Protection Against Environmental Mutagens and Carcinogens (ICPEMC) (*78, 93*). The NIH/NTP is currently conducting a systematic genetic toxicity assay of chemicals, both carcinogens and non-carcinogens, tested or under test in the rodent, two-sex/species carcinogenesis assay. The major categories of genetic toxicity are represented, and the chemicals are tested under code.

IV. PRACTICAL ASSAY UTILIZATION

A. Assay Selection

The proposed use of short-term tests to detect or predict chemical carcinogens is based on two factors: first, that they require less time to conduct than a rodent carcinogenicity study; and, second, that they are less costly. Currently used tests require from a few days to several weeks to conduct, and the costs may range from 1000 to 20,000 dollars per chemical.

Since there has been little success in establishing a cause-effect relationship between specific genetic changes and cancer, all categories of induced genetic change may be potential mechanisms by which cancers arise, and this is reflected in the variety of endpoints detected by short-term tests. Current short-term testing practices generally involve groups of tests selected on the basis of theoretical prudence rather than on an empirical demonstration of their ability to predict carcinogenicity. By theoretical prudence, it is meant that a range of organisms (bacteria, yeasts, cultured mammalian cells, intact rodents) and endpoints (gene mutations, chromosomal damage, DNA damage, and *in vitro* neoplastic transformation) are employed in an attempt not to miss any effect that might be related to the carcinogenicity of the test agent. However, until the time that basic research on mechanisms of cancer induction provide us with a better understanding of the process, it will be necessary to base testing strategies on a combination of theoretical prudence and correlative evidence obtained by comparing short-term test results with carcinogenicity test results.

In the selection of short-term tests, factors other than ability to discriminate between carcinogens and noncarcinogens must be considered. Reproducibility of test results is a paramount consideration that applies not only to reproducibility within a laboratory but also to agreement of test results among laboratories. When testing chemicals, the ability to reproduce test results qualitatively is more important than quantitative reproducibility. Quantitative differences in test responses represent the degree of response and may be attributed to protocol variables. However, qualitative differences are more serious and affect the judgment of whether a test chemical is "positive" or "negative." Therefore, short-term test selection should be based on reproducibility as well as reliability, sensitivity, specificity, and accuracy. In addition, the degree of development of a particular assay system should also be taken into consideration when selecting tests for use in a screening program. This includes a consideration of the number of laboratories performing the assay, degree of protocol standardization, and a consideration of the number of chemicals and chemical classes which have been tested in the assay.

B. Assay Application

The application of short-term tests to chemical safety evaluation raises questions at several levels of the process. As discussed above, assay performance must be known to determine which tests are useful. Next, it must be decided how many tests to use and in what scheme or order they will be utilized. Tier and Battery testing approaches have been proposed. In the Tier approach, the choice of assay system varies depending on the activity of the chemical in the previous system, beginning usually with the *S. typhimurium* assay. Therefore, decisions are made after each test result is obtained. With the Battery approach, the test chemical is assayed in a group (battery) of systems and a decision on the activity of the chemical made when all results have been obtained.

Once test results from the short-term test scheme have been obtained, it must then be decided how to utilize the results. Within the framework of testing or evaluating chemicals for potential carcinogenicity, where possible regulatory action on the chemical may be involved, short-term test results can be used to influence the process at numerous points including:

(a) The nomination and/or selection of the chemical for prechronic and chronic studies;

(b) The selection of prechronic studies to be conducted;

(c) The decision, used in combination with prechronic results, to proceed with chronic studies;

(d) The evaluation of chronic toxicity results, as a source of additional information;

(e) The design of postchronic studies, again as an additional source of information, to further elucidate mechanisms of activity.

In the industrial setting, short-term tests can be (and are) used extensively in product development, process improvements, product registration, evaluation of occupational environments, etc.

It is generally agreed that a scheme employing multiple tests is a better approach to carcinogen screening than the use of a single test. The tests used should not be limited to prokaryotic or lower eukaryotic test systems and should include assays for more than one genetic endpoint A problem that is immediately encountered when multiple test systems are used, however, is a mixture of positive and negative results. The resolution of this problem is not easy, and several authors *(94–96)* have attempted to deal with the issue. For the present, there are at least three approaches to dealing with such conflicting test results. One may: (1) Use a weight-of-evidence approach to call a chemical positive by some predetermined criterion; (2) use one's best-scientific-judgment to reach a conclusion on a chemical-by-chemical basis; or (3) simply postpone judgment until the time that a sufficiently large data base is available to permit an unequivocal conclusion from any pattern of positive and negative results. This last choice is rarely acceptable, and current practice generally utilizes some combination of the first two. The systematic accumulation of additional knowledge on cross-system testing of various classes of chemicals should provide insight into the proper choices of short-term systems in assessing potential carcinogenic activity.

C. Future Directions

Short-term tests for genetic toxicity and other effects continue to hold promise of improving our ability to identify potential chemcial carcinogens. However, there is at present insufficient data available to justify the use of current tests to supplant animal bioassays. To improve the interpretation of short-term test results, there is a need for a systematic effort to obtain across-test results using *optimal* test protocols and coded chemicals, with particular

emphasis on non-carcinogens. It is clear from available results that no one assay system is adequate, but it is not yet possible to determine which combination of test systems are most appropriate for most carcinogens. Studies are needed to determine if human cells or tissues would be better predictors of human carcinogenicity than the currently used rodent systems. Some carcinogens, by virtue of their intrinsic mechanism of action, will not be identified by available tests, and we must continue to search for assay systems that accommodate the various molecular mechanisms.

Concommitantly, we must continue to improve our understanding of the results of rodent assays for carcinogens. Where there is a dichotomy of results between genetic toxicity or other short-term test systems and the results of rodent carcinogenicity, appropriate follow-up studies in the appropriate systems should be conducted to determine the basis for such differences.

V. SUMMARY

While many assay systems have been developed and proposed to detect or assess the genetic toxicity of chemicals, they can be generally grouped into four categories: Gene mutation, chromosome effects, DNA damage, and transformation. The internal momemtum of the field has resulted in the emergence of a few systems or tests in each category that have been used extensively to assess potential carcinogenicity, and the various assays within each grouping have characteristic strengths and weaknesses. The test systems must be demonstrated to have reliability, sensitivity, specificity and accuracy and to be reproducible both within and between laboratories. The various systems also measure different biological endpoints, and there is no reason to expect that all chemicals will cause an effect in all systems. Since no causal relationship has been established between any specific mechanism of induction and any specific type of neoplasia, we are presently limited in our ability to predict potential carcinogenicity of a chemical, particularly when there is apparent disagreement between different *in vitro* test results.

The consensus of available information suggests that short-term tests, when properly used and validated, can provide strong indication of potential carcinogenicity. However, based upon our limited knowledge of the mechanisms of cancer induction, it appears that there will be classes of carcinogens that are not detected by currently available short-term tests. Chemicals which act by a genetic mechanism but which have a high degree or organ, species, or sex specificity may be predictably difficult to detect in any *in vitro* genetic toxicity system since the short-term system may not adequately simulate the basis for these specificities. Additionally, chemicals which appear to act by non-genetic mechanisms would not be detected in currently available short-term tests.

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Chapter 3—Long-Term Carcinogen Bioassay

I. LONG-TERM CARCINOGEN BIOASSAY: GUIDELINES FOR PROTOCOLS

A. Background

The current carcinogen bioassay in rodents has its origins in research efforts, begun in the 1920s, that sought to determine the carcinogenic potential of chemicals as well as to delineate the mechanism by which they produce cancer (*1, 2*). Animal strains were developed and tested for their specific sensitivity or resistance to certain types of cancer. These studies had as their central focus the understanding of the mechanism of carcinogenesis (*1, 2*). While these experiments led to the induction of cancer in laboratory animals and revealed many new carcinogens, most of the investigators did not intend their highly specialized test systems to be used as routine methods for testing large numbers of chemicals. Only in the mid 1960s, with the advent of bioassay program at the National Cancer Institute (NCI), did large-scale systematic testing using a relatively standard protocol really begin (*3*). As a consequence, only recently has there been a reasonably adequate data base on a large number of diverse chemicals tested in a relatively uniform way (*4*). The lack of such a data base, during the earlier developmental period, contributed to some degree of confusion and speculation as to how carcinogens should be tested and how the results from such tests should be interpreted. One finding was clear; known human carcinogens, with the single exception of arsenic, are carcinogenic in appropriately conducted studies in some animal system.

This does not mean that all chemicals found carcinogenic in animals will turn out to be carcinogenic in humans. Many substances are known that seem to be carcinogenic in one animal species but not in another. But a finding of carcinogenicity in rodents is proof that the chemical is carcinogenic in a mammalian species. This must be taken as strong evidence that the chemical can be a carcinogen in man, unless there is compelling epidemiological evidence to the contrary. The knowledge and experience accumulated over the last decade, while by no means answering all questions, have focused the issues and provided a basis for developing some common procedures for conducting and interpreting long-term bioassays.

B. Critical Design Criteria

Several national and international groups have published guidelines on the design and conduct of long-term bioassays (*5–15*), and the issue continues to be pursued. For example new guidelines are currently being developed by the NTP Ad Hoc Panel on Chemical Carcinogenesis Testing and Evaluation. Essentially, the long-term test involves testing compounds in animals to obtain information relevent to humans. While assessing the results of toxicological testing of any chemical, the limitations of the tests must be borne in mind. Of necessity, animal systems are used and the results then extrapolated to humans. Such extrapolations may not always be accurate either qualitatively or guantitatively. In some areas of cancer testing, uncertainty still exists concerning the most appropriate experimental design. For example, there are varying opinions on the optimum duration of a study, the number of doses tested and the number and types of species of test animals that are considered appropriate. It is probably unwise to adopt rigid "standard" test methods for all chemicals; judgment must be exercised to select an appropriate model for a particular chemical (*12*). Obviously, due to limitations of sample size (the number of animals on test), low incidence effects can go unrecognized. Consequently, although the results of carcinogenicity testing will, in many cases, give good indications of possible hazard, they do not eliminate the need for continuing careful observations of humans (*5*). In fact, most known human carcinogens, such as 2-naphtylamine and chlornaphazine, were first discovered by observing humans, and only later were they found carcinogenic in animals. The reverse was true for other compounds such as DES(diethylstilbestrol) vinyl chloride or bis(chloro-methyl)ether.

The following constitutes a series of major issues which should be carefully considered in the design of a carcinogen bioassay.

1. Species and strain of animal. Ideally, the appropriate animal species and strain is one, which, for the chemical tested, is able to predict human response accurately. However, the fact is that only three species have been routinely used in carcinogen bioassay (*16*). All three are rodents: the mouse, the rat and the hamster. The hamster is probably the least desirable because of the lack of comparable familiarity in its use as an animal model. Only these species generally meet the

requirements that the animals be readily available, that the bioassays are likely to be relevant to humans, and that the bioassays be cost effective and relatively quickly performed. Included in these requirements are: (1) The life span of the species must be of reasonable length, long enough to allow time for tumors to develop and short enough to be economically feasible (2–3 years); (2) the animal should be small and should live and breed well in captivity; (3) there should be similarity to humans in regard to metabolism and pathology responses; (4) strains should be those most likely to be susceptible to cancer from the particular chemical yet not hypersensitive. Only three species and a few strains currently meet these specifications, although there are potentially many more genetically derived strains which can provide a wide range of diversity in their metabolism of and response to carcinogens or carcinogenic precursors. There is still no scientific consensus over whether inbred or outbred strains of rodents are better for long-term studies (*17*). While the use of inbred strains may produce more precise and more stable biological responses (*18, 19*), more prosaic strains may more accurately reflect human response, are less expensive, often hardier and less prone to high incidences of spontaneous tumors. When the test substance is chemically related to other human carcinogens, the strain chosen can be that used for the carcinogenic chemical analogue. Extensive experience in using a particular strain is often a strong reason for continuing its use despite its acknowledged limitations (*14*). One major advantage is the availability of abundant data on spontaneous tumor rates at specific organ sites.

Because of genetic differences in tumor susceptibility the use of only a single strain of animal rather than an array of strains represents an experimental compromise, but an essential one given the large cost of a single long-term study. The possibility of a false negative result is reduced by the current recommendation to use two species instead of one in a carcinogen bioassay. More than 90% of the time these species are the rat and mouse. The Fischer inbred (F–344) rat and the B6C3F1 hybrid mouse are commonly chosen for carcinogen bioassay, in large part because of the experience gained by the NC1 from their use (*4, 19, 20*). Despite its long history, the continued use of the B6C3F1, hybrid mouse by the NTP is currently under review because of the difficulty in interpreting the significance of proliferative liver lesions (*4–6, 20–22*). The merits of using only a rat strain instead of both a rat and mouse strain have also been recently discussed (*23*). This issue and others relating to species selection will be considered in the NTP Report on Chemical Carcinogenesis Testing and Evaluation.

2. Animal care and diet. Stringent control of environmental conditions and proper animal care techniques are mandatory for meaningful results (*12*). Access to animal facilities should be limited to essential personnel to prevent excessive traffic and the transmission of disease.

Factors such as housing conditions, intercurrent disease, drug therapy, impurities in diet, air, water, and bedding, and animal care facilities can significantly influence the outcome of animal experiments.

The control of intercurrent infectious diseases or parasites is facilitated if rodents are bred and maintained in conditons free from specific pathogenic organisms. Animals from outside sources should not be placed on test without an adequate period of quarantine. Bedding to be used in long-term studies should be absorbent, sterilizable and free of pesticides, other toxic contaminants, or enzyme inducing substances. Animals should be housed in quiet, well-ventilated rooms, having controlled lighting, temperature and humidity. It is advisable to balance dose groups over rows, columns and racks to allow for potential location effects across dosage levels. Alternatively it may be advisable to rotate cages or racks periodically to balance potential sources of variability. Eye lesions (retinal and lenticular degeneration) have been observed with animals kept in cages in closest proximity to light. Experiments should not be initiated until animals have been allowed a one to two week period of acclimatization to environmental conditions.

The absence of biases in selection and allocation of animals between control and treatment groups, as regards diet, husbandry, necropsy and pathology is crucial *(15)*. Since mice are reservoirs of asymptomatic viral disease, it is best to house mice and rats separately where possible. However, it is acceptable practice to house rats and mice in the same room if: (1) They are free of disease; (2) they come from the same supplier; and (3) they are being treated with the same chemical. It is preferable not to mix animals from different suppliers or from two locations of the same supplier. Housing disease-free animals in the same room reduces the chance for differences due to environmental variables. If a population of animals is diseased, then consideration must be given to aborting the study and starting over. Drug therapy should be avoided in bioassays since it is a confounding factor.

Control animals and test animals should be housed in the same room unless there is a possibility of cross-exposure. The availability of hoods, laminar air flow rooms, caging devices and personnel practices all affect the extent to which experiments should be separated or combined. To minimize the chance for inadvertent cross-exposure of animals to the test substance, it is advisable to test only one chemical in each room. If more than one chemical is tested in a room, the actual cross-contamination of chemicals within the room must be measured. Good laboratory practice need not rule out all flexibility nor restrict the use of judgment or impose unnecessary expenses (*26*).

Cages, racks and other equipment must be regularly and thoroughly cleaned. Periodic analysis of the basal diet should be conducted for both nutrients and unintentional contaminants, including carcinogens. The results from such analyses should be retained and included in the final report on each test substance. The essential dietary requirements of rodents are relatively high in protein and low in calories derived from fat (about 2–4% of calories). In the administration of substances by gavage using vegetable oils, the amount of fat ingested in rats can reach 30% (*25*). These facts, coupled with emerging data on the influence of dietary protein and fat on cancer incidence, and the presence of trace levels of carcinogens in animal diets may be important to future re-evaluation of bioassay results. Furthermore, the quality of the agricultural crops that go into animal feed can vary seasonally. Varying amounts of naturally occurring enzyme inducers from plant and fish material in animal feeds may affect the course of a long-term test for carciogenicity. It is therefore important to document and retain pertinent information on diet source and quality.

When the test substance is administered in long-term studies, stability tests are essential. Properly conducted stability and homogeneity tests, prior to the chronic study, should be used to establish the frequency of diet preparation and monitoring required. Similar tests are required for exposure atmospheres (in inhalation tests) to determine the necessity of rotating animals within the exposure

chamber and the frequency of monitoring required. The stability of the neat chemical, if it is to be used for a long time, as in long-term skin-painting studies, should also be determined.

If diets are sterilized, the effects of such procedures on the test substance and dietary constituents should be known. Appropriate adjustments to nutrient levels should be made.

During carcinogenicity tests, investigators should be aware of potential chemical contaminants in the water used. Although water approved for human consumption is generally satisfactory, the investigator should determine the levels of potential contaminants that are likely to influence the outcome of the study. The analyses of the water supply should be included in the reports of these studies.

3. Test and control groups. The number of animals to use has been the subject of great concern because of the fact that the test animals may be serving as surrogates for more than 200 million people in the U.S., and potentialy for far more worldwide. While it is desirable to enhance the sensitivity of the test, it is not feasible to use very many animals. Furthermore, a moderate increase in the group size provides relatively little increase in the statistical power of the test. Therefore, careful attention must be paid to experimental design to assure the maximum reliability of the study and that the results are amenable to statistical evaluation. The use of adequate randomization procedures for the proper allocation of animals to test and control groups is of particular importance. A sufficient number of animals should be used so that at the end of the study enough animals from each group are available for thorough pathological evaluation. For such reasons, it has been recommended that each dose group and concurrent control group should contain at least 50 animals of each sex (*4, 11, 19*). If interim sacrifice(s) is included in the study plan, the initial number should be increased by the number of animals scheduled for the interim sacrifice(s).

At least one concurrent untreated control group, identical in every respect to the exposed groups, except for exposure to the test substance, should be used. An additional concurrent vehicle control group should also be utilized in special circumstances, such as when an emulsifier of uncharacterized biological activity is used as an aid in dispersing the test chemical into the diet, or when it is necessary to use a solvent or vehicle to dissolve the test compound for administration to the test animals. In certain studies, such as with inhalation exposures, that require unique housing conditions, it may also be appropriate to include an additional concurrent control groups housed under conventional conditions.

Occasionally a positive concurrent control group is useful, particularly when there is reason to believe that the strain of animals may be resistant to the particular class of carcinogens or that a previously sensitive strain has become insensitive because of genetic drift. A positive control can also provide some information on the relative carcinogenic potency of the tested chemical. In routine carcinogenicity testing, no positive controls need be used (*4, 11*).

4. Dose levels, frequency and route of exposure. If a single bioassay is to be used both for detection and for risk assessment, at least three dose levels in addition to the concurrent control group are recommended. The question of what maximum dose should be administered may be the most controversial issue concerning bioassays (*10, 26*). The highest dose level currently recommended is that just high enough to elicit signs of minimal toxicity without significantly altering the normal life span due to effects other than carcinogenicity (*7*). The dose of test substance should not comprise so large a fraction of the animal's diet that the required nutrient composition of the diet is altered, leading to nutritional imbalances. This maximum tolerated dose (MTD) is ordinarily determined in a 90-day study; and was initially based on a weight gain decrement, *i.e.*, the highest dose that will produce a slight depression in body weight (approximately 10–12%) if administered over a lifetime. NTP has more recently suggested refinement of MTD selection on the basis of a broader range of biological information. Other signs of toxicity that may be used to establish the MTD include primarily gross and microscopic pathology, but alterations in serum enzyme levels, hematological effects or other physiological, biochemical or pharmacological indices of abnormality may be useful. The important contribution of pharmacokinetic studies to the selection of the MTD is the information such studies provide on the presence of dose-dependent and time-dependent processes affecting the disposition of substances in the body (*27–33*). Such information can identify disproportionate changes in internal concentrations of the chemical or its metabolites with administered dose and also can indicate possible accumulation of the chemical or its metabolites with repeated exposures. When this information is available and effectively applied to dose selection (including the MTD) and utilized in determining the shape of the dose-response curve, carcinogenic responses observed at high doses can be more accurately extrapolated to dose levels in the range of human exposure. To be of maximum use in the dose selection process this information should be obtained early, if possible before or during the prechronic phase of the bioassay.

Lower doses are ordinarily simple fractions of the MTD (½, ¼ etc. . .). The selection of these doses should be based on the results of adequate subchronic studies, pharmacokinetic data, and on anticipated human exposure. The precise objective of the study is also important. Because of cost, a single long-term study may be utilized to obtain data on chronic toxicity, on carcinogenic potential and for carcinogenic risk assessment. The present discussion envisions the combination of both the qualitative objective of a carcinogen bioassay, *the detection of carcinogenic potential,* and the quantitative objective, *obtaining dose-response data for risk assessment,* into a single bioassay. If only one of these objectives is sought, it may be advisable to select the doses differently. The purpose of using the MTD is to provide maximum opportunity for the detection of a neoplastic response. The purpose of several lower doses is to provide adequate information on the shape of the dose response curve for risk assessment and to ensure a meaningful comparison with the control even if the MTD was unfortunately selected at too high a level. The pathological response observed in the subchronic study and the slope of the subchronic dose-responses curve should aid in the selection of the range and number of doses for the long-term study. For example, a steep dose-response curve would suggest closer spacing of intermediate doses than a shallow dose-response curve. The existance of metabolic saturation (as indicated by pharmacokinetic data) at doses well below those identified by pathological criteria suggest a spacing of doses designed to determine both whether the highest dose has any carcinogenic effect and to adequately define the dose-response curve for the saturable process. This may require additional doses. Generally four doses (occasionally three) will be necessary to adequately define the dose-response curve, assuming an appropriately chosen MTD. Since the MTD is an estimate at best, the value of additional doses is generally difficult to judge. If the estimated MTD eventually produces

moderately high or excessively high tumor incidence, additional lower doses may aid in defining the shape of the dose-response curve and may even salvage a possibly invalid quantitative study. If the estimated MTD produces no tumors, or a low incidence of tumors, the additional doses will have been unnecessary. As indicated above, the best guide to the number of doses is the acquisition of knowledge on the pathological and pharmacokinetic criteria upon which a sound, scientific judgment can be based. (The National Toxicology Program [NTP] will be making available more detailed recommendations for prechronic testing and dose selection from its Ad Hoc Panel on Chemical Carcinogenesis Testing and Evaluation). Interruptions in the administered dose may permit some cellular repair and reduce the sensitivity of the test. Therefore, if the chemical is administered in the drinking water or mixed in the diet, it should be continuously available. The frequency of exposure may vary according to the route chosen or may be adjusted according to the toxicokinetic profile or stability of the test substance (See Section 2 above). Protocols for inhalation or for dermal exposure are usually subject to special constraints (*11*).

The route of administration used for the bioassay is critical for both its qualitative and quantitative objectives but in different ways. If the route of administration results in the absorption, distribution and metabolic activation (if required) of the substance, it is reasonable to regard the test as relevant for a *qualitative* demonstration of human carcinogenic hazard. This comparison is obviously most directly made when the route used in the test and the route of human exposure are the same, but as long as the criteria above are satisfied, the results of animal studies are generally considered qualitatively meaningful.

If, because of its palatability, solubility, stability or volatility, a substance can not be given in feed or water, oral gavage may have to be considered. This is clearly less desirable, however, since single large boluses can result in absorption and pharmacokinetic patterns different from those anticipated from human exposures (See also Section 2). Sometimes, the use of gavage can be avoided by gradually increasing dietary concentration of the test substance to gain acceptance, by altering other dietary components to increase the palatability or by microencapsulation.

Certain site specific tumors, *e.g.*, bladder carcinoma following bladder implantation and subcutaneous sarcomas following injection, may not be relevant for human oral exposure. The presence of tumors remote from the site of administration and a knowledge of site-specific metalbolism play a significant role in the final evaluation. Some routes of administration may fail to provide adequate metabolic activation or exposure of target tissues and therefore lead to false negative results (*11*). Such data require careful evaluation.

When an assessment of human risk is desired, it is desirable to obtain sufficient data to permit a reasonably accurate estimate of the dose of the carcinogen reaching the target tissue. In some instances, *e.g.*, for substances used on the skin, this may require a bioassay to detect tumorigenic potential and a separate study of the substance's permeability across the skin to measure the amount absorbed. In inhalation studies, this may require a separate study for determining the amount of inhaled material deposited on, or absorbed by the respiratory tract.

5. Duration of study. Test animals should be exposed for the majority of their normal life spans. While there are certain animal test systems which offer the possibility of inducing cancer within only a few weeks or months, such systems at the present time are useful mainly as research tools to explore specific, well-defined questions. They cannot be relied upon to test unknown substances for carcinogenicity and are insufficient as a primary basis for regulation.

Treatment is preferably begun as soon after weaning as possible (no later than 6 weeks) and continued for the major portion of the animals' lifespans. This is a least 18 months for mice and hamsters and 24 months for rats. In some instances where the cumulative mortality at the planned time of sacrifice is still very low, *e.g.*, less than 10%, a longer duration may be appropriate. Some protocols call for treatment soon after birth (neonatal) or during fetal development (*in utero*). The rationale is based on the greater susceptibility of certain organ systems to carcinogens during their early development. However, there are logistical problems which preclude using neonatal or *in utero* systems for routine bioassays.

Termination of the study is ordinarily acceptable when the number of survivors in the low dose or control group is reduced to 20–25%. Generally, because of difficulties produced by naturally-occurring tumors, long-term studies are conventionally terminated by week 100 for hamsters, 120 for mice and by week 130 for rats, regardless of mortality. When there is an apparent sex difference in response, each sex should be considered a separate study (*9*). If the high does group dies prematurely from obvious toxicity, this should not trigger termination of the lower dose groups or controls. A negative test is ordinarily accepted by regulatory agencies if: (1) No more than 10% of any group is lost due to autolysis, cannibalism or management problems; and (2) survival of all groups (per sex per dose) is no less than 50% at 80 weeks for hamsters, 96 for mice and at 104 weeks for rats (*12*).

Rigid rules for termination are not helpful, the best guide is professional judgment, experience and careful observation of the condition of the animals. The longer the test continues, the greater the opportunity for the development of tumors (*34*). On the other hand, the sensitivity of bioassays decreases with time, because of the natural appearance of age-related tumors in the controls. In theory, it is necessary to know both the incidence and growth rate of naturally-occurring tumors and experimentally-induced tumors at various organ sites in the sex and strain of animal used in order to determine the optimal time for termination. This information is ordinarily not available until the end of the test and while serial sacrifices are useful, they are considered too expensive for routine testing of chemicals.

6. Data collection and reporting. Animals should be checked carefully at least twice each day. Observations should be sufficient to detect onset and progression of all toxic effects, as well as to minimize loss due to diseases, autolysis, or cannibalism. Body weights should be recorded individually for all animals once a week during the first 13 weeks of the test period and at least once every 4 weeks thereafter. Loss of body weight should trigger careful clinical examination of the animal and its sacrifice, if necessary. Food intake should be determined weekly during the first 13 weeks of the study and then at approximately monthly intervals, unless health status or body weight changes dictate otherwise (*12*).

Clinical signs and mortality should be recorded for all animals. Special attention must be paid to clearly visible tumor development; the time of onset, location, dimensions, appearance and progression of each grossly visible or palpable tumor should be recorded.

The pathological examination, macroscopic, as well as microscopic, is the cornerstone of the carcinogenicity study. A thorough gross necropsy with subsequent selection of appropriate lesions for histopathology is mandatory. It is vital that the sampling among the test and control tissues be uniform so that no bias is introduced into the comparisons. Microscopic examination of both test and control tissues is required. While an all-inclusive microscopic examination of all tissues is theoretically desirable, the resource limitations may dictate a more selective approach such as the one recently proposed by the National Toxicology Program or earlier by the National Cancer Institute (*35,36*). The quality, extent and completeness of the documentary record of the bioassay are of critical importance in establishing its validity for scientific and regulatory purposes. It is crucial that the physical evidence, *e.g.*, the original tissue-sections and slides, is accurately prepared and maintained. Sponsors of bioassays that are to be submitted to regulatory agencies should be familiar with additional requirements of GLP's (Good Laboratory Practice)(*24*).

II. INTERPRETATION AND EVALUATION OF LONG-TERM CARCINOGEN BIOASSAYS

A. Background

Several attempts have been made over the last 10 years to construct a suitable operational definition for a chemical carcinogen (*6, 7, 10, 11, 37, 38*). Though none of these have succeeded fully, there is common agreement that a chemical carcinogen is a substance which induces cancer by some chemical/biological mechanism. A chemical carcinogen may be a substance which either significantly increases the incidence of cancer in animals or humans or significantly decreases the time it takes a naturally-occuring (spontaneous) tumor to develop relative to an appropriate background or control group. Either phenomenon is said to represent the effects of a carcinogen (*10*).

Just as there were no standardized or uniform protocols for testing chemical carcinogens during the early developmental period of the field, there are now no universally agreed upon ways of interpreting carcinogenicity data. In past years, a substance was not labeled a carcinogen unless the evidence was quite substantial. Usually, the identified carcinogen was used as a research tool to study the process of carcinogenesis, so that many experiments were performed with the compound. This intense study usually dispelled any doubt as to whether the substance was actually a carcinogen. This degree of confirmation gradually decreased as more of the experimentation turned from research on the process of carcinogenesis to detecting as many chemicals as possible that might pose a cancer risk to humans. For this latter purpose, which began in earnest in the mid 1960s with the "screening" bioassays conducted by NCI, it was necessary to devise "decision rules" by which to declare a chemical a carcinogen (*3*). Experience has taught that these should be regarded as general guidelines in evaluating carcinogenicity data and that final decisions are best made after careful communication between pathologists, toxicologists and statisticians. Most useful to the process is the experience and the data derived from large numbers of recent tests using a uniform protocol.

With some oversimplification, the task of the pathologist and toxicologist is to decide whether a lesion is cancerous or pre-cancerous and whether it is related to exposure to the test chemical. The statistician, on the other hand, has the task of calculating the mathematical probability of whether the tumors occurred by chance or as a result of treatment. Neither of these tasks is simple or completely independent of the other and, most importantly, each requires experience and judgment if sensible decisions are to be made.

B. Toxicological Issues in Bioassay Evaluation

1. Use of the maximum tolerated dose (MTD). Largest doses (*i.e.* doses far exceeding human exposure levels) have been strongly recommended by several national and international bodies in order to overcome the inherent low sensitivity of bioassays (*11, 12, 38*). These recommendations have been controversial because high doses may themselves produce altered physiologic conditions which can qualitatively affect the induction of malignant tumors. Normal physiology, homeostasis and detoxification or repair mechanisms may be overwhelmed and cancer, which otherwise might not have occurred, is induced or promoted. If qualitatively different distribution, detoxification or elimination of the test chemical is produced at the highest dose, a toxic response at this dose may not be indicative of effects at low exposure levels. The cancers which arise from high doses of corticosteroids, estrogens, certain sulfonamide compounds and from some instances of bladder implantation may result from such "secondary" effects (*39*, and see Chapter 1). This concern is not easily resolved, for if the dose is not high enough, carcinogens may remain undetected by traditional bioassays.

The concept and operational definition of the MTD have undergone modification during the last several years in response to some of these concerns. The 1971 FDA Advisory Committee on Protocols recommended that: "*Testing should be done at doses and under experimental conditions likely to yield maximum tumor incidence*"(*6*). However, as the use of these tests for human risk assessment increased, it became vital not only to detect carcinogens qualitatively (*i.e.*, avoid false negatives), but also to estimate effects at low dose levels. both the National Cancer Advisory Board Subcommittee (NCAB) (1977) and the Interagency Regulatory Liason Group (IRLG) (1979) (*11*) cautioned against the use of a dose so high that it produced "*unwanted toxic side effects*" (IRLG) or "*unphysiologic conditions [which] may in themselves enhance tumor formation*" (NCAB). Recent publications have emphasized the need to select the doses not only on the basis of the results of subchronic toxicity studies, but also on the basis of what is known about the pharmacokinetics and metabolism of the test substance (*10, 26*). Better techniques to observe and detect significant differences in metabolism and pharmacokinetics thoughout the dose range used are being developed; these should help in a better determination of the MTD (*27, 33*). There should be a reasonable scientific certainty that the dose used meets the objectives of maximally enhancing the sensitivity of the test without introducing qualitative distortions in the results.

2. Promoters vs. Initialors, current experimental status. In Chapter 1 of this report, the evidence for the belief that cancer occurs through at least a two stage process consisting of initiation and promotion was discussed. The basic question of whether tumor promotion in a general feature of carcinogenesis or is only characteristic of some organ systems is still debatable, although more and more evidence for the initiation-promotion process in a variety of organs is becoming available (*40* and Chapter 1.) The question naturally arises as to whether such promoting agents can reliably be distinquished from initiators by traditional bioassays.

While a number of examples of promoting agents are well documented; most of the work on their mechanism has been done on skin, *e.g.*, the phorbol esters in epidermal carcinogenesis.

Other examples are butylated hydroxyanisole in pulmonary carcinogenesis, phenobarbital in hepatocarcinogenesis and estrogenic hormones in breast cancer. Some know promoting agents also have weak tumorigenic activity and some are also initiators, *i.e.* complete carcinogens. Carcinogens may act as promoters at some tissue sites and initiators at others. It is very difficult both in principle and in practice to confirm the claim that a given chemical acts by promotion alone. If such a mechanism is postulated for a specific chemical, data on the purported mechanism at the affected tissue sites and dose response data would be needed.

3. Need for bilogical significance, other data. There is no simple or general solution to the problems which arise when attempting to interpret carcinogenicity data. Over recent years, review groups charged with the responsibility to evaluate carcinogenicty data and come to some decision regarding the carcinogenicity of the chemical have recognized the need to consider all of the available information which may bear on such a decision (*5, 6, 8–10*). Such information includes historical data on control animals, information from *in vitro* mutagenicity or neoplastic transformation systems, toxicological information which might indicate that the organ or tissue which is at risk for carcinogenicity appears to be a target for the toxicity of the compound and any other relevant information. Mutagenicity, DNA repair and neoplastic transformation studies can sometimes be used in aiding judgments on carcinogens (*41*). For example, if the data indicating carcinogenicity are of only marginal significance, negative findings in properly designed and well-conducted *in vitro* tests, depending upon their relevance to the specific situation, may lead to a conclusion that the chemeical is probably not carcinogenic. On the other hand, were the results from *in vitro* testing clearly positive, and if evidence existed to show that the organ in which the cancer question arose was also the toxicological target of the chemical, the conclusion is likely to be that the chemical is carcinogenic. To make these judgements, it is important that there be a good interaction and deliberation among scientists from different disciplines.

C. Issues of Pathology in the Interpretation of Tumor Data

1. Tumor number, type and site in the assessment of incidence. As mentioned earlier, a carcinogen may be defined as a substance which increases the incidence of cancer above the spontaneous backgroung rate Section II, Part A). However, from a partical, point of view, the most important question is: How does one estimate or deduce cancer incidence from tumor data? For instance, should all cancers in the animal be combined and the total number of tumors in treatment groups compared to total cancers in the untreated controls? Alternatively, should carcinomas be separated from sarcomas since they are derived from different tissue? Should the comparisons between treated and controls be restricted to specific organ sites and, if so, should all tumors be conbined, or only certain types? Other questions are: Should benign and malignant tumors be separated or combined; if tumors occur at miltiple organ sites, can they be combined and how should it be done; should cancers which shorten the life of the animal be separated from those which do not? The questions and many more must be answered before cancer incidence(s) can be estimated. Unfortunately, there is no universal agreement among experts in the field relevant to the rules for calculating cancer incidence that is applicable to "all" carcinogens "all" of the time. Generally, most experts agree that the incidence of total tumors at all organ sites is not a very useful expression of cancer incidence, nor in the calculation of the incidence of total benign or total malignant tumors. Most useful appears to be the number of histologically unique tumors at specific organ sites (*42*).

The grouping of lesions for evaluation should be based on commonality of histogenetic origin. Therefore, sarcomas should not be combined with carcinomas for the purpose of establishing a value for the incidence of cancer at a specific organ site. It is often necessary, at least in the judgment of many pathologists, to combine certain benign tumors with malignant ones occurring in the same tissue and at the same organ site. This practice can make the total neoplastic response (benign and malignant) clearly significant despite the lack of statistical significance in the tumors diagnosed as malignant. These pathologists believe that truly benign tumors in rodents are rare and that most tumors diagnosed as benign really represent a stage in the progression to malignancy. For some tissue sites, this view is widely accepted. Examples of this are adenomas versus adenocarcinomas in the pituitary, thyroid, lung, kidney tubules, and according to some experts, in mouse liver. In each of these cases, it is argued that the judgment of the pathologist as to whether the lesion is an adenoma or an adenocarcinoma is so subjective that it is essential they be combined for statistical purposes. It is also argued, in these specific cases, that the adenoma is a precursor of the adenocarcinoma. Indeed, the Subcommittee on Environmental Carcinogenesis of the National Cancer Advisory Board recommended in 1976 that these lesions be combined for statistical purposes (*38*). Most U.S. regulatory agencies have followed this recommendation. Ordinarily the tumor or cancer incidence is calculated as the number of tumor-bearing animals having tumors at a specific organ site divided by the total number of animals that survived long enough on experiment to have been at risk for that specific type of tumor. For reasons discussed in the statistical part of this section, life shortening tumors should not be combined with non-life shortening tumors.

2. Time to tumor. A positive result in a carcinogenesis bioassay can be based on evidence of a substantially decreased latency period, as well as on the induction of an increased incidence of malignant tumors. A good discussion of the precautions that should be observed in order to establish decreased latency is given in the 1979 IRLG report (*11*). Such data, in conjunction with incidence data, can be useful to distinguish between the relative potencies of carcinogens.

3. Problems in tumor diagnosis. A major problem facing those who must make either scientific or public health policy decisions based on carcinogenicity data is that the diagnosis of pathological lesions is subjective and pathologists may disagree on diagnosis. Frequently, the disagreement is not as serious or far ranging as it may appear to nonpathologists. The disagreement may be focused on an issue where neither pathologist is absolutely certain and each is forced to offer his "best opinion." In practice, for most compounds, NCI and NTP have used panels composed of 2 to 4 pathologists to review and analyze the lesions that have been observed (*35, 42*). This procedure helps to provide consistency in diagnosis, but it may not solve all the problems. For instance, most pathologists do not review the microslides "blind." They know which slides come from control animals and which from treated animals. The extent to which this information leads to bias in diagnosis is not known (*35*).

A common problem with the interpretation of pathological data

concerns the selection of the tissues at necropsy, how the tissues were prepared, the slides mounted and so on. For instance, a few years ago most investigators did not open the skulls and carefully examine the brain. In other cases, only brains appearing abnormal were examined in detail. Currently, the brain as well as other tissues such as nasal turbinates are routinely examined histologically (*34, 42*), though the techniques vary somewhat. As a consequence, spontaneous tumors of these tissues are not being reported. Depending upon how extensively these tissues are being sectioned for histological analysis the observed incidence may vary from low to moderately high. Such modifications in the pathology protocol, if not recognized and understood, could lead to serious errors in judgment concerning the carcinogenicity of a chemical.

Critical to decisions about carcinogens is the biological significance and human relevance of certain types of tumors, particularly the liver tumors in the mouse. This matter has been the subject of heated debate for the past 15 years. Some scientists are certain that the mouse liver is overly sensitive and will respond to almost any toxic insult by developing cancer. Other scientists are just as certain that the mouse liver is a reliable indicator of carcinogenicity and as good a predictor of potential human risk as any indicator available. In one review, 61 of 85 chemicals (73%) that increased the incidence of liver tumors in mice also induced tumors in other tissues of mice and/or in rats (*20*). Some toxicologists believe that part of the problem stems from work on C3H strains of mice where the background liver tumor incidence is high and false positive errors are possible. (See below Sec. D.) Generally, there is consensus that the mouse liver model in principle does have significance in terms of human risk, but unambiguous diagnosis between "benign" or "hyperplastic" liver nodules and malignant neoplasia remains elusive and there is no apparent scientific consensus.

In addition to liver tumors, other tumors, including lymphomas in the mouse, which appear to be of viral origin, have been questioned as to their relevance to human cancer. As a general matter, toxicologists must question the relevance to humans of any experimental tumor which has a known viral background where the virus may be unique to the animal. This includes a variety of lymphomas and sarcomas in rats and mice, as well as mammary tumors in the mouse. Likewise, the relevance to human exposures of the induction of bladder cancer in rodents which are shown to have bladder stones and crystaluria only at high doses of the test substance is questionable.

D. Evaluation of Statistical Significance

1. Statistical tests and procedures. For the analysis of tumor incidence data, a widely-used method for comparing experimental and control groups is Fisher's exact test (*43*). This analysis is generally carried out in conjunction with a Cochran-Armitage trend test (*44, 45*) which examines the relationship between tumor incidence and dose. The trend test has the advantage of utilizing cancer incidence data for all doses and as a result is somewhat more sensitive than pairwise comparisons to the detection of carcinogenic effects.

The statistical procedures mentioned above for the analysis of tumor incidence data do not take survival differences into account (*15*). This can be a problem with chemicals that produce a life-shortening effect. Although "survival-adjusted" tumor incidence analyses (*15, 46, 47*) are more complex, they have the advantage of adjusting for intercurrent mortality and of being sensitive to shortened latency period as well as to increased tumor incidence. These procedures require the determination of whether tumors in individual animals are "lethal" or "incidental" with respect to the underlying cause of death. This determination may be difficult if not impossible to make for many animals, but experimentalists should try to distinguish in their records between lethal and incidental tumors.

While it is customary practice in the conduct of bioassays to regard an increased tumor incidence that is statistically significant (*e.g.*, $p < 0.05$) as reasonable assurance that the effect is real and not due to chance alone, the final judgment regarding a compound's carcinogenicity is rarely based on a single finding of statistical significance (*47*). One must be assured that the effects observed are biologically significant as well. Other factors that must be taken into account include: (1) The reproducibility of the effect in other doses and/or in other sexes or species; (2) the historical incidence of the tumor in question; (3) the survival histories of dosed and control animals; and (4) evidence of hyperplasia, metaplasia or other signs of an ongoing carcinogenic process.

The 0.05 p-value is a reasonable statistical benchmark with a history of use in the bioassay field. It would be imprudent to disregard it as an index of significance without good reason. It would be equally unwise to regard it as an absolute requirement or a *sine qua non* without considering the weight of biological evidence. For example, doubling or tripling the incidence of a tumor that occurs at low incidence in the controls may not be statistically significant, but may indicate a biological effect that should not be dismissed. Similarly, the finding of nominal statistical significance ($p = 0.05$) at a single tumor site may be less important to the final evaluation than knowledge of the target site and the lack of consistency with related biological findings. As stated by IARC (*15*):

> The p-value from a good experiment is an objective fact, subject to public agreement. The weight to be given it and to the available pieces of information is not.

2. Problem of False Positives and False Negatives. Because of the time and expense involved, most chemicals, if tested at all, are tested in only one bioassay. It is vital that this test have good sensitivity since otherwise many true carcinogens would remain undetected (a false negative). The test must also possess a high degree of *specificity* since there are economic losses as well as disincentives for testing if safe, useful substances are mistakenly declared carcinogens (a false positive).

a. False Negatives

The typical bioassay, due to inherent limitations (low number of animals and biological variation) cannot reliably detect an increased tumor incidence of much less than 10–15%. High test doses are one way around this limitation, but as discussed above (Sec. II, Part B, 1), this can introduce confounding factors if the dose is to high. In addition, the possibility always exists that for a specific substance, the most sensitive species may be inappropriate for qualitative extrapolation to humans. Until more is known concerning the mechanism of cancer and the similarity in response between man and animal, this uncertainty will persist.

Confidence in an apparently negative bioassay increases with: (1) The number of animals used; (2) the extent to which its duration approaches the animals' expected lifetime; and (3) the adequacy of the gross and histological examination of both control and treated groups. Corroborative evidence such as experimentally consistent biological results in different species or sexes, or at different doses, strengthens the likelihood that the bioassay is correctly interpreted. Rigid rules or definitions are not very useful. The ultimate decisions

must be based on the knowledge of experienced pathologists and toxicologists, the weight of corroborative evidence and a careful statistical evaluation.

The spontaneous tumor incidence can be of considerable importance in the interpretation of results from carcinogenicity studies. If, for example, the effect of a chemical is to double or triple the background tumor incidence, tissue sites with low spontaneous tumor rates are more likely to yield false-negative results than are sites with high spontaneous tumor rates. For example, if a tumor is a rare tumor even a slight increase in incidence may be biologically significant and may be considered adequate evidence of carcinogenicity (*43*). This factor must be taken into account in the overall evaluation of the data. For such tumors (*e.g.* with spontaneous tumor rates of 1% or less), the utilization of historical control data may be particularly useful in increasing the sensitivity of the study for detecting carcinogenic effects. All recent work emphasizes the fact that the evaluation of the bioassay is not a simple nor routine statistical exercise, but a multidisciplinary process requiring the interaction of toxicologist, pathologist and statistician.

b. False Positives.

Appropriate precautions in the design and evaluation of bioassays can minimize the chance of false positive results. The test substance must be free of carcinogenic contaminants and appropriate doses and routes of exposure must be used. However careful attention to these and to other factors cannot eliminate entirely the possibility of either false positive or false negative results. These problems are fundamental to the proces of drawing inferences from observed sample data.

Many investigators familiar with data from bioassays believe that in practice the overall false positive rate does not greatly exceed 0.05 (*43,44*). Others are not as certain, and all admit that this is an important problem area that must be considered in the interpretation of carcinogenesis bioassay data. The very effort to be as thorough and as complete as possible in the selection of tissue at necropsy, and in the detection of responses from various doses, increases the chance for a false positive error. Typical bioassay protocols require sectioning and analysis of tissues from 20–30 sites in two species, in two sexes, and, at the least, two dosage levels. It has been suggested that the multiple tests for significance applied to these many sites produce an unacceptability high overall false positive rate. (The argument is that if 'n' independent tests are concluded at the 'a' significance level, the probability of finding a significance somewhere [the false positive rate] is $[1-(1-a)^n]$. For $n=20$ and $p=0.05$ for a single dose-sex comparison, this probability is about 0.64.)

However, recent investigators have shown that this argument overestimates the likely false positive rate of the bioassay. Gart, *et al.* (*43*), using historical incidence rates for B6C3F1 mice, found the probability of at least one significant result at the 0.05 level at some site in at least one sex was only about 8%. In a commonly used strain of rat (F–344) the same probability was approximately 21%. These findings are will below the 64% value cited above. One reason for this difference is that tumor incidences are discrete court data, and in this situation, the actual significance level of test procedures comparing tumor rates is always less than the nominal level, often considerably less.

This is particularly true for tumors having a low spontaneous incidence. Even the estimated false positive rates reported by Gart, *et al.* (*43*) may be too high, since (as noted earlier) the final judgment that a compound is carcinogenic is rarely based on a single isolated "significant" increase in tumor incidence. Generally more stringent evidence is required, such as the reproducibility of the effect in other doses and/or other sexes or species. For example, if a chemical is judged carcinogenic only if it is positive ($p<0.05$) at some tissue site for *both* the low and high doses, the overall false positive rate for a two sex, two species experiment has been estimated to be 5.1% (*49*).

In a recent examination of 25 NTP feeding studies, a simple statistical rule was derived by Hasemen (*48*) which appears to mimic closely the scientific judgment process used in these experiments. This "rule" was as follows: Regard as carcinogenic any chemical that produces a high-dose increase in a common tumor that is statistically significant at the 0.01 level or a high-dose increase in an uncommon tumor that is statistically significant at the 0.05 level. The overall false positive rate associated with this particular decision rule (which appears to approximate closely the overall evaluation process) was estimated by Haseman and found to be no more than 7–8% for the current NIP two-sex, two-species protocol (*50*).

In summary, in the interpretation of tumor incidence data an investigator should be aware of the false positive issue. In the overall evaluation process, one should be guided by (but not rely exclusively upon) the statistical significance of an observed tumor increase. This awareness will help minimize the likelihood of a false positive result.

3. Use of historical controls. It is extremely important for the interpretation of a bioassay that the variability of the incidence of spontaneous tumors in the strain of animals used be established with the highest precision possible. These variations present problems in interpreting the results of bioassays. NTP has recognized this problem and has continued to accumulate data from untreated and corn-oil gavage control groups for the strains of animals used (*19*). With such data, the toxicologist may conclude that a study yielding statistical significance is not biologically significant or conversely that an effect is real, even though there is no "significant" difference between test and concurrent controls. Of 27 bioassay study reports issued by the NCI from 1978–1980, historical controls were used in 14 studies to show that an apparent increase of a specific tumor was not related to treatment (*50*). In 13 studies, the use of historical controls showed that an increase in tumors was related to treatment. Historical control data can be valuable when used appropriately, especially when the differences in incidence rates between treated and concurrent negative controls are small and can be shown to be within the anticipated historical incidence. However, the use of historical control data is not without its own problems. Over the course of time, the thoroughness of pathologic evaluations has improved and pathologic diagnosis has evolved and nomenclature has changed. There is also the possibility that the genetic susceptibility of the strain has shifted. The sources of variability in historical control data should be identified and, if possible, controlled. Obviously one has more confidence in the most recent historical control data from the same laboratory conducting the current study than in a compilation of pooled older data from other laboratories. Several procedures have recently been proposed for utilizing historical control data in a formal testing framework (*51–53*). The relative merits of these methodologies are currently being investigated by the NTP.

III. SUMMARY

Although the identification of carcinogenic substances has long been

of interest to the scientific community, until the 1960's the focus of most studies was research, not testing for substances which may pose a public hazard. The National Cancer Institute, and later the National Toxicology Program, have conducted a number of test-oriented studies, the chronic bioassays, and have also attempted to standardized many important parameters in conducting these studies. Type and number of animals, dose level and route, and study duration are fairly uniform in an effort to make the data base as comparable as possible from test to test.

Certain issues remain as problems. One of these is the use of the maximum tolerated dose (MTD) in long-term studies and the appropriateness of dose route, schedule, and length of exposure. Use of the MTD, if not an ideal solution to the problem of bioassay sensitivity, is appropriate if it is properly determined. Another problem is the interpretation of tumor data. This includes tumor number, type, time to tumor, tumor diagnosis, etc. and the significance of certain tumors. Certain guidelines have been recommended, with the proviso that they are to be used in conjunction with sound judgment.

Furthermore, although several methods of statistical analyses of long-term test results have been developed, the questions of false negatives and false positives and the use of historical controls, suggest that the evaluation of a long-term test is not a routine statistical exercise, but is instead a multidisciplinary process requiring the interaction of toxicologist, pathologist, and statistician. The utilization of long-term animal studies for quantitative human risk assessment has accentuated and focused attention on the real scientific uncertainties involved in high-to-low dose and animal-to-human cancer risk extrapolations. Nonetheless such animal studies, with all their limitations, remain the best way of predicting effects in humans when epidemiological data is unavailable.

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Chapter 4—Current Views on Epidemiological Methods

I. INTRODUCTION

Epidemiology is generally defined as the study of the distribution and determinants of disease in human populations, and thus it involves two major approaches (*1*). Descriptive studies examine the "distribution" of disease and are usually employed to generate etiological hypotheses, while analyticl studies are used mainly to test hypotheses and identify the "determinants" of disease. A primary objective of epidemiology is to identify and quantify relationships between exposure to chemicals and deleterious health effects. The associations may lead to causal inferences (*2*), which in turn provide the basis for instituting preventive measures for various diseases.

II. STRENGTHS AND LIMITATIONS OF EPIDEMIOLOGY

A. Strengths

In contracts to studies in other biological systems, epidemiology directly evaluates the experience of human populations and their response (risk of disease) to various environmental exposures and host factors. Thus, it if often possible to evaluate the consequences of an environmental exposure in the precise manner in which it occurs and will continue to occur in human populations. This include such important considerations as dose, route of exposure and concomitent exposures to other exogenous and endogenous factors. Through epidemiological studies human cancer has been linked to a number of lifestyle and other environmental hazards, including tobacco products and alcohol, ultraviolet and ionizing radiation, certain occupational and medicinal chemicals, dietary factors, and some infectious agents (*3–5*). Epidemiology has played a central role in detecting carcinogenic exposures, and it has complemented studies in laboratory animals in clarifying the carcinogenic potential of specific agents (*61*). Another strength of the epidemiologic approach is its ability to provide insights into the mechanisms of huma carcinogenesis. Thus, epidemiological observations have complemented experimental evidence that carcinogenesis is a multi-stage process, and that many cancers may result from the cumulative effect of environmental factors and host susceptibility states that accelerate the transition rates at various stages of carcinogenesis (*7*).

B. Limitations

Although epidemiology is the only means of assessing directly the carcinogenic risks of environmental agents in humans, the method has several limitations that are difficult to overcome (*1, 8*). One problem is that evidence of an environmental hazard is usually obtained from persons with high or intermediate levels of exposure. Just as for studies in laboratory animals, detecting causal relationship at low exposure levels is difficult in epidemiology, since the observed associations with disease are usually less pronounced and may have alternative explanations, including those related to chance, errors, biases or confounding variables. To provide a valid basis for risk estimates, large numbers of human subjects are often needed, especially if the exposure is low or rare, or if the excess risk is small compared to that ot the baseline incidence rate. Another obstacle to epidemiology is the long latency period between exposure and the development of cancer. This complicates the detection of relationship and, of course, makes it impossible to identify the carcinogenic risks to humans of agents newly introduced into the environment. Another common problem in epidemology it that of exposure assessment. Often the specific exposure of interest cannot be measured directly so that surrogate measures must be used (*e.g.* occupation, place of residence). Since exposure data are usually derived from historical records generated for other purposes or from the recollections of subjects, opportunities for either random or biased misclassification of exposure are frequently encountered. In addition, appropriate study groups are often simply unavailable or inaccessible. Furthermore, it may be difficult to implicate specific carcinogens when environmental hazards involve complex exposures to a variety of agents, the effects of which are to difficult to disentangle. Still another difficulty is the inability of epidemiological studies to adjust for unknown risk factors, since control can be introduced only when the risk factors are already recognized. Thus, when a particular factor is related to exposure and disease outcome, it may be confounding and give the appearance of an association when in fact none exists, or it may inflate or decrease the magnitude of an association. In view of these difficulties, it is not surprising that epidemiological data exist for only a small proportion of the many chemicals that have been shown to be carcinogenic in laboratory animals.

III. DETERMINING CAUSALITY

In interpreting epidemiological findings, one is guided by the magnitude of the risk estimates, their statistical significance (likelihood of being due to chance), and the rigor of the study design to avoid various kinds of bias, including those related to selection, confounding, classification, and measurement (*2, 9*). A determination of causality in epidemiology is bolstered by dose-response relationships, the consistency and reproducibility of results, the strength and specificity of the association, its biological plausibility, and other considerations. Thus inferences from epidemiology are not made in isolation, but should take into account all relevant biological information. Although epidemiological and other observations can accumulate to the point that a causal hypothesis is

likely, it is not possible to ever prove causality (in the strict sense, a hypothesis can only be disproven). Nevertheless, a causal can be sufficently probable, as in the case of cigarette smoking and lung cancer, to provide a reasonable and even compelling basis for preventive and public health action.

IV. EPIDEMIOLOGICAL STUDIES

A. Descriptive and Correlational Studies

Descriptive (or demographic) studies are concerned with identifying the distribution or patterns of disease in populations (*1*). It is a basic tenet of epidemiology that diseases, including cancer, do not occur randomly, but fluctuate according to factors such as age, sex, race, time and geographical location. The use of rates as measures of diseasa frequency is fundamental in describing patterns of cancer among these population groups. Prevalence, incidence and mortality rates of cancer define the levels of risk prevailing in different populations and permit comparisons between groups. Descriptive surveys of cancer occurrence have been valuable in formulating etiological hypotheses and providing direction for analytical studies, which are then necessary to establish whether risks are associated with particular exposures (*10*). Thus, improtant leads to etiology have come from population-based cancer surveys, have revealed substantial international variations in cancer incidence, shifts in risk among migrant populations, changes in risk over time, and geographical peculiarities from mapping cancer morality at the county level (*4*).

Descriptive studies may utilize the correlational (or ecological) approach, in which the rate of disease in a popluation is compared with the spatial or temporal distribution of suspected risk factors (*10*). This type of study may be particularly helpful in developing or refining hypotheses about carcinogenic risks, but falls, short of establishing causal relationships. Correlational studies have the advantage of being much less expensive and time-consuming than analytical studies, because they often utilize mass statistics previously collected for another purpose (*9*). The primary weakness of such studies, as with descriptive studies generally, is that data are collected on populations, rather than individuals. In other words, the rate of disease and the prevalence of exposures to variables of interest are known for various population groups, but information on the exposure status of persons, who have the disease and those within each population is not known. Thus, one cannot infer from the correlations of the population levels that the exposure of concern is associated with the risk of developing disease within each population (*9*). For example, in early surveys of lung cancer, the international variation in mortality rates and temporal increases among males appeared consistent with the reported patterns of cigarette smoking, but these correlations by themselves may have been circumstantial rather than causal, since a variety of other exposures (e.g., occupational hazards, air pollution) also varied concomitantly with the patterns of lung cancer. It took the analytical studies that pursued these tests to establish cause-and-effect relationships between smoking and lung cancer. Correlational studies also may provide supporting evidence in evaluating relationships detected by analytical studies. This is illustrated by the more recent temporal increases in lung cancer among females, who have lagged about 20 years behind males in their adoption of smoking habits. Another example is the temporal variation in endometrial cancer incidence, showing a rise and fall in rates asociated with the usage of estrogenic drugs for menopausal symptoms (*11*). Because correlational studies deal with aggregate exposures and disease occurrence at the population level, they are often seriously limited by the imprecise measurements of exposure and the many potentially confounding variables. However, occasionally the correlational approach may provide evidence that strongly suggests a practical causal relationship, as with aflatoxin, which has been linked to primary liver cancer based on concomitant geographical variation with the intake of contaminated foodstuffs.

B. Analytical Studies

In order to test etiological hypotheses and to identify and quantify carcinogenic risks to man, it is necessary to conduct analytical epidemiological studies (*9–10*). These studies are the principal means for determining the human health hazards of specific environmental exposures and agents. In contrast to descriptive surveys, data are obtained on disease occurrence and putative risk factors for specific individuals, using mainly the case-control or cohort method. Thus, by grouping exposed individuals and comparing them to those unexposed, after controlling for all other relevant variables, the risk of disease associated with exposure can be estimated. While it is important not to impose unnecessary constraints on epidemiological investigation, there are some methodological guidelines to consider in designing a study. In particular, the study groups should be sufficiently large, and the time intervals between initial exposure and tumor onset sufficiently long, to identify the lowest excess risk considered important to detect. Reliable and valid estimates of exposure should be sought, with quantitative measurements to permit dose-response evaluations. Studies should be designed in a manner that minimizes potential sources of bias, and permits detection and control of confounding variables. Because the putative exposure may act either at an early stage or at a late stage of carcinogenesis (or both), it is possible to provide insight into the mechanisms of action by examining risk in relation to several temporal aspects of exposure. The studies should also strive to identify interactions of particular exposure with other risk factors that may contribute to the carcinogenic process.

Analytical epidemiological investigations are essential to achieve a better understanding of the causes and means of preventing cancer. These studies cover a broad range of exposures with special relevence to public policy. Occupational studies have been a time-tested means of identifying carcinogens, but they require further emphasis to assess industrial hazards suspected on the basis of experimental, clinical, and field observations. Radiation studies also need increased emphasis to clarify the effects of low-level exposure and the shape of the dose-response curve. Drug studies have been useful both for direct evidence of risk associated with taking certain medications and also for insights into mechanisms of human carcinogenesis. They require an expanded effort to evaluate the late effects of estrogenic compounds, immunosuppressive and cytotoxic agents, and other medications suspected of having carcinogenic activity. Because of increasing clues about nutritional risk factors, emphasis is needed to clarify the role of dietary components including fat, fiber, micronutrients, trace elements, and food additives as well as cooking practices. The influence of general environmental pollutants remains an epidemiological challenge and requires more intensive evaluation through analytical studies, some of which may integrate appropriate environmental and body-burden measurements. Finally, multidisciplinary projects combining epidemiologic and experimental approaches to chronic disease have recently gained impetus, and should be encouraged to evaluate the influence of

oncogenic viruses, dietary and metabolic factors, host susceptibility, general environmental pollution, and other causative factors that may continue to elude detection by traditional observational methods.

1. Case-control studies. These studies start by identifying persons with a particular disease (cases) and a group of similar persons without the disease (controls). Information of past exposure to known or suspected risk factors is then collected from interviews, questionnaires, medical records, occupational logs, or other sources. The frequency of a particular exposure among the cases is compared with that in the control group, after making appropriate adjustments for other relevant differences between the two groups. If the proportion of cases with a certain exposure is significantly greater than that of the controls, an association between exposure and disease may be indicated. The case-control approach is especially well-suited in studying relatively rare conditions, such as most cancers, where the putative exposure is common in the general population (*e.g.* menopausal estrogens and endometrial cancer), or when the exposure is rare but accounts for a large portion of a particular cancer (*e.g.* vinyl chloride and liver angiosarcoma) (*12*).

2. Cohort Studies. These start by identifying a group of individuals with a particular exposure and a similar group of unexposed persons and follow both groups over time to determine subsequent health outcomes. The rates of disease in the exposed and unexposed groups are then compared. Information on disease frequency and other factors may be identified from medical records, occupational records, physical examinations, interviews, questionnaires or death certificates. An association between exposure and disease may be indicated if the rates of disease are greater in the exposed group than in the unexposed group. These investigations may be based on current exposure and future health outcomes (prospective cohort study), but more commonly they utilize past exposure information and disease occurrence (retrospective cohort study). Instead of an unexposed comparison group, general population mortality or incidence rates (specific for age, sex, race, and calendar time) are often used to determine the expected number of cases of disease. This method assumes that in the absence of specific exposure the study group would have had the same probability of developing the disease as the general population, but differences in ethnic, socio-economic and other variables must be considered in evaluating the validity of this assumption. The cohort approach is used mainly when it is possible to evaluate heavy exposures in clearly defined subgroups of the population. Thus it has been especially helpful in assessing the carcinogenic risk from occupational hazards or medical exposures such as radiation and certain drugs.

The statistical measures of association most often used in analytical studies are the odds ratio and the relative risk. The odds ratio is usually associated with the case-control study and represents the odds or probability of disease occurrence in the exposed compared with unexposed individuals. An odds ratio of 1 indicates no association between exposure and disease, assuming that proper adjustments for confounding factors have been made. The relative risk is a measure of association in cohort studies and is defined as the ratio of the disease rate in the exposed group to that in the unexposed group. For this reason it is also known as the rate ratio, and it permits a direct estimate of the risk of disease associated with a particular exposure. When the disease is rare, when incident cases are collected, and when cases and controls are representative of the same populations, the odds ratio is a good estimate of the relative risk (*12*). The magnitude of the odds ratio or relative risk is a measure of the strength of an association, although they are both subject to unknown or unmeasured biases which may distort their true value. Another term often used in epidemiology is the population attributable risk or etiologic fraction which is the absolute amount of disease contributed or caused by a specific exposure.

Both the case-control and cohort methods are characterized as having certain strengths and weaknesses, although they complement each other in the testing of specific etiological hypotheses. Case-control studies provide a more efficient means of studying rare diseases, with fewer individuals needed for study as compared with the cohort approach; a shorter time period for study completion and generally lower costs as compared with the cohort method; an opportunity to evaluate simultaneously several causal hypotheses as well as interactions (the extent and manner in which two or more risk factors modify the strength of one another); and a capacity to evaluate the effects of common exposures as well as those rare exposures which may account for a large proportion of the cases. On the other hand, the case-control approach has some problems in directly estimating the risk associated with a particular exposure, except in special circumstances noted above; in reducing certain biases (*e.g.* selection, historical recall) that affect the comparability of cases and controls; and in providing detailed and precise information on exposures occurring in the past (*1*). Such investigations also, by definition, can only evaluate one disease or outcome at a time.

The advantages of cohort studies are their capacity to estimate directly the risks attributed to a particular exposure, since incidence or mortality from disease is actually being measured; to reduce subjective biases by obtaining information before the disease develops; to determine associations between a particular exposure and multiple health outcomes; and to evaluate temporal relationships such as latency period and duration of effect. However, cohort studies are usually expensive and complex untertakings. They require large numbers of exposed individuals, particularly when relatively rare events such as most cancers are being investigated; long periods of follow-up to accomodate the latency period for chronic diseases such as cancer; and special handling of problems associated with persons lost to follow-up and with biased estimates of risk as from the "healthy worker effect" of occupational studies (*1*).

3. Intervention Studies. Also referred to as experimental studies (*7*), these represent a third strategy of analytical epidemiology, which is especially useful in confirming causal relationships suggested by case-control or cohort studies. This approach may be applied in programs designed, for example, to reduce cigarette smoking and alcohol intake, modify diet, control occupational pollutants, or evaluate candidate preventatives (*e.g.* vitamin A supplements, hepatitis-B vaccine). Ethical considerations are obviously critical when developing this approach, and after intervention the statistical procedures resemble those employed for cohort studies.

V. BIOCHEMICAL EPIDEMIOLOGY

It seems likely that some limitations of cancer epidemiology may be overcome by incorporating laboratory methods in analytical investigations. This has been a valuable routine practice in infectious disease epidemiology for the past century. This approach, sometimes called biochemical or molecular epidemiology (*13*), has only

recently developed in cancer epidemiology. There is current enthusiasm for these kinds of investigations, since they merge the strengths of observational human studies with newly developed experimental probes to derive information that could not be developed by epidemiology or laboratory study alone. The laboratory aspect may make it possible to define past exposures and subclinical or preclinical response to initiators, promoters, and inhibitors of carcinogenesis, or to evaluate host-environmental interactions. There is special interest at present in using this technique to clarify carcinogenic risks associated with nutritional influences or specific environmental agents that can be detected in tissues or body fluids. Opportunities are also available to assess specific host factors that influence susceptibility to carcinogenesis, including endocrine parameters, immunocompetence, and genetic markers. Techniques are being refined to detect and quantify particular carcinogens or their metabolites in tissues or body fluids through chemical analyses, mutagenesis assays or immunologic detection techniques. It is already possible to measure the interaction of specific agents with cellular target molecules, for example, through adduct formation with proteins and nucleic acids, excretion levels of excised adducts, or markers of altered gene expression (*13*). The task of identifying the effects of lifestyle and other environmental and host factors is obviously formidable. Biochemical epidemiology represents an innovative approach that may help to elucidate further the causes of cancer and the actual mechanisms of carcinogenesis.

IV. IMPLICATIONS OF NEGATIVE STUDIES

Epidemiological observations often provide regulatory agencies with health information which is helpful in establishing sound, defensible rules governing workplace exposures as well as exposure to general environmental contaminants. The clinical and laboratory observations, and subsequent epidemiological confirmation, linking hepatic angiosarcoma and exposure to vinyl chloride led directly to safeguarding of workers by regulatory limitation of permissible exposure levels. Although epidemiological studies can never "prove" the absence of an association, sufficiently large and well-controlled studies that fail to detect a hazard can also be useful. Specifically, for the types of populations studied, for the doses and duration of exposure to the putative agent, and for the assessed time following exposure, likely upper bounds on the estimates of risk can be made, as well as the statistical likelihood of the study to identify an effect. As an example, the results of a large collaborative study of bladder cancer and artificial sweeteners were interpreted as indicating that saccharin use was not a significant public health problem (*14*).

The likelihood of a study to identify an effect, if one is really present, is referred to as the statistical "power" of the study. Its estimation involves consideration of the size of the study group, the number of subjects exposed, and the level of excess risk which is considered important not to miss. With this information, the power of case-control and cohort studies can be calculated and thus some index of confidence can be attached to the observation of no association. The statistical power of "negative" investigations should be routinely considered when such studies are reviewed.

Regulatory agencies are often in the position of making decisions not simply on the effect of an exposure on the "average" exposed population, but on the effects among particularly susceptible subgroups of this population (*e.g.*, the concern over the acute effects of air pollution on infants, the very old, and the infirm). The risk of malignancy following exposure to a carcinogen is rarely uniform across all subpopulations but is routinely modified by genetic constitutions, demographic characteristics (*e.g.*, age, race, sex), and exposures to other substances. Such risk modifiers can act either to eenhance risk, such as the capacity of cigarette smoking to multiply the risk of lung cancer associated with asbestos exposure, or to reduce risk, such as the recently emerging evidence that certain dietary factors may inhibit the carcinogenic process. Epidemiological data are particularly, and often uniquely, relevant to these issues. Because of this, analyses of risk among subgroups of an exposed population are particularly germane to regulatory agencies. At the same time, these types of analyses are challenging to interpret, since variation between groups can easily occur due to chance or the differential operation of some type of bias.

Because of the central importance of epidemiology in cancer risk assessment, it is important to develop and strengthen programs of epidemiologic research, and to ensure the conduct of studies to measure health effects whenever relevant human exposure has occurred. Collaborative studies among Federal agencies and other groups are critically needed to evaluate urgent issues involving scientific, regulatory or public policy concerns, as well as to stimulate the epidemiological application of technical and data resources that are used by the government and other institutions for different purposes. Because of the international peculiarities in cancer occurrence, collaborative studies with investigators in other countries should also receive greater emphasis to pursue a wide variety of etiological leads. In addition, further statistical investigation is needed to develop and test multi-cause and multi-stage models of carcinogenesis, and to clarify the many issues involved in extrapolating results from experimental testing to the human experience.

VII. SUMMARY

Epidemiological investigations comprise one of the major strategies in creating the scientific base necessary for regulatory decision-making. Descriptive epidemiological studies, including ecological or correlational approaches are useful in generating and refining hypotheses about potential cancer risk factors. Well-designed, well-conducted, and well-evaluated analytical epidemiological studies of either the case-control or cohort variety can test such hypotheses and provide the basis for practical causal inferences that are especially useful for public health decisions. The strengths of these studies lie in their capacity to assess directly the carcinogenic risks of environmental agents in humans (often with the dose levels and manners of exposure that are most relevant) and in their ability to provide insights into mechanisms of human carcinogenesis that can assist in extrapolation of risk estimates to dose levels or similar agents not yet studied. The lack of evidence of a hazard from an epidemiological investigation can also be useful in that, within the scope of the study, likely upper bounds on the estimates of risk can be made, as well as an estimation of the statistical power of the study to have detected an effect, if one were really present. However, the epidemiological method is often hampered by the long latent period that exists between exposure to a carcinogenic agent and the development of cancer, by the inability to control for the confounding influences of unknown risk factors, by problems in assessing specific agents when the human exposures are to mixtures, by the frequent absence of appropriate groups

for study, and by a variety of difficulties associated with accurate and unbiased historical exposure assessment or disease ascertainment. In addition, the epidemiological method shares in the difficulties encountered by experimental studies in the direct detection of relatively low-level risks. In general, the strengths and weaknesses of the epidemiological method form a useful complement to the strengths and weaknesses of laboratory approaches to carcinogenesis. This, coupled with the direct assessments of risks and the results of interventions allowed by epidemiology, makes a strong argument for the conduct of epidemiological studies and inclusion of their results in regulatory decision-making, whenever relevant exposure has occurred in human populations.

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Chapter 5—Chemical Exposure Assessment

I. INTRODUCTION

For the purpose of this document, a chemical exposure assessment is that process which seeks to define the quantity of a chemical which comes into contact, or may come into contact, with human populations. This information then can be coupled with toxicity data to allow estimates of the potential risk from a carcinogen. Exposure assessments may also be used to identify and predict the effects of prospective control options or to measure the effectiveness of intervention activities designed to limit exposure. An assessment may address sources of human exposure, the intensity, routes and conditions of exposure, the frequency and duration of exposure, and the segments of population exposed. In certain simple situations an assessment may only need to consider well defined individual exposures that can be measured directly. In more complicated circumstances, broad systematic surveys and extensive mathematical computations may prove necessary (*1–3*). Exposure assessment is often the most resource demanding portion of the evaluations of chemical risks performed by the various Federal agencies.

Many authorities agree that the weakest link in our understanding of the environmental health studies is our knowledge of human exposure. (*4*)

The great diversity of different sources and routes of chemical exposure complicates a review of this area. In the Federal Government, the source of a specific chemical exposure has served as a guiding principle in defining the responsibilities of different regulatory agencies. Separate responsibilities exist for exposure to chemicals through the ambient environment (air, water, and waste sites), food, drugs, consumer products, and the workplace environment. In each area an array of specialized estimating techniques, data sources, and expertise have been developed. The hundreds of thousands of possible combinations of factors which might be included in a specific exposure assessment make it extremely unlikely that any two exposure assessments of the same chemical will be identical. Each Federal agency tends to focus on those aspects of exposure which are relevant to the laws which it administers (*5–25*). This chapter addresses some of the common considerations in methodology, as well as the broad issues and difficulties that are relevant to exposure assessments. Three appendices provide more detail on aspects of exposure assessments dealing with food, consumer products, and potential carcinogens in the environment.

Despite the overall grouping according to source of exposure, it is important to recognize that the path that a chemical follows from its source to the exposed target can be quite complex and may involve a number of different media. For example:

(a) Chemicals released into one medium (*e.g.*, the air) may later transfer to other media (*e.g.* soil or water);

(b) Low ambient levels of a compound may be magnified through bioaccumulation of the compound through the food chain;

(c) Chemicals may be degraded and new compounds formed during environmental transport and desposition;

(d) A chemical used in an article may be released into the environment years later when the article is disposed of as waste; and,

(3) Workers may carry a chemical home on their work clothing leading to a continuing exposure of their families.

II. METHODOLOGY OF EXPOSURE ASSESSMENT

There is a diversity of procedures for estimating exposure (*26*). Although exposure estimating techniques are becoming more sophisticated at this time there is no universally accepted minimum set of specifications for the reliable estimation of exposure (*27*). Exposure assessment is rapidly developing as a technical specialty, and even recent major reports on risk assessment only mention exposure briefly (*28–32*). There are, however, a number of general approaches discussed below which may be applicable to the conduct of most exposure assessments.

As a useful simplification, exposure assessment studies can be divided among those that rely more heavily on direct measurement of chemical exposure and those where exposure is predicted, or "modeled".

A. Monitoring Studies

The direct monitoring approach is exemplified by the development of practical personal monitors which measure directly concentrations of chemicals in the air which individuals breathe (*33, 34*). An exposure assessment can be based on the range of personal exposure data generated by these monitors when used with an appropriate study group. However, it should be noted that the detection limits attained by personal monitors may pose

limits in some studies and that most personal monitoring techniques currently provide information on average exposure but not on the time course or peak levels of exposure.

Monitoring of pollutants in the air and water has probably generated the greatest quantity of data among all exposure study approaches. Some examples of these type of studies include:

(a) Carbon monoxide exposure has been examined extensively using personal and population monitoring (*35–42*);

(b) Air pollution in the city of St. Louis was studied for several years (*43–44*), producing over one million data points per day during much of the program;

(c) The plum from a power plant (*45*), was studied intensively to define the transport and chemical transformation of the emissions from a single point source;

(d) Other techniques have been used to monitor emissions from entire cities to refine our understanding of the atmospheric transport of chemicals over large geographic distances (*46*);

(e) Significant monitoring studies have also been conducted for a wide range of organic and inorganic compounds in marine, freshwater, and surface environments (*47–60*);

(f) Extensive studies have been conducted to determine the levels of bioaccumulated pesticides and other chlorinated compounds in edible fish and shellfish.

In the workplace monitoring is the principle methodology for determining the levels of exposure to specific chemicals. The monitoring is usually site-specific, and generally is not used to estimate the total exposure of the entire workforce. The Occupational Safety and Health Administration (OSHA) and the National Institute of Occupational Safety and Healthy (NIOSH) have established data management systems for assimilating and aggregating data from workplace measurements. At times, these two agencies collaborate in the preparation and publication of occupational health surveys that describe exposures to certain chemicals across broad segments of an industry or occupation.

There is no monitoring system in place for determining the levels of exposure to substances in consumer products. Exposure estimates are generally based on *ad hoc* short-term surveys, laboratory studies and mathematical modeling. For example, monitoring systems have provided for many years extensive information, on the levels of pollutants in the ambient air from the combustion of fossil fuel. No such parallel exists for these same pollutants generated from the combustion of fuel indoors. However, several monitoring studies of indoor air pollutants have now generated data on exposures to combustion products from gas or kerosene appliances in the home (*61–63*).

Chemical contaminants in the U.S. food supply are monitored through the FDA's Total Diet Studies, an annual program which involves purchase and analysis of approximately 200 foods in grocery stores across the United States. Other monitoring systems used to measure exposure to chemicals in food are described in Appendix A entitled "FDA Information Sources for Exposure Estimates" (Sec. IV A).

Chemicals are also monitored in humans as a means of exposure evaluation (*64–74*). In a national program, human tissue has been analyzed on a regular basis to monitor selected, persistent chemicals such as DDT and PCBs (*75, 76*). Tissue, secreta or excreta, or any combination of these, can be assessed and compared to an appropriate reference (*77*). Such data can be used not only as a measure of overall individual exposure, but also as a measure of the effectiveness of regulatory actions when the monitoring is conducted for sufficiently long times to reveal trends. Chemicals or classes of substances for which there is some evidence that biological monitoring may be useful for detecting evidence of a substantial internal dose on an individual or group basis include: inorganic and organometallic substances, aliphatic, alicyclic and aromatic hydrocarbons, aromatic amines, ketones, aldehydes, phenols and pesticides (*77–80*). In summary, monitoring can provide estimates of individual exposure and data to define the connection between the sources of a chemical and exposure to humans. Monitoring activities can encompass studies of the sources of chemicals, the ambient environment, the human environment of the home and workplace, the food and water consumed, as well as the doses absorbed and retained by the human body.

B. Modeling

Modeling is a second broad approach utilized in exposure as sessment. Here the term modeling is used broadly to describe the construction of a methodology through which diverse data on different factors can be combined to predict levels of human exposure in the absence of complete monitoring data. Models are predictive tools used when direct measurement of exposure would be prohibitively time-consuming and expensive, and when the relationship between the sources of a chemical and the eventual exposure is complex.

Models often begin as an effort to describe and generalize theoretically a phenomenon observed in the laboratory or field. Monitoring data bases are used to construct mathematical relationships among variables of concern (*e.g.*, meteorological parameters and the temporal/spacial distribution of chemicals emitted from a source). For example, the air monitoring data from the St. Louis and the power plant plume studies cited above have been used to build and refine modeling tools for predicting population exposure to contaminants in the air.

Given the wide variety of possible situations requiring exposure assessment, it is not surprising that many different models have been developed. A recent catalogue of the models available for use in regulatory decision-making identified 156 models, most of which can be applied to exposure assessments (*81–83*). A review of these models is beyond the scope of this chapter, but descriptions of various types of models are informative and can be found in the references (*17, 27, 60, 84–111*).

In general, models are most helpful when average, or idealized estimates of exposure are satisfactory. Even though the level of sophistication of a particular model may be high, the predictions may still be crude, because any model is an simplified description of the natural phenomenon it depicts. There is a need for more research to validate most models, since the accuracy of their predictions is often unknown or only roughly known. In addition, the accuracy of the exposure estimates made by models can be no better than the quality of the input data used. The use of models does not compensate for poor data, and in certain instances, may obscure the uncertainty inherent in the exposure predictions. The use of scientific judgement in interpreting results is essential.

C. Microcosms

The use of microcosms to study pollutant behavior provides an approach that combines features of both monitoring and modeling studies.

The transport and transformation processes which occur between the source of a chemical and the eventual human exposure can be difficult and expensive to study in nature, and in the absence of data on these processes, models cannot be constructed. Microcosms, which attempt to recreate

portions of the environment in the laboratory, can provide an alternate means for defining these processes. They have the added advantage that many variables can be controlled. Ideally, a microcosm, when properly validated, faithfully mimics the processes occuring in nature. By adding a chemical to such a system, its subsequent partitioning amongst the components of the environment, together with the associated chemical and biological conversions, can be studied in a single integrated experiment.

Marine, freshwater, terrestrial, subsurface or aquifer, and atmospheric microcosms have been studied (*84, 112–130*). For example, the laboratory microcosm concept has received increasing attention recently in studies which seek to predict residential exposure to products of combustion or air pollutants (*131, 132*). Limited validation of predicted, versus measured, levels of products of combustion in a residence has shown such predictions to be useful in assessing exposure (*129, 130*).

D. Human Factors

In exposure studies using monitoring, modeling, or a combination of approaches, the actual behavior of the human population under study must be taken into consideration. Some examples illustrate this: (1) The amount of time that an individual spends indoors compared with outdoors will affect the risks associated with either outdoor or indoor air pollution; (2) failure of workers to wear protective equipment can increase their occupational exposure to hazardous compounds; and, (3) consumer exposure to vapors during the use of various products will decrease proportionally with increases in the amount of ventilation provided in the home.

Human behavior is often evaluated using information gathering techniques somewhat similar to opinion polls or marketing studies. In such a study, a randomly selected population is asked a series of questions that define aspects of their behavior that can effect chemical exposure. On an occupational setting "time-motion" studies of the periods of employee contact with varying work environments can contribute to an exposure assessment.

The exposure to direct and indirect food additives is monitored by the FDA using a number of complex studies of human eating habits. Surveys of food additive use have been undertaken since 1973 with the help of the National Academy of Sciences, as have studies of the migration of chemicals from packaging materials into foods (*15, 19, 23, 25*). Other related work has determined the frequency of consumption of individual foods and individual food serving sizes, with the data compiled in such a way as to be compatible with the population data found in the U.S. Census (*22*). These surveys and studies have produced a complex array of information which then is converted by the FDA into estimates of population exposure to direct and indirect additives in human food (*16, 24, 135*). Some of the same data are used by EPA in setting tolerances for pesticide residues in food crops (*14*).

Structure-Activity Relationships

Data now exist on the chemical, physical, and toxicological characteristics of a large number of chemicals, as does information on their transport, transformation, and environmental fate. Thus, some correlations now can be made between the structure of certain chemicals and the properties they exhibit, a process called structure activity analysis. Under favorable conditions, these correlations allow rough predictions to be made of the characteristics of chemicals which have not been studied, reducing the amount of testing necessary to make at least an initial judgement of the risks which they may pose (*99, 136–142*). Structure-activity relationships can be used to delineate the general properties of interest, but they are not generally a substitute for actual measurements.

The use of structure-activity relationships may allow preliminary exposure estimates to be made even when there is a scarcity of data on a specific chemical. Structure-activity analysis is a relatively new fields, and the available tools are still crude. The user must exercise scientific judgement in interpreting the results, because substantial work remains to be done in refining and validating these techniques.

F. Integrated Exposure Assessments

Most assessments performed in support of rule-making consider only a single source or route of exposure. Such assessments are appropriate in the case when only one source or route of exposure is significant. However, certain recent exposure assessments on chemicals with multiple routes of exposure have considered all routes simultaneously (*144*). In a pilot effort, an exposure assessment has been prepared which considers six related halogenated solvents and all routes of exposure simultaneously (*145, 146*). This assessment, in combination with hazard data, attempts to provide a risk assessment data base for all six solvents and all routes of exposure. Using this approach, all regulatory options and combinations of options may be considered in seeking the most effective means of reducing risk.

The preparation of such integrated exposure assessments for widely used chemicals is very difficult and resource intensive and requires the contributions of specialists in many disciplines. The difficulty and expense of integrated assessments may limit the broad application of these valuable tools.

Monitoring of the levels of chemical contamination in human tissue, blood and urine, as discussed above, can provide a second method of assessing the total human exposure to certain chemicals depending on metabolism and persistence in the body.

G. Data Bases and Data Management

Research by the Federal regulatory agencies on human exposure has produced a large body of data which can be used in performing assessments. One recent index identified 319 data bases, many of which could be of value in exposure assessment (*82*). For example, monitoring data are reported regularly for National Pollution Dicharge Elimination System (NPDES) permits, issued under the Clean Water Act, thereby affording information on 133,000 sources of chemicals found in surface water (*147*). The EPA's *Handbook for Performing Exposure Assessments* lists 12 regularly used automated data bases on chemicals in the environment (*148*). Monitoring data on air emissions from many sources and ambient air quality data from over 4,000 active air monitoring sites across the country are included in the Aerometric and Emissions Reporting System (AEROS) (*149*). In addition, many major research efforts (*e.g.*, the St. Louis air pollution study) generate large data bases useful in exposure assessment (*43, 44*).

Many data bases which do not deal directly with chemicals are also useful. The data of the U.S. Census provide information helpful to determine populations at risk. The National Climatic Center maintains detailed weather records, while the U.S. Geological Survey has a massive data base on water on a regional and state basis (*150, 151*). The EPA has been constructing a comprehensive data base on organic chemical manufacturing (*152*).

As the number of data bases and models available for exposure assessment grow, it will become increasingly difficult to access and manipulate the large quantities of information and broad assortment of

techniques without computer systems. Preliminary exposure assessments, reviews of the relative effectiveness of regulatory control options, and many other assessment-related tasks, which in the past required substantial effort, can be accomplished rapidly with limited accuracy at a computer terminal, calling upon data bases and models as needed (*153–157*).

III. BROAD ISSUES AFFECTING EXPOSURE ASSESSMENTS

A. Extrapolation and Non-Representative Systems

Exposure assessments, in a manner often analogous to risk assessments, may require extrapolation from a limited number of sites, to a large population. Such extrapolations carry with them uncertainties that need to be reflected in the final assessment.

In some cases, the exposure measured may not correlate well with the actual experience of the larger populations. In such cases, the non-representative nature of the exposure measurement may give rise to an assessment that is inaccurate. Such errors can arise especially when microcosm measurements and models are used instead of extensive monitoring networks.

B. Quality Assurance

Measurements of chemicals at the trace levels of concern, as needed for many exposure assessments, is a difficult exercise in analytical chemistry and can lead to errors and uncertainties which should be considered in preparing an assessment. Until recently, extensive quality assurance information was not a routine part of most research, testing, and monitoring programs. To improve this situation some agencies have instituted quality assurance procedures which require that records be maintained on the accuracy and reliability of every chemical measurement associated with research, monitoring, and compliance enforcement (*158, 159*). Two examples of such state-of-the-science projects are the EPA-Chemical Manufacturers Association Joint Study on water treatment systems and the Love Canal Monitoring Study (*160, 161*).

The quality assurance portion of the Love canal Monitoring Study provided information on the accuracy and reliability of the analyses of chemicals at trace levels in air, water, and soil. The results demonstrated the limitations inherent in the measurement of complex mixtures in a variety of matrices. The overall results in the Love Canal studies suggest that the most advanced analytical techniques correctly identify trace levels of an organic chemical in complex environmental mixtures with approximately 70 percent certainty.

To date, the major efforts on quality assurance have been devoted to chemical analyses of environmental materials. As discussed, other data contribute to the exposure assessment, *e.g.*, information generated through microcosm studies, human behavior, or modeling. There is a need for further validation of such tools to assure their accuracy and reliability in estimating exposure (*162–165*).

C. High risk populations

Subgroups of the population may be particularly at risk from exposure to a chemical. These groups may be exposed to unusually high levels of a chemical or may be especially sensitive to the toxic properties of a compound. The existence of subgroups of either type could lead to a compound producing a substantial risk even though the average exposed individual may experience little, if any, risk. A thorough exposure assessment needs to consider the possibility that high risk populations or situations exist. Many, or most, current exposure assessments do not have enough data to allow an evaluation of the effects of a chemical on high risk populations.

D. Refinement of Assessments

At the initial consideration of a chemical, only crude data relating to exposure will generally exist. Such crude data may allow a rough estimate of likely exposure; this preliminary estimate may be useful to decision makers in assigning priorities and resources. It is also possible that crude data may allow an estimate of the maximum or minimum exposure that may be expected to occur. Such an analysis may effectively rule out, or indicate the presence of, a significant risk. Specifically, a "worst case" estimate, where all assumptions are chosen so as not to underestimate the possible exposure, may indicate that little risk exists if significant exposures are not predicted.

As more resources are devoted to an exposure assessment and more studies conducted, a refined assessment is generated. Often there will be several stages of refinement of an assessment, and the degree of refinement and accuracy finally required will be related to the certainty needed to enable risk management decisions.

E. Relationships to Biological Dose

The data generated in an exposure estimate must ultimately be coupled with biological data on the hazards presented by a chemical in order to determine the actual risk presented by the exposure. In order to achieve this coupling, the estimated human dose must be related to the doses received in the human or experimental studies that generated the information on the biological hazard. The type of exposure data needed can vary for different risk estimation procedures. For example, for risk estimation using a dose-response relationship that is not linear in the range of human exposure, information on the frequency distribution of different exposure levels in the population is needed, instead of simply an estimate of the average exposure.

This comparison can be complicated by differences in the frequency, duration, intensity, and route by which the two doses were received. This is particularly relevant since human exposures to a single chemical may follow many different patterns ranging from a high single exposure to a low level lifetime exposure. Humans will also often be exposed through several routes: Ingestion, inhalation and dermal. Because of the diversity of human exposures frequently there will not be toxicological data available which was obtained under the same exposure conditions. In those cases, careful review and expert judgment enter into the application of the exposure data.

Recently, there has been considerable interest in the possibility of relating human chemical exposures to hazard studies by utilizing biological indices of the effects of the different exposures. Specifically, it has been suggested that the quantity of a carcinogen reaching and interacting with DNA be directly compared in exposure and hazard studies. This topic receives fuller discussion in Chapters 1 and 4 of this document. It should be noted that at the present time, data to allow such comparisons are generally not available, and considerable research still is needed in order to assess the practical applicability of this approach.

F. Overall Limitations of Exposure Assessments

Many exposure assessments are unable to distinguish all of the parameters that are important in determining possible health effects. These include variations of exposure with time, including peak versus average exposures, and annual versus daily exposures. In addition, exposure assessments rarely, if ever, are able to estimate the dose that actually reaches a biological site where an effect may occur. As a consequence, some information is often available about the

magnitude, frequency, or duration of exposure, but rarely is information available that is adequate to accurately determine all three. In addition, the population whose exposure is being assessed will often be exposed by more than one route from a number of different sources. As a result, estimates addressing single routes or sources of exposure are often inadequate to represent what is actually occurring. Environmental monitoring data, models, and microcosms may sometimes be inadequate, and of limited value, and may lead to a false sense of security if broadly applied without consideration and enumeration of their limitations.

Finally, there are a number of factors that are a part of both a hazard assessment and an exposure assessment which usually are not completely determined. These factors include the age distribution of the exposed population, special sub-populations that may be particularly sensitive to low doses, cumulative exposures, latency, host factors, or populations which may be exposed to particularly high concentrations. As a result, there are generally unknown data and uncertainties associated with exposure assessments at many points. It is important that the assessor describe the data that are missing, the associated uncertainties at each step of the assessment, and the assumptions made when filling in the gaps.

At present, therefore, there is a great deal that can be improved in carrying out exposure assessments. Informed decision making often requires consideration of a complex array of information, rather than a single numerical estimate of exposure. To the extent possible the ultimate use of the data should be defined, and the exposure assessment tailored accordingly. The limits of the assessment, both conceptual and methodological, need to be described, and all the uncertainties enumerated. Quality assurance programs and efforts should be included as well as a description of efforts made to validate laboratory studies and mathematical modeling; in general, careful scientific review of all elements of an exposure asssessment should be stressed.

IV. APPENDICES

A. Appendix A—FDA Information Sources for Exposure Estimates

Survey, epidemiological, toxicological, and analytical data used by the Bureau of Foods in determining the human health consequences of exposure to many of the categorical agents which the agency regulates are derived from a variety of sources. For example, NIOSH and OSHA provide data on occupational exposure and CDC provides data for a variety of exposure sources. The scientific literature and various reports provide a wide variety of animal and human data. In addition, data are obtained on types and amounts of foods eaten, concentration of food contaminants and human health effects.

1. Food consumption. Some principle sources of food consumption data include: (1) The U.S. Department of Agriculture (USDA) Nationwide Food Consumption Survey (NFCS); (2) National Health and Nutrition Examination Survey (NHANES); and (3) Market Research Corporation of America (MTCA) survey data. Sources of food composition data include: (1) USDA: Handbook 456, Handbook 8, National Nutrient Data Bank file; (2) NHANES: Model Gram and Nutrient Composition files; and (3) MRCA: Lead content of foods and methylxanthine content of foods (based on data from Total Diet Study and industry). Additional information of some of these sources is provided in the following discussions:

a. Nationwide Food Consumption Survey. The results of the Nationwide Food Consumption Survey (NFCS) 1977–78 provide data on the kinds and quantities of foods and nutritive values of diets ingested by men, women and children of different ages classified by various household characteristics. Dietary information obtained for individuals included the kind and amount of each food eaten; the time the food was eaten, the type of service, and the cost. Individuals were also asked if the day's intake was typical and if they were on a special diet, were vegetarians, or took vitamins, minerals or other supplements. Reported are average intakes per day and per eating occasion for foods most commonly eaten by individuals who participated for 3 days in the NFCS conducted by the U.S. Department of Agriculture.

b. National Health and Nutrition Examination Survey.

Data were collected for NHANES II through response to questionnaires on medical history, food consumption, and health-related behavior. Data also were collected through direct medical examination. NHANES II was conducted on a nationwide probability sample of approximately 20,000 persons ages 6 months to 74 years from the civilian non-institutionalized population of the United States. Food consumption data is of the form of quantities of food consumed and frequency of eating in a 24-hour recall period.

c. Market Research Corporation of America Surveys.

One of the largest proprietary surveys of food intake is one conducted by the Market Research Corporation of America (MRCA). This corporation conducts the Menu Census survey which is designed to collect detailed information for one year on the ultimate disposition of all food products in terms of their consumption by individuals or their use in preparation of other dishes consumed by the individuals. Only information on frequency of eating is reported; that is, quantities are not included. Each Menu Census consists of 4,000 households. Each household reports all food preparation and consumption at home and away from home for 14 consecutive days in daily diaries. Brands and food packaging materials are also described. The sample is balanced within each quarter as closely as possible to the U.S. Census by various demographic characteristics, including region, household size, household income and other socioeconomic variables.

Pertinent comparisons among these three data sources are given in the following table:

Characteristic	USDA NFCS 1977–78	NHANES 11 1976–80	MCRA Menu Census VI 1977–78
Sample size	30,770	20,322	11,150.
Length of dietary survey	3 days	1 day	14 days.
Dietary methodology	24-hr. recall (one-day) records (two days).	24-hr/recall	Daily diary.
Collection methodology	Recall: interviewers record: self-administered.	Interviewer	Self-administered via mail.
Reporter	Individual subject	Individual subject	Main food preparer.
Place of recording	Home	Mobile exam center	Home.
Food quantities	Yes	Yes	No.
Drinking water	Yes	No	No.
Processing/packaging information.	No	No	Yes.
Other surveys in this series	1965–66	1971–74	1957–75.

2. Total diet studies. The Food and Drug Administration uses several surveillance and regulatory programs to monitor the amount of chemical contaminants in the U.S. food supply. Most of these programs measure

contaminants in raw or unprocessed foods.

The Total Diet Studies monitor levels of chemical contaminants and essential minerals in table ready food and consider dietary intake of these substances by various age-sex groups. The Total Diet Study is an annual program which involves the purchase of approximately 200 foods in grocery stores across the United States and the analysis of these foods for essential minerals, toxic elements, radionuclides, industrial chemicals and pesticides. The food list and diets, beginning in April 1982, were revised to reflect the present food supply and the current food consumption habits. The number of age-sex groups was increased to eight (infants, young children, male and female teenagers, male and female adults, and male and female older persons) in order to expand the coverage of the U.S. population. Foods were analyzed individually, rather than in commodity groups, to obtain information on the contribution of specific foods to the daily intake of minerals and contaminants.

The diets are based on data from the 1977–78 USDA Nationwide Food Consumption Survey (NFCS) and the Second National Health and Nutrition Examination Survey (NHAMES II) carried out by the National Center for Health Statistics in 1976–80. Two hundred and thirty-four foods are collected from four geographic regions (northeast, south, west, and north central) and analyzed by the Kansas City Field Office Laboratory for 11 essential minerals and more than 120 chemical contaminants. The essential minerals analyzed for are copper, iron, magnesium, manganese, potassium, phosphorus, calcium, sodium, iodine, selenium, and zinc. The daily intake by weight of these 234 foods has been weighted to represent 100% of the usual diet for the eight age-sex groups. These estimated food intakes are used to assess daily contaminant and mineral intake.

3. Food Additives.

a. National Academy of Science Survey Data.

The NAS surveys provide the agency with a data base for the concentration of additives used in food. To ensure confidentiality the NAS maintains the raw data from the surveys. These data have been obtained from mailed questionnaires that have been sent to over 2000 firms with approximately 1100 responding. The values obtained from the NAS are used as the substance concentration value in estimating intakes.

The surveys approach the question of usage of food additives from two directions: (1) How much poundage is used annually; and (2) what is the level of use in each of the firms products.

b. Bureau of Foods Data Base.

The Bureau of Foods' database for food additives comprises food additive safety information for substances added directly to food in the United States. Nearly 1600 items (over 1300 synthetic flavoring substances, nearly 300 direct additives, and some 70 color additives and color diluents) supply data on human exposure levels, chemical structure, and toxicological parameters. The computer database is searchable by software programs that permit sorting of the data on many parameters, including lowest effect levels, test animal species, toxicological effects and organ sites, as well as exposure and chemical structure categories.

This database comprises one module of the Bureau's SIREN (Scientific Information Retrieval and Exchange Network) system, the other two being the food additive information system (FAIS) and the new animal drug information system (NADIS) containing over ½ million indexed records across two FDS bureaus.

4. Census Data. Census data on the count and characteristics of the population are obtained from the Bureau of the Census. The agency has census files for 1960 and 1970 for the total population counts for each U.S. county or county equivalent, such as independent city and within each county equivalent by sex, race, and 5-year age interval. These data are used in calculating rates in the population. Population estimates for the years 1971–1978 are available.

5. Fish Intake Data. Fish intake data are important to FDA in regulating food safety and has been used in evaluating the hazard of mercury, dioxins, and other contaminants of fish. The sources of national fish production data are the National Marine Fisheries Service (NMFS) and the USDA. NMFS calculates an annual estimate of the per capita consumption of seafood from data on the total catch of commercial seafood. The estimate does not include commercial fresh water fish, recreationally caught fish or marine fish sold at roadside stands. The NMFS also supplies a database on the mercury content found in fish. The USDA calculates annual per capita fish intake by adding an estimate of recreationally caught fish and the other type of data to the commercial seafood production to calculate the total fish consumption.

6. Natural Toxicants. A natural toxicants literature file is maintained which contains reprints of articles relative to the occurrence and health effects of mycotoxins including plant and marine toxins. In addition, information is maintained on the level of mycotoxins in various commodities in the U.S.

7. Elemental analyses. Data from the U.S. Geological Survey on elemental analysis of soils, waters, and vegetation provides background information on geographic differences in elements likely to be in the human diet.

8. Special studies. Consumer interview surveys are conducted periodically on topics of special interest, which may grow out of immediate or potential health risks to the public or the need for information not currently available in areas of regulatory concern to the agency. The studies are designed internally, executed under extramural contract and the data are delivered on computer tape for internal tabulation and analysis.

9. Literature. A bibliography file for articles written by FDA employees is maintained. This file together with computerized cross index contain articles on such subject as analytical methods and food contaminant levels.

B. Appendix B—Exposure Assessment at EPA

1. Introduction. An exposure assessment is an estimate of the amount of a given chemical substance that is absorbed by individuals over time. This integral portion of the risk assessment is a growing technical speciality whose complexity has long been noted but has only recently been addressed using the sophisticated scientific tools recently been addressed using the sophisticated scientific tools available (*28,29*).

The process involves consideraton of the magnitude, frequency and duration of encounters between individuals and the chemical in question. In some instances (*e.g.*, prescribed dosing with drugs), the information is rather precisely known. In the case of exposure to chemicals of environmental concern, however, the assessment process in often associated with a dearth of data and assumptions/approximations must be made to fill in the gaps. For example, while some data may be available on the "direct exposure" from the emissions of a manufacturing plant, estimates of the "indirect exposure" resulting from potential bioaccumulation in the food chain may be less precisely known.

In recent years, data bases have been compiled, computer models developed, laboratory/field measurement taken and "standard operating procedures"

adopted (*30–32*) that have narrowed the uncertainty associated with some of these estimates.

2. Defining the exposure assessment. Before beginning an exposure assessment, it is necesary to define clearly the product needed in terms of purpose, breadth, depth and approach. This conceptual scheme is being developed in detail in a seven volume set of information by the EPA (*166*).

Depending on the answers provided to these questions, different resources are available to construct the exposure asessment. Some of the more important resources are discussed below.

3. Monitoring. In many cases, site-specific monitoring is performed in order to generate qualitative or quantitative data for an exposure assessment. For example, more than 5000 water, soil, and sediments samples have been analyzed for the presence of 2,3,7,8-tetrachlorodibenzo-p-dioxin in the state of Missiour; groundwater and vertical soil cores have been analyzed for ethylene dibromide in Hawaii, California, and Georgia; and stack emissions have been sampled for heavy metals.

In addition to site-specific information, qualitative and quantitative exposure information is available from the various monitoring networks which have operated over the years to collect data on chemicals in different envonmental media. For example, the Mussel Watch Program (*53,59*) has analyzed shellfish in the U.S. estuatine waters for a variety of pollutants. Shellfish are filter feeds and are generally efficient bioconcentrator of water contaminants; the residues in these organisms serve as sensitive markers for upstream pollution of water which feed the estuaries.

In addition, great quantities of analytical chemical information on U.S. waters can be accessed through the computer data based, STORET. These data represent information gathered over the past years from every major watershed in the U.S.

Increasingly, the problem of groundwater contamination is of concern. Little systematically collected information on this environmental compartment is available at this time, although more effort is being expended to identify and quantitate levels of certain chemicals such as aldicarb and ethylene dibromide at selected sites.

EPA has gathered information on atmospheric pollutants for many years. As part of the national efforts to the quality of the ambient air, innumerable measurements have been made at various times and locations on certain pollutants, namely carbon monoxide, sulfur oxides, nitrogen oxides, particulates, hydrocarbons, and photochemical oxidants. Much of this information is available in computer files maintained by EPA, Ofice of Air Programs in Research Triangle Park, NC.

In a broader prespective of "monitoring"—where the chemical is in the environment—EPA's Office of Toxic Substances maintains and has access to file which identify chemcial substances which are manufactured in or imported into the U.S. Some types of geototal production figures are generally available, along with graphic information on the location of production sites. This information is useful in generating a "material balance" of the a chemical in the environment).

EPA often relies on data generated by other Federal agencies (*e.g.* FDA, NIOSH and the Department of Labor) to estimate the exposure likely to be encountered from eating food or being in the workplace.

Increasingly, interest is expressed in determining more direct measurement of human exposure to environmental pollutants. For years, EPA has maintained the National Human Adipose Tissue Network which collects adipose tissue from selected cadavers in such a way as to obtain a rigorous statistical sample of the U.S. population. These tissue samples are analyzed for a variety of organic chemical residues so that trends and potential problem chemicals can be identified. Further, the Agency publishes a summary of studies on residues in humans which have appeared in the scientific literature.

An ambitious program underway at the EPA, called the Total Exposure Assessment Methodology (TEAM) study (*66–71*), combines personal monitor results (*34*) with analyses of food, beverages, water, human blood plasma and serum, urine, breath and mothers' milk to characterize the individual exposure of large test populations to a variety of organic chemicals over extended periods of time. Such data also will be useful in determining what portion of a particular chemical is actually absorbed by the body and how absorption varies from one individual to another at different exposure levles. The actual dose of a chemical which determines the health outcome from the exposure is often different from the apparent exposure level (*167*). The goal of the TEAM program is to develop an individual exposure monitoring methodology for use in estimating population exposures, including analytical chemical techniques of proven accuracy and reliability, tools for conveniently collecting detailed information on the activities of individuals on a 24-hour a day basis, and tools for managing, analyzing, and interpreting the data produced by such studies.

In sum, the Agency has broad environmental monitoring data on a number of chemical substances in various media. The information too often is not sufficient in depth, detail, and validation to provide precise data in a given exposure situation. Further uncertainties are introduced when attempts are made to extrapolate these data to absorbed dose. Therefore, while the Agency is indeed building an exposure data base, the range of uncertainty surrounding any exposure situation can be significant.

4. Modelling. The questions of "indirect exposure" ofter center on the transformation, transport, and ultimate fate of a chemical once it is released into the environment. While direct monitoring can provide some data in this regard, important detailed qestions of chemical kinetics, distribution between media, potential uptake by biological organisms, and the like cannot easily be derived from such information. Two approaches to filling this gap are through the use of microcosms and through the use of mathematical modelling.

a. Microcosms. A microcosm is a recreation of a portion of the environment in the laboratory—a physical model of nature. Ideally, the microcosm faithfully mimics the processes occurring in nature. By adding a chemical to such a system, its subsequent partitioning amongst the components of the environment, together with the associated chemical and biological conversion, can be studied in a single integrated experiment.

Marine, freshwater, terrestrial, atmospheric and subsurface or aquifer microcosms are available and have demonstrated utility. Much of our knowledge of the chemistry which occurs in the atmosphere has been generated using smog chambers (*80, 112*), *i.e.* atmosphere microcosms. Marine microcosms are now being used to understand the complex processes which affect the fate of a chemical in the ocean where it can be transformed by the benthate community, and eventually concentrated up the food chain leading to human food (*113–116*). Terrestrail micorcosms are being used to define more precisely the fate of a chemical in soil-plant-water systems (*127–129*). Subsurface or aquifer microcosms have been created using special drilling techniques which allow a column of material to be removed from an aquifer

in an undisturbed and uncontaminated state (*130*). Such colums are then used to study the chemical and biological conversions underground.

One of the continuing questions raised about microcosms is how well do their results actually mimic what would occur in the "real" environment itself. In recent years, increased effort has been aimed at validating these systems and gaining an appreciation of the limitations of their data. At this time, however, the risk assessor must recognize this inherent potential source of error.

b. Mathematical modeling. One of the most frequently used tools in exposure assessment is mathematical modeling. Most such models begin as an effort to describe theoretically the phenomena observed in the laboratory or field. Large monitoring data bases are used to construct mathematical relationships between variables of concern (*e.g.*, meteorological parameters and the temporal/spacial distribution of chemicals emitted from a source). These relationships constitute the model which, because of the inherent complexity, often requires a computer for its use. Models are predictive tools used when direct measurement of exposure would be prohibitively time consuming and/or expensive and when the relationship between the sources of a chemical and the eventual exposure is complex.

Given the wide variety of possible situations requiring exposure assessments, it is not surprising that many different models have been developed. A recent catalogue of the models available for use in regulatory decision-making (*81*) identified 156 models, most of which can be applied to exposure assessments (82, 83). A description of the general features of some advanced models is informative (*85*).

Ambient air modeling has reached the highest level of complexity with a capability for considering numerous point, line, and area emission sources simultaneously (*86–88*). Several models (*84*) predict the complex chemical conversions occurring in air during transport of pollutants. One model allows prediction of the half-life and reaction products for an organic chemical in air (*89*). Models currently under development address the problems of predicting exposure on a regional basis (*90*) and in areas with rough terrain (*91*). The *Handbook for Performing Exposure Assessments* (*166*) lists a number of routinely used air models available through NTIS.

Models are also available for the indoor air environment. The breadth and complexity of such modeling varies in proportion to the complexity of the environment being modeled. Even a single room or residence model may become quite complex when considerations of air filter efficiencies, particulate agglomeration/planting-out, nonspecific heterogeneous decay of reactive pollutants, multiple sources, sinks and varying sources strengths are encountered. Additional difficulties of assessing infiltration rates, and the partitioning of ventilation rates among discrete volumes in a building have led to the use of compartmented models (*92*). The contribution of varying levels of ambient pollutants to the indoor environment has been evaluated by a time-segmented model which has undergone limited field validation (*134*).

As a result of the Great Lakes research program (*93–97*) and research into the environmental fate of pesticide (*98–99*), models are available which describe the movement of chemicals in fresh water aquatic environments. Studies on the ocean disposal of municipal wastes have led to models for chemicals in coastal waters (*100–102*). Recent work on terrestrial microcosms has provided input data for a terrestrial model (*103*) which includes consideration of plant uptake. A number of models are available which describe leaching and runoff of chemicals to streams (*81*). The newest areas of modeling are ground water (*60,104–108*), human micro-environments and activity patterns (*109–111*), food consumption (*17*) and multimedia environmental partitioning (*168, 169*).

As models increase in complexity, the ability to predict exposure generally becomes more accurate. This additional accuracy, however, is purchased at the price of additional input data (*135*). The choice of models available for a particular assessment may be reduced by a limited data base.

In general, models are most helpful when rough estimates of exposure are required. Even though the level of sophistication of a particular model may be high, the predictions are still crude because any model is an oversimplified description of the natural phenomenon it depicts. There is a need for more research to validate most models, since the accuracy of the exposure estimates made by models can be no better than the quality of the input data. The use of models does not compensate for poor input data, but in certain instances may obscure the true uncertainty inherent in the exposure predictions. In sum, the modelling as well as in monitoring, the Agency can obtain valuable information. At the same time it needs to be recognized that this information might be accompanied by potential significant uncertainties. Nevertheless, the use of scientific judgment in interpreting results is essential.

C. Appendix C—Chemical Exposure Assessment for Consumer Products

Assessing human exposure to toxic chemicals from consumer products is a vital part of CPSC's chemical hazard work and is the element which most distinguishes CPSC's efforts from the activities of other Federal agencies. The range of uses of chemical compounds in consumer products is great and the ways that consumers utilize a single product may vary considerably. For example, the techniques required for assessing exposure to a gas that may be emitted from building materials into home air and for a dye or other agent contained in cloth that may contact the skin have little in common. Most experience in exposure assessment from products has been gained over the past few years. Because of this, CPSC approaches exposure assessments on a case-by-case basis with each study in general requiring original experimental or theoretical work. Nonetheless, the general activity of exposure assessment can be described as a four step process:

(1) Determine the fact of the release of a compound from products and estimate the quantity of release. The degree of difficulty of this step can vary greatly. For example, it is straightforward if the compound of interest is contained in an aerosol product. It may require extensive experimental study if the compound is contained in a plastic matrix that is subjected to a variety of uses. More often than not in CPSC's experience, experimental studies are required. The presence of a compound in a consumer product does not imply that release actually occurs.

(2) Relate the quanity of release with the level of human exposure (to the outside of the body) from use of the products. A series of analyses are required for this step. First, use patterns for the products must be determined; both the most typical use patterns and those that could lead to lower or higher degrees of exposure must be considered. Experience of staff, information from industry, and consumer surveys can provide this information. Then, for each specific use, the data on chemcial release must be used to estimate the actual amount of contact the user has with the chemical. For a chemical emitted into the home air, data on release rate, use patterns, home volume, and air exchange rate can be combined in a mathematical model to estimate the average and peak levels in the air. On

the other hand an experimental study could be conducted to measure actual air levels from a certain product use. As another example the quantity of a liquid that comes into contact with skin can be measured.

(3) Determine the entry of the material into the body. This step can be straight forward if the toxicity information on a chemical was obtained by a route of exposure comparable with consumer use. On the other hand, particularly in the case of dermal exposures, data in entry of a compound into the body is fequently lacking. In that case experimental studies, such as painting the skin of an experimantal animal with a radio-labeled quantity of the compound of interest, may be conducted.

(4) Combine the data in steps 1 through 3 for a complete estimate of human exposure to a compound. This estimate can then be combined with health hazard information (toxicity) in evaluating human risks; it can serve as the basis required for a mathematical estimation of risk.

These steps are presented as one sequence however, exposure estimation is often an interactive procedure. One uses available, limited information to make preliminary estimates of risk that may (if sufficiently conservative) eliminate concern about an exposure or may be successively refined by gathering data where it is most needed.

In addtion, in certain studies, some of the above steps may be combined rather than considered separately. For example, a chemically treated cloth may be placed in contact with the skin of an experimental animal and the amount of uptake of the chemical by the animal measured. This experiment provides information that could separately be obtained by measuring both quantities released from the cloth and rates of penetration of the chemical through the skin. As another example, personal air monitoring can take into account both release rates from products and patterns of product use.

Exposure assessment for chemicals in consumer products is a developing science which makes innovative use of standard physical and chemical data, demands development of new experimental procedures, and combines relatively "hard" experimental data with "soft" data on widely varying human behavior patterns. While each exposure assessment is now a new undertaking, certain basic techniques (such as air level modeling) are finding repeated application. In the next several years the knowledge now being gained should lead to more readily standardized and more easily performed exposure assessments.

V. SUMMARY

Exposure assessment is a co-equal component, along with hazard assessment, in the evaluation of human risk. The assessment of exposure to chemicals by direct routes (*e.g.*, breathing emissions from an industrial stack) and indirect routes (*e.g., pollutants accumulating through the food chain) depend upon analytical chemical monitoring data, results of modelling estimates, and assumptions needed to fill in data gaps. The field of exposure assessment is rapidly developing and only recently have attempts been made to develop systematic approaches to the problem. Although current efforts are often associated with considerable uncertainty, the increasing sophistication being brought to bear on the issue holds the promise of greater confidence in these estimates in the future.*

Methodologies can be broken up into two broad categories, monitoring studies, which depend more on the measurement of exposure, and mathematical modeling, which use analysis to define the exposure. Microcosms, as samples of the environment, provide data for both approaches. Human factors, however, are important and must be considered.

An important part of the assessment process is the marshalling of the appropriate data bases, and some of the data bases used by three regulatory agencies are listed in appendices.

Broad issues affecting assessments include the question of extrapolation from representative systems to large populations, quality assurance, the question of high-risk populations; and the approach of coupling exposure data to actual biological dose to improve assessments, are emphasized, with a discussion of the limitations of assessment as it is being done today.

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Chapter 6—Utilizing Scientific Data in Assessing Human Cancer Risk Associated With Chemical Exposure

I. INTRODUCTION

Assessment of human cancer risk associated with some specified chemical exposure is a complicated scientific endeavor that requires careful review of all pertinent information by appropriately trained individuals. This process relies heavily on information derived from epidemiological, clinical, and long-term animal studies. Short-term test results and information on structure-activity relationships, comparative metabolism, pharmacokinetics and mechanisms of action also contribute, in varying degrees, to the assessment.

While there is general agreement within the scientific community about the steps involved in the risk assessment process, a number of specific issues related to these various steps are still uresolved *e.g.* the combining of positive and negative data when evaluating carcinogenic potential and the selection of a dose-response model for making low-dose risk projections. The execution of any given risk assessment may also be hampered by the existence of critical gaps in the data underlying the assessment. Because these issues and data gaps can be pivotal in the process, it may be necessary to make judgments about these unresolved issues and assumptions to adjust for deficiencies in the underlying data base that will permit risk assessments to be completed. These judgments and assumptions should be plausible and, to the extent, possible, be based on the scientific information on hand. However, the validity of these judgments and assumptions often cannot be conclusively established, so the risk assessment process should not be viewed as strictly "scientific" in the usual sense of the word. Instead, risk assessment involves a complex blend of current scientific data, reasonable assumptions and scientific judgments that permit decisions to be made in the absence of complete information.

With the passage of time the scientific data base grows, information gaps are filled, and perceptions change. This process of evolution and maturation results in a need for periodic reformulations and restatements of the appropriate guidelines for risk assessment.

The present chapter describes the basic framework for carcinogenic risk assessment and attempts to reflect what general agreement currently exists within the scientific community. It is intended to provide a bridge between the scientific data base on carcinogenicity developed in previous chapters and the various Federal regulatory agencies that are charged with the responsibility of protecting the general public from exposures to carcinogenic agents.

II. STEPS IN THE ASSESSMENT PROCESS

There are four steps or components (1) that are typically involved in carcinogenic risk assessment. The first, which is often referred to as hazard identification, entails a qualitative evaluation of both the data bearing on an agent's ability to produce carcinogenic effects and the relevance of this information to humans. The second, exposure assessment, is concerned with the number of individuals who are likely to be exposed and with the types, magnitudes, and durations of their anticipated exposures. The third component, hazard or dose-response assessment, uses the information on carcinogenicity from the hazard identification phase together wtih mathematical modeling techniques to estimate the magnitude or an upper bound on the magnitude of the carcinogenic effect at any given dose level. Finally, one may combine the information from the first three components or steps to characterize the carcinogenic risk associated with the expected human exposure to the compound of interest.

A. Hazard Identification

Due to the lack of complete information, there may be some uncertainty involved in determining whether or not an agent poses a carcinogenic hazard to humans. While information on human exposures and effects is particularly valuable, too often such data either do not exist or are inadequate, and one must rely primarily on information from long-term animal bioassays in assessing the potential for carcinogenic response in humans. In reviewing animal studies, each relevant study must be evaluated as to the limits of inference implied by the experimental design, the results, and the conclusions. Although strict criteria for evaluating carcinogenicity data have not been developed for all circumstances, there seems to be reasonably good agreement amony scientific groups as to the general elements to be included as a part of qualitative carcinogenic assessments (See also Chapter 1) (*2–8*).

Epidemiological studies can, under certain circumstances, provide direct measures of carcinogenic effects in humans (See also Chapter 4). For example, some epidemiological investigations are able to associate cancer incidence or mortality with exposure to specific chemicals, industrial processes, or components of an individual's life style. Analytical studies, i.e., case control and cohort studies, are especially important indicators of possible human carcinogenic risk, but case reports and descriptive studies may also be supportive. Consistent results in independent studies, freedom from bias and confounding factors, reliable exposure data, reasonable follow-up time, dose-related responses and high levels of statistical significance are among the factors leading to increased

confidence in a conclusion of carcinogenicity. Even if an epidemiological investigation fails to demonstrate an increased incidence of carcinogenicity among the exposed study members, an upper confidence limit on the risk measure used in the study can indicate the maximal level of risks likely to be incurred by a similarly composed segment (*i.e.* in terms of age, race, sex, etc.) of the general population.

Evidence from long-term animal bioassays (see also Chapter 3) constitutes the second major class of information bearing on the carcinogenicity of chemicals. The primary factors that are considered in the evaluation of carcinogenicity are higher tumor incidence and shorter latency in treated groups relative to controls. Findings are strengthened by the existence of positive effects in more than one treated group or sex. Additional support comes from positive results observed with different routes of exposure, in replicated experiments, in different animal strains and species, and in multiple organs or tissues. Attention is also given to the magnitude of tumor increase in treated animals, the existence of dose-related trends, the degree and extent of malignancy at a given site as a function of dose and time, the evaluation of concurrent non-neoplastic pathology in treated attempting to use epidemiological data in cancer risk assessment is the lack of appropriate historical exposure information.

In an exposure analysis, a group or groups of individuals are identified and described with respect to their population size and composition, and the route (*e.g.* inhalation, dermal, ingestion), magnitude, frequency, and duration of their exposures. In addition, consideration must be given to both direct exposures (*e.g.* drugs or occupation) and indirect exposures (*e.g.* food or air) that result from a chemical's transport through various environmental compartments before impacting on humans.

For a given exposure source the concentration or amount of the chemical in that medium is determined by measurement, estimated by modeling, calculated from physical-chemical properties and other information on the agent, or projected from data on surrogate chemicals. Common values might include ambient airborne concentrations given as parts of chemical per million parts of air or the number of milligrams of a drug per dose. Measurements, estimates or assumptions then need to be made concerning the exposure of humans to the chemical through a given medium, *e.g.* the frequency of consumption of a specific food containing a pesticide residue or the frequency, pattern, duration and conditions of use of a consumer product containing a cleaning solvent. Next, assimilation of the chemical into the body is considered; again there is reliance on whatever pharmacokinetic data or estimates are available. Values may be expressed in a number of ways such as the percentage of dose absorbed from the gastrointestinal tract, the movement of so many micrograms of chemical across a given area of skin over a certain time period, or the percent of the inhaled material absorbed in the respiratory tract.

All the above information, *i.e.* population identification and characterization, chemical concentration in a given medium, the nature and pattern of exposure and finally the assimilation of the chemical into the body is assembled and analyzed. Information on multiple sources of exposure may then be combined into a single measure of overall exposure.

Tremendous variability in exposure exists among members of a population. People change jobs or place of residence, convert from well water to municipal water, occasionally take prescription/non-prescription drugs, etc. Each of these differences among persons contributes to the uncertainty associated with any exposure value. To the extent possible, the degree of uncertainty in exposures should be discussed and estimated.

C. Hazard or Dose-Response assessment

Hazard or dose-response assessment is a quantitative exercise that attempts to describe the expected human response to any given level of a carcinogenic exposure. The response is typically characterized in terms of either a specific risk estimate of an upper bound on the underlying risk. This step in the risk assessment process relies heavily on data from exposed humans and on observations of animals employed in long-term cancer studies. Long-term animal screening studies have traditionally focused on the detection of carcinogenic potential. As a result, they are usually based on exposures at or near the test animal's maximum tolerated does level. Since these doses are often order of magnitude higher than those encountered by humans, some form of mathematical low-dose extrapolation procedure is required to estimate the expected response at the exposure levels typically of concern in the environment. In addition a species extrapolation or scaling factor is usually employed when projecting anticipated human cancer risk from experimental data. Low-dose extrapolation may also be an important consideration for epidemiologically-based assessments, since the available human data may often involve relatively high level occupational exposures.

1. Low-dose extrapolation. Low-dose carcinogenic risk estimation is based on mathematical modeling that attempts to characterize explicitly the unknown, underlying relationship between exposure and response or to place an upper bound on the dose-response relationship.

Linear extrapolation procedures are often employed for estimating the low-dose risk. In the absence of background response a commonly used approach is to draw a straight line from an upper (binomial) confidence limit on the observed response rate at the study exposure level to the origin. If background is present, the procedure can be modified by making specific assumptions about the nature of background in order to take its effect into account (*9, 10*). Two of the more appealing features of this procedure are that it is easy to apply and that it will generate an upper bound on the unknown, underlying cancer risk in most instances. The most frequent criticisms directed against it are that it may be unduly conservative and that it fails to utilize all of the study data if several exposure levels are employed. Recently, an interesting modification of the linear extrapolation procedure has been proposed by a number of investigators (*11, 12*). They suggested that some type of mathematical dose-response model should be fit to the experimental data, the estimated response and associated model-based confidence limit for a preselected level of exposure should be determined, and that linear extrapolation should then be used to project an upper bound on risk for the low-dose level of interest.

When low-dose extrapolation is based on an attempt to characterize the underlying dose-response relationship, one of three general classes of models (*i.e.* tolerance distribution models, mechanistic models, or time-to-tumor models) is usually employed.

The tolerance distribution models assume that each member of a population has a threshold or tolerance level below which that individual will not respond to the exposure in question. It is also presumed that the variability among individual threshold levels can be described in terms of a probability distribution. For this class of models the

probability that a particular individual will exhibit a carcinogenic response when exposed at dose level *d* is the same as the probability that the individual's tolerance level is less than *d*. The familiar probit, logit, and Weibull dose-response models can all be generated by adopting different probability distributions to describe the population's tolerance variability (*13*). The best known of the low-dose extrapolation techniques based on tolerance distribution models is the Mantel-Bryan procedure (*14, 15*), which employs a probit model. Although the Mantel-Bryan procedure was originally regarded as a conservative approach to the estimation of low-dose risk since it employs a fixed, presumably conservative estimate of slope and extrapolates from an upper confidence limit on the observed experimental response, subsequent research (*16*) has shown that in the low-dose region the probit model tends to produce relatively high "safe-dose" estimates when compared to other extrapolation procedures. As a result of this characteristic and other criticisms that have been raised against the Mantel-Bryan procedure (*16*), its use in quantitative risk assessment has markedly declined.

The class of mechanistic models, *i.e.* the one-hit, multistage, and multi-hit models, derives its name from the presumed mechanism of carcinogenesis upon which the models in the class are based. Each of these models reflects the assumption that a tumor originates from a single cell that has been damaged by either the chemical or one of its metabolites.

The simplest of the mechanistic models is the one-hit model (*13*) which assumes that damage to the target cell sufficient to cause a tumor results from a single "chemical hit." This model is essentially linear in the low-dose region. Since it has only a single parameter other than background, it will not always provide an adequate fit to the experimental observations.

The multistage model, developed by Armitage and Doll (*17*), is perhaps the most frequently employed of all low-dose extrapolation models currently in use. It reflects the observation that a developing tumor goes through several different stages, which can be affected by the carcinogen in question, before it is clinically detectable. The multistage model will often be approximately linear in the low-dose region, and so its risk estimates are sometimes regarded as being relatively conservative. Furthermore, the procedures most commonly used to generate upper confidence bounds for the multistage model lead to estimates that are linear at low doses (*18, 19*).

The multi-hit model (*13, 20*) assumes that the target cell must absorb at least *k* chemical hits before the cell achieves its carcinogenic potential. Some investigators regard the generalized multi-hit model, where *k* can be any non-negative value, as being more flexible than the multistage model; and its use in risk assessment has been recommended (*21*). However, there are research results (*22*) that indicate a number of important, practical problems associated with its application, such as the fact that model hyperlinearity may produce extremely conservative estimates of safe dose levels, or that the multi-hit model can also indicate a "safe dose" at levels higher than some doses that actually produced deleterious effects.

The last class of models employed in low-dose extrapolation is the time-to-tumor models. These models, which attempt to describe the complex relationship between dose, tumor latency, and cancer risk, include the lognormal distribution (*9*), the Weibull distribution (*23*), and the Armitage-Doll (*17*) and the Hartley-Sielken (*24*) models. While time-to-tumor models can lead in many instances to a more complete characterization of the underlying carcinogenic process, the quality of the available data may not permit their application or, at the very least, is often not sufficient to allow any discrimination among such models using goodness-of-fit criteria. Furthermore, a recent analysis (*25*) of a simulated data base containing information on time-to-tumor occurrence indicated that low-dose risk estimates generated by a variety of extrapolation procedures occasionally differed from the actual risk by three or more orders of magnitude even when this additional information was included in the modeling process. It also appeared that, on the whole, incorporation of time-to-tumor data did not substantially increase the precision of low-dose risk estimation relative to modeling based only on quantal response information.

When data on the time of tumor occurrence or detection are available, some investigators have proposed that alternative measures or risk based on the concept of time-to-tumor, such as the "mean-free" dose or "late-risk" dose (*26*), be used in the cancer assessment process. However, a detailed evaluation of these measures (*27*) indicated that they suffer from a number of shortcomings and are probably most meaningful when used in combination with the more traditional measures, like the lifetime probability of tumor.

As the preceding discussion has indicated, some uncertainty is associated with the use of most if not all of the commonly employed extrapolation models. Furthermore, goodness-of-fit to the experimental observations is not an effective means of discriminating among models (*28*). Thus, no single low-dose extrapolation procedure has yet gained universal acceptance within the scientific community.

Model selection is further complicated when background tumor incidence is present and presumed to be induced by a mechanism or mechanisms distinct from that associated with the chemical under study. In this instance the various mathematical models may fit the observable data equally well and still generate low-dose risk estimates that may differ by many orders of magnitude. On the other hand if background additivity is assumed, *i.e.* if it is presumed that there is a common mechanism of tumor induction, then all models are essentially linear in the low-dose region (*29*). Even if only a small portion of the background incidence is associated with the same mechanistic process as the study chemical, linearity will tend to prevail at sufficiently low doses (*30*).

All of the preceding discussion has implicitly assumed that the carcinogenic dose-response relationship of interest is that which associates the probability of tumor onset with the administered dose or exposure levels. However, in the case of experimentally-derived data, saturation of critical enzyme systems may occur at high dose levels, and so the real dose of interest may be the biologically effective dose that reaches the actual target site. Since the relationship between the effective dose and the administered dose may be non-linear, pharmacokinetic considerations can significantly modify low-dose risk estimates regardless of the model employed *(31–34)*.

2. Other estimation procedures. Traditionally, the approach to quantitative hazard evaluation for non-carcinogenic, toxicological endpoints has been based on the use of safety factors. With a safety factor approach an "acceptable" exposure level is determined by dividing the no observed effect level (NOEL) from laboratory-based chronic toxicity tests by an appropriately chosen safety factor. In theory the safety factor that is selected attempts to reflect both the possibility of an increased sensitivity of humans relative to laboratory animals and the

variation in susceptibility within the human population.

In spite of its common use, there are a number of potential problems associated with the safety factor approach. The observation of no treatment-related effects at a given dose level may depend, at least in part, on the number of animals exposed at that particular level. Furthermore, the determination of a NOEL ignores the shape of the dose-response curve, even though it would seem that a curve that has a shallow slope in the experimental NOEL region potentially represents a greater toxicological hazard than one that rises steeply in this region. In addition, there is no biological justification for the general use of any specific safety factor. Another important consideration that would argue against the use of a safety factor approach in cancer risk assessment is the fact that this approach assumes the existence of a true population threshold below which no adverse effects can occur. Even if the concept of individual thresholds could be supported, the well-recognized genetic variability in the human population would effectively prevent the estimation of a general population threshold value. Moreover, given the high level of background cancer present in the human environment, it seems unlikely that one could rule out the possibility that a new chemical exposure, however limited, might augment an already ongoing mechanistic process and thereby produce a collective or additive exposure that exceeds the unknown threshold level *(35)*. While recent attempts to categorize carcinogens as acting directly or indirectly on the genome have renewed interest in the possible use of the safety factor approach, most scientists believe that there is not sufficient biological understanding of these processes to make such classifications for the carcinogenic effect of an agent on the total organism at the present time *(36)* (See also Chapter 1).

Another measure that is occasionally proposed for use in cancer hazard evaluation is the relative potency index. Relative potency calculations are based on standard measures of toxicity, such as the ED50. Such measures are limited from an extrapolation viewpoint in that they attempt to compress an entire dose-response curve into a single number suitable for comparative purposes. Therefore, depending upon which toxicological measure underlies its derivation, a relative potency index may offer little insight into the relative risk in the low-dose region.

3. Extrapolation of low-dose risk estimates to target populations. Low-dose risk estimates derived from laboratory animal data still must be extrapolated to the human population. This process is complicated by a variety of factors that differ among species and potentially affect the response to carcinogenic exposures. Included among these factors are differences between humans and experimental test animals with respect to life span, body size, genetic variability or population homogeneity, existence of concurrent disease, pharmacokinetic effects such as metabolism and excretion patterns, and exposure regimen (See also Chapter 1).

The traditional approach to the species extrapolation issue has been to use some standardized baseline for making interspecies comparisons. Commonly employed standardized dosage scales include mg/kg (body weight)/day, ppm in the diet or water, mg/m^2 (body surface area)/day, and mg/kg (body weight)/lifetime. A number of studies *(37–39)* have used the few epidemiologic and laboratory data sets available in the literature involving comparable carcinogenic exposures to evaluate the relative reliability of these various scales for animal-to-human extrapolation. While no single scale emerged as the clear choice in all cases, it does appear that the best agreement between observed and predicted human cancer risk is often obtained when a mg/kg/day or a mg/m^2/day dosage scale is employed *(38, 39)*. However, it must be emphasized that experience in this area is very limited and that the use of any standardized dosage scale for species scale-up is only a crude approximation to a more detailed adjustment that considers the spectrum of factors that can lead to differential species' responses. Furthermore, recent research *(40)* into this issue has indicated that the previously observed *(39)* strong quantitative correlation of various agents' carcinogenic potencies in mice and rats may be explained by a corresponding correlation of maximum tolerated dose levels for these same agents. The general implications of this finding for quantitative species extrapolation are not fully understood at this time.

In addition to the empirical comparisons discussed above, there are a number of biological issues that bear on the choice of a particular dosage scale in species scale-up. For example, it may be important to know whether the parent compound, one or more of its metabolities, or some combination of the two, is responsible for the observed carcinogenic activity. Similarly, the nature of the biochemical target site and the various factors determining the rate, duration, and extent of the toxicologic reaction may be relevant to the selection process. However, while any meaningful information on the underlying carcinogenic mechanism(s) should, if possible, be taken into account when choosing a dosage scale, such specific information often will not be available.

While no extrapolation across species is involved when epidemiological data are used in risk estimation, the marked variability in human sensitivity must be taken into account. Furthermore, there are a number of other problems that may be encountered with attempting to use epidemiological data to construct estimates of liftime risk for a subset of the general population. In the absence of specific knowledge about the synergistic or antagonistic potential of the exposure of interest, additivity of effects is often assumed. This assumption can lead to either an under or over estimation of the true carcinogenic risk presented by the exposure under consideration.

Epidemiological investigations are often conducted for only a limited period of time, and failure to adjust properly for incomplete follow-up of subjects can significantly affect the estimation of life-time risk. Similarly, estimation of lifetime cancer risks is also complicated if the available epidemiologic data involves exposures that fall far short of a normal lifespan. For example, if a multistage mechanism is assumed, then the effect of early termination of exposure will be dependent on the stages of the carcinogenic process that are influenced by the exposure *(41, 42)*.

D. Risk Characterization

The final step in the risk assessment process, risk characterization, usually involves a total evaluation of the qualitative evidence, the exposure information, and the quantitative results. The final product of this evaluation is, typically, the generation of a quantitative estimate of the human cancer risk associated with the projected exposure profile.

As discussed earlier, the qualitative evidence is evaluated by a weight-of-the-evidence approach. Uncertainties in the data are resolved using best scientific judgement. While no overall measure can be given of the uncertainty, the decision-maker needs to be aware of the strengths of these qualitative data when making this dichotomous determination. The results of a total risk assessment should be expressed in such a way that there is a clear distinction drawn between a chemical for which the

qualitative evidence is overwhelming and a chemcial for which the qualitative evidence is only marginally persuasive.

As developed in Chapter 5, the exposure assessment may contain numerous uncertainties. For example, the assessment may reflect inherent limitations, such as those associated with analytical monitoring or modeling techniques. Further, assumptions are sometimes necessary in the absence of data in order to generate an assessment; *e.g.*, the amount of soil ingested by a child. In many such cases, "reasonable worst case" assumptions are made so that one errs on the side of pubic safety. The exposure assessment should be expressed in such a way that these uncertainties and assumptions are evident to the decision-maker.

Description of uncertainy is also important in the development of the quantitative estimate of human cancer risk. Unfortunately, the description of uncertainty in this step of the assessment process is often limited to the statistical uncertainty involved in low-dose extrapolation as expressed through the calculation of confidence limits for risk estimates.

As has already been noted, the choice of a particular low-dose extrapolation model can have a pronounced influence on the estimated low-dose risk. Therefore, it has been proposed *(43)* that an indication of the variability introduced by model selection be obtained by consideration the range in the magnitude of low-dose risk estimates associated with the more commonly employed models.

Furthermore, if laboratory data are utilized in estimating low-dose risk, some attempt can be made to describe the biological variability associated with the process of species scale-up by contrasting estimates based on different dosage scales and animal test systems.

Finally, it is important in the characterization of human cancer risk to summarize briefly any judgements or assumptions that may have entered into the risk assessment process to insure that they are clearly differentiated from scientific fact *(1)*.

III. EMERGING AREAS OF SCIENCE EXPECTED TO IMPACT ON REGULATORY ACTIONS

Although no one can predict with certainty what and when major breakthroughs will occur in science, many emerging areas of science can be expected to affect significantly cancer risk assessment and related regulatory decisions in the future.

Greater knowledge of the metabolic pathways of chemical compounds and the pharmacokinetics of such agents in various animal species should help regulatory agencies to ascertain whether carcinogenicity tests have been performed in an animal assay system which is relevant to man. Metabolic pathways for activation of a chemical carcinogen known to be important in humans but not present in the animal assay system used lessen the validity of the data for human risk evaluation. Similarly, factors such as diet, age, stress, sex, hormonal status, etc. can influence the metabolic conversion of chemicals to ultimate carcinogens and may be important in hazard evaluations conducted on proposed compounds.

DNA adducts remaining in organs *in vivo*, in the absence of tumors in a test animal species, may be innocuous, or they may indicate physiological peculiarities in the test system that prevent progression to overt tumors. Such inhibitory factors may or may not be present in other assay systems or in man. Alternatively, failure to demonstrate tumor formation may indicate the need for promoter activity or interaction with other modifying agents. Substantial adduct formation without resulting biological manifestations may suggest either that the lesions induced are innocuous or dictate that more testing is needed to access the human exposure experience (*i.e.* multiple exposure factors, promoting agents, nutrition, etc.).

Most prescreen assays for chemical carcinogens presently rely primarily on chemical interaction with DNA (point mutation assays, DNA damage and repair). This approach may be inadequate since certain chemicals may not induce cancer by direct interaction with the DNA. New assays for carcinogenicity are being developed to include animal models where these factors can be taken into consideration in the evaluation of chemical agents.

Since tumor induction is generally considered to be a multi-stage process, each stage may be under independent genetic control. Test systems are being developed and used that are based on animals believed to be defective in genetic factors similarly to those defects that predispose humans to cancer induction. Such test systems may also be used to screen sensitivity to selected carcinogens for subpopulations of humans with similar genetic characteristics.

A relationship seems to exist between altered DNA and carcinogenesis. The presence of carcinogen-altered DNA is being explored as a possible test system to detect persistent damage at the molecular level after exposure to suspect carcinogenic chemicals. Such a system could be used to screen exposed human populations for altered DNA bases using monoclonally-derived specific antibodies to modified bases. Such assays may also help place in perspective effects on the DNA arising from endogenous vs. exogenous DNA damaging agents. This screening would be an example of using a marker for altered cells important to the carcinogenic process. Additional biomarkers should be developed for cells in all stages of carcinogenesis. Such tests might be expected to identify the carcinogenic potential of suspect agents and the population(s) at risk for possible future development of cancers.

Certain DNA base alterations may occur in regions of the genome that seem to be unimportant for cancinogenesis. It is important to know which alterations are necessary for initiation of a tumor cell and which are masked or not expressed. Information is being assimilated on types of alterations in "control" regions and the relationship of the number of altered bases in these regions to tumor formation. These data will provide information needed to differentiate those insults to DNA that are critical from those that are not. If multi-critical sites must be altered in a particular manner, this approach may be used to examine multi-stage phenomena of cancer. The measurement of risk from particular carcinogens at the cellular level would then be based on a more selective effect than the level of total DNA adducts.

Other areas of research that may in time have an effect on regulatory decisions include the development of model systems to assay for compounds influencing promotion and progression of initiated populations, elucidation of factors controling cellular differentiation, and tests for chromosomal rearrangements and oncogene activities. Each of these areas of study will not only expand our knowledge of mechanisms but also permit a more realistic assessment of risk. Besides improving assessment, increased knowledge of mechanism may also result in a greater ability to render carcinogenic agents biologically innocuous, removing hazards.

IV. SUMMARY

The assessment of human cancer risk associated with different chemical exposures is seen to be a complex mixture of currently available scientific data, assumptions and judgments based on prevailing scientific thought, and policy decisions. The process involves the identification of potential human cancer hazards, usually based on epidemiological, clinical, and long-term

animal studies, the determination of potential human exposure profiles, the estimation of the unknown, underlying relationship between exposure and response, and, finally, the combination of the results of these exercises to characterize the expected human cancer risks. Some degree of uncertainty is involved in all phases of this process, and as a result, no simple, standardized format has yet been developed for evaluating human cancer risk, even though a number of basic principles have emerged. It is apparent that human cancer risk assessment is still in an evolutionary state and that a number of emerging areas of science will impact on this process in the future.

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[FR Doc. 84-13136 Filed 5-21-84; 8:45 am]

BILLING CODE 8C 4140-01-M

federal register

Tuesday
May 22, 1984

Part III

Department of the Interior

Fish and Wildlife Service

50 CFR Part 17

Endangered and Threatened Wildlife and Plants; Review of Invertebrate Wildlife for Listing as Endangered or Threatened Species

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

Endangered and Threatened Wildlife and Plants; Review of Invertebrate Wildlife for Listing as Endangered or Threatened Species

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of review.

SUMMARY: The U.S. Fish and Wildlife Service identifies invertebrate animal taxa native to the United States being considered for addition to the List of Endangered and Threatened Wildlife. Although "candidate" species receive no substantive or procedural protections under the Endangered Species Act, the Service encourages federal agencies and other planners to take such taxa into account in environmental planning under the National Environmental Policy Act and similar statutes. Also identified in this notice are those invertebrate taxa that were previously under consideration for listing, but that are currently presumed either to be extinct, to not be valid species or subspecies, or to be more abundant and widespread than previously thought and/or not subject to identifiable threats.

DATE: Comments may be submitted until further notice.

ADDRESSES: Interested persons or organizations are requested to submit comments to: Director, U.S. Fish and Wildlife Service, Department of the Interior, Washington, D.C. 20240. Comments and materials relating to this notice are available for public inspection by appointment during normal business hours at the Service's Office of Endangered Species, Suite 500, 1000 North Glebe Road, Arlington, Virginia.

Information relating to particular taxa may be obtained from appropriate Service Regional Offices listed below:

Region 1.—California, Hawaii, Idaho, Nevada, Oregon, Washington, American Samoa, Guam, Territory of the Northern Marianas, and Trust Territories of the Pacific.

Regional Director (ARD/FA), U.S. Fish and Wildlife Service, Suite 1692, Lloyd 500 Building, 500 N.E. Multnomah Street, Portland, Oregon 97232 (503/231–6131 or FTS 8/429–6131).

Region 2.—Arizona, New Mexico, Oklahama, and Texas.

Regional Director (ARD/AFF), U.S. Fish and Wildlife Service, P.O. Box 1306, Albuquerque, New Mexico 87103 (505/766–3972 or FTS 8/474–3972).

Region 3.—Illinois, Indiana, Iowa, Michigan, Minnesota, Missouri, Ohio, and Wisconsin.

Regional Director (ARD/AFF), U.S. Fish and Wildlife Service, Federal Building, Fort Snelling, Twin Cities, Minnesota 55111 (612/725–3596 or FTS 8/725–3596).

Region 4.—Alabama, Arkansas, Florida, Georgia, Kentucky, Louisiana, Mississippi, North Carolina, South Carolina, Tennessee, Puerto Rico, and the Virgin Islands.

Regional Director (ARD/FA), U.S. Fish and Wildlife Service, The Richard B. Russell Federal Building, 75 Spring Street, S.W., Atlanta, Georgia 30303 (404/221–3583 or FTS 8/242–3583).

Region 5.—Connecticut, Delaware, District of Columbia, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont, Virginia, and West Virginia.

Regional Director (ARD/FA), U.S. Fish and Wildlife Service, Suite 700, One Gateway Center, Newton Corner, Massachusetts 02158 (617/965–5100 ext. 316 or FTS 8/829–9316, 7, 8).

Region 6.—Colorado, Kansas, Montana, Nebraska, North Dakota, South Dakota, Utah, and Wyoming.

Regional Director (ARD/FA), U.S. Fish and Wildlife Service, P.O. Box 25486, Denver Federal Center, Denver, Colorado 80225 (303/234–2496 or FTS 8/234–2496).

Region 7.—Alaska.

Regional Director (ARD/AFF), U.S. Fish and Wildlife Service, 1101 East Tudor Road, Anchorage, Alaska 99503 (907/263–3539 or FTS 8/263–3539).

FOR FURTHER INFORMATION CONTACT: John L. Spinks, Jr., Chief, Office of Endangered Species, U.S. Fish and Wildlife Service, Washington, D.C. 20240 (703/235–2771), or the appropriate Regional Office.

SUPPLEMENTARY INFORMATION:

Background

The Endangered Species Act of 1973 (16 U.S.C. 1531 *et seq.*) requires a determination of whether species of wildlife and plants are endangered or threatened based on the best available scientific and commercial data. For many years, the U.S. Fish and Wildlife Service (hereafter the Service) has been gathering data on taxa of invertebrates (sponges, crustaceans, arachnids, insects and mollusks), native to the United States, that have appeared, at least at times, to warrant consideration for addition to the List of Endangered and Threatened Wildlife. The accompanying table identifies many of these taxa (including, by definition, biological subspecies) and assigns each to one of the following three categories.

Category 1 comprises taxa for which the Service currently has substantial information on hand to support the biological appropriateness of proposing to list the species as endangered or threatened. Currently, data are being gathered concerning essential habitat needs and, for some taxa, data concerning the precise boundaries for critical habitat designations. Development and publication of proposed rules on such species is anticipated.

Category 2 comprises taxa for which information now in possession of the Service indicates that proposing to list the species as endangered or threatened is possibly appropriate, but for which conclusive data on biological vulnerability and threat(s) are not currently available to support proposed rules at this time. Taxa in this category for which there have not been authenticated records since 1963 are indicated by an asterisk (*); some of these are possibly extinct, but further biological research and field study are needed to ascertain their status with any confidence. It is likely that many of the taxa in this category will not warrant listing, while some will be found to be in greater danger of extinction than some taxa in category 1. It is hoped that this notice will encourage the necessary research on vulnerability and/or threats for these taxa.

Category 3 comprises taxa that are no longer being considered for listing as endangered or threatened. Such taxa are included in one of three subcategories depending on the reasons for removal from consideration.

3A. Taxa for which the Service has persuasive evidence of extinction. If rediscovered, however, such species might acquire high priority for listing. At this time, the best available information indicates that the taxa included in this category, or the habitats from which they were known, are in fact extinct or destroyed, respectively.

3B. Names that, on the basis of current taxonomic understanding, usually as represented in published revisions and monographs, do not represent taxa meeting the Act's definition of "species." Such supposed taxa could be reevaluated in the future on the basis of subsequent research.

3C. Taxa that have proven to be more abundant or widespread than was previously believed and/or those that are not subject to any identifiable threat. Should further research or changes in land use indicate significant

decline in any of these taxa, they may be reevaluated for possible inclusion in category 1 or 2.

The Service hereby solicits data concerning the taxa in the accompanying table. Especially sought is information—

(1) Indicating that a taxon would more properly be assigned to a category other than the one in which it appears;

(2) Nominating a taxon not included in the table;

(3) Recommending an area as critical habitat for a candidate taxon, or indicating why it would not be prudent to propose critical habitat for a taxon, or why critical habitat may not be determinable for a taxon;

(4) Documenting threats to any of the listed taxa;

(5) Pointing out taxonomic changes for any of the taxa;

(6) Suggesting new or more appropriate names; or

(7) Noting errors, such as in the indicated distributions.

The Service intends to consider all data received in response to this notice, to make appropriate amendments to the accompanying table, and to indicate intentions with regard to future listing actions. Substantive changes in status may be announced by periodic notice in the **Federal Register.**

The following table is arranged in a general systematic order, beginning with sponges and ending with mollusks. For each taxon, the assigned category appears on the left, followed by the common name, the scientific name, the family name, and the known distribution, usually indicated by abbreviations of State names. For mollusks the authority and date for the scientific name is given, because of unusual instability in systematics of those groups. The species may no longer occur in some of the areas shown. Some taxa have been included that have not yet been formally described in the scientific literature. Such taxa are indicated by the abbreviation "sp." after the generic name, or "ssp." after the generic and specific names.

A provisional vernacular name in English or Hawaiian is given for most species. Some are vernacular names actually in common use, and in some groups whose systematics most need revision these are about as informative as the current scientific name in Latin. Most of the taxa are rare, however, and the obscurity of many almost guarantees that no name has much history of use. Group names such as snail, amphipod, or dragonfly have been appended to many names to clarify distinctions from other invertebrates or plants with similar or confusing names; such extra qualifiers would probably be dropped from any name that came into truly common use. These provisional names may be changed or discarded if their use is later found to be inappropriate.

This notice was prepared by the zoologists in the Service's Office of Endangered Species in Washington that specialize in invertebrate species, and the Endangered Species Program staff of the Service's Regional Offices and Field Stations.

List of Subjects in 50 CFR Part 17

Endangered and threatened wildlife, Fish, Marine mammals, Plants (agriculture).

Dated: April 24, 1984.

G. Ray Arnett,

Assistant Secretary for Fish and Wildlife and Parks.

Category and common name	Scientific name	Family	Distribution
SPONGES			
3B—Muscular sponge	*Anheteromyia biceps*	Spongillidae	MI.
2—Carolina sponge	*Corvomeyenia carolinensis*	Spongillidae	SC.
2—Oklawaha sponge	*Dosilia palmeri*	Spongillidae	FL, Mexico.
2—Kissimmee sponge	*Ephydatia subtilis*	Spongillidae	FL.
2—Pennsylvania sponge	*Heteromeyenia longistylis*	Spongillidae	PA.
2—Oneida sponge	*Spongilla heteroslerifa*	Spongillidae	NY.
3B—Spongy sponge	*Spongilla spongiosa*	Spongillidae	SC.
FLATWORMS (Turbellaria)			
2—(No common name)	*Kenkia rhynchida*	Kenkiidae	OR.
2—(No common name)	*Macrocotyla glandulosa*	Kenkiidae	MO, IA.
2—(No common name)	*Procotyla typhlops*	Kenkiidae	MD, VA.
3A—Holsinger's groundwater planarian	*Sphalloptena holsingeri*	Planariidae	VA.
2—Refton Cave planarian	*Sphalloplana pricei*	Planariidae	PA.
3A—Bigger's groundwater planarian	*Sphalloplana subtilis*	Planariidae	VA.
BRANCHIOPODS (Crustaceans, Subclass Branchiopoda)			
2—Mono Lake brine shrimp	*Artemia monica*	Artemiidae	CA.
ISOPODS (Crustaceans, Order Isopoda)			
2—Clifton Cave isopod	*Caecidotea barri*	Asellidae	KY.
2—Bat Cave isopod	*Caecidotea macropoda*	Asellidae	OK.
2—Nickajack Cave isopod	*Caecidotea nickajackensis*	Asellidae	TN.
2—Rye Cove Cave isopod	*Lirceus culveri*	Asellidae	VA.
2—Lee County Cave isopod	*Lirceus usdagalun*	Asellidae	VA.
AMPHIPODS (Crustaceans, Order Amphipoda)			
2—Central Missouri cave amphipod	*Allocrangonyx hubrichti*	Crangonyctidae	MO.
2—Oklahoma cave amphipod	*Allocrangonyx pellucidus*	Crangonyctidae	OK.
3C—Kansas well amphipod	*Bactrurus hubrichti*	Crangonyctidae	KS, MO, OK.
3C—Anomalous spring amphipod	*Crangonyx anomalus*	Crangonyctidae	IN, KY, OH.
3C—Appalachian Valley cave amphipod	*Crangonyx antennatus*	Crangonyctidae	AL, IL, TN, VA.
2—Pennsylvania cave amphipod	*Crangonyx dearolfi*	Crangonyctidae	MD, PA.
2—Florida cave amphipod	*Crangonyx grandimanus*	Crangonyctidae	FL.
2—Hobbs' cave amphipod	*Crangonyx hobbsi*	Crangonyctidae	FL.
3C—Minor cave amphipod	*Crangonyx minor*	Crangonyctidae	IA, IL, IN, MI, Canada.
3C—Packard's cave amphipod	*Crangonyx packardi*	Crangonyctidae	IN, KY.
2—Illinois cave amphipod	*Gammarus acherondytes*	Gammaridae	IL.
2—Bousfield's amphipod	*Gammarus bousfieldi*	Gammaridae	KY.
2—Noel's amphipod	*Gammarus desperatus*	Gammaridae	NM.
2—Diminutive amphipod	*Gammarus hyalleloides*	Gammaridae	TX.
2—Pecos amphipod	*Gammarus pecos*	Gammaridae	TX.
2—Kauai cave amphipod	*Spelaeorchestia koloana*	Talitridae	HI.
3C—Allegheny cave amphipod	*Stygobromus (=Stygonectes) allegheniesis*	Crangonyctidae	MD, NY, PA.
2—Tidewater interstitial amphipod	*Stygobromus (=Apocrangonyx) araeus*	Crangonyctidae	VA.
2—Arizona cave amphipod	*Stygobromus arizonensis*	Crangonyctidae	AZ.

Category and common name	Scientific name	Family	Distribution
2—Balcones cave amphipod	*Stygobromus (=Stygonectes) balconius*	Crangonyctidae	TX.
2—Barr's cave amphipod	*Stygobromus (=Stygonectes) barri*	Crangonyctidae	MO.
2—Bifurcated cave amphipod	*Stygobromus (=Stygonectes) bifurcatus*	Crangonyctidae	TX.
2—Bowman's cave amphipod	*Stygobromus (=Stygonectes) bowmani*	Crangonyctidae	OK.
2—Clanton's cave amphipod	*Stygobromus (=Stygonectes) clantoni*	Crangonyctidae	KS, MO.
2—Burnsville Cove cave amphipod	*Stygobromus (=Stygonectes) conradi*	Crangonyctidae	VA.
2—Cooper's cave amphipod	*Stygobromus (=Stygonectes) cooperi*	Crangonyctidae	WV.
2—Cascade Cave amphipod	*Stygobromus (=Stygonectes) dejectus*	Crangonyctidae	TX.
2—Elevated Spring amphipod	*Stygobromus (=Stygonectes) elatus*	Crangonyctidae	AR.
2—Greenbrier Cave amphipod	*Stygobromus (=Stygonectes) emarginatus*	Crangonyctidae	MD, WV.
2—Ephemeral cave amphipod	*Stygobromus (=Apocrangonyx) ephemerus*	Crangonyctidae	VA.
3C—Central Kentucky cave amphipod	*Stygobromus exilis*	Crangonyctidae	AL, KY, TN.
2—Ezell's Cave amphipod	*Stygobromus (=Stygonectes) flagellatus*	Crangonyctidae	TX.
3C—Shenandoah Valley cave amphipod	*Stygobromus (=Stygonectes) gracilipes*	Crangonyctidae	MD, PA, VA, WV.
2—Grady's cave amphipod	*Stygobromus gradyi*	Crangonyctidae	CA.
2—Devil's Sinkhole amphipod	*Stygobromus (=Stygonectes) hadenoecus*	Crangonyctidae	TX.
2—Hara's cave amphipod	*Stygobromus harai*	Crangonyctidae	CA.
2—(No common name)	*Stygobromus heteropodus*	Crangonyctidae	MO.
2—Malheur Cave amphipod	*Stygobromus hubbsi*	Crangonyctidae	OR.
2—Tidewater amphipod	*Stygobromus (=Stygonectes) identatus*	Crangonyctidae	VA.
3C—Iowa amphipod	*Stygobromus iowae*	Crangonyctidae	IA.
2—Long-legged cave amphipod	*Stygobromus (=Stygonectes) longipes*	Crangonyctidae	TX.
3A—Rubious Cave amphipod	*Stygobromus (=Apocrangonyx) lucifugus*	Crangonyctidae	IL.
2—MacKenzie's cave amphipod	*Stygobromus mackenziei*	Crangonyctidae	CA.
3C—Southwestern Virginia cave amphipod	*Stygobromus mackini*	Crangonyctidae	TN, VA.
2—Mountain cave amphipod	*Stygobromus (=Stygonectes) montanus*	Crangonyctidae	AR.
2—Morrison's cave amphipod	*Stygobromus (=Stygonectes) morrisoni*	Crangonyctidae	VA, WV.
2—Bath County cave amphipod	*Stygobromus (=Stygonectes) mundus*	Crangonyctidae	VA.
2—Norton's cave amphipod	*Stygobromus (=Apocrangonyx) nortoni*	Crangonyctidae	TN.
2—Onondaga Cave amphipod	*Stygobromus onondagaensis*	Crangonyctidae	MO.
3C—Oregon cave amphipod	*Stygobromus oregonensis*	Crangonyctidae	OR.
2—Ozark cave amphipod	*Stygobromus (=Stygonectes) ozarkensis*	Crangonyctidae	AR, MO, OK.
2—Minute cave amphipod	*Stygobromus (=Apocrangonyx) parvus*	Crangonyctidae	WV.
2—Peck's cave amphipod	*Stygobromus (=Stygonectes) pecki*	Crangonyctidae	TX.
2—Pizzini's amphipod	*Stygobromus (=Stygonectes) pizzinii*	Crangonyctidae	DC, MD, PA, VA.
2—Wisconsin well amphipod	*Stygobromus putealis*	Crangonyctidae	WI.
2—Reddell's cave amphipod	*Stygobromus (=Stygonectes) reddelli*	Crangonyctidae	TX.
2—Alabama well amphipod	*Stygobromus smithi*	Crangonyctidae	AL.
2—Spring cave amphipod	*Stygobromus (=Stygonectes) spinatus*	Crangonyctidae	WV.
2—Stellmack's cave amphipod	*Stygobromus (=Stygonectes) stellmacki*	Crangonyctidae	PA.
2—Subtle cave amphipod	*Stygobromus (=Apocrangonyx) subtilis*	Crangonyctidae	IL, MO.
3C—Potomac groundwater amphipod	*Stygobromus (=Stygonectes) tenuis potomacus*	Crangonyctidae	DC, MD, PA, VA.
2—Wengerors' cave amphipod	*Stygobromus wengerorum*	Crangonyctidae	CA.
CRAYFISHES AND SHRIMPS (Crustaceans, Order Decapoda)			
1—Shasta (=Placid) crayfish	*Pacifastacus fortis*	Astacidae	CA.
2—Alabama cave shrimp	*Palaemonias alabamae*	Atyidae	AL.
1—California freshwater shrimp	*Syncaris pacifica*	Atyidae	CA.
2—Mona cave shrimp	*Typhlatya monae*	Atyidae	PR, West Indies.
2—(No common name)	*Cambarus batchi*	Cambaridae	KY.
2—Big South Fork crayfish	*Cambarus bouchardi*	Cambaridae	KY, TN.
2—Greensboro burrowing crayfish	*Cambarus catagius*	Cambaridae	NC.
2—New River riffle crayfish	*Cambarus chasmodactylus*	Cambaridae	NC, VA, WV.
2—Chickamauga crayfish	*Cambarus extraneus*	Cambaridae	GA, TN.
2—Obey crayfish	*Cambarus obeyensis*	Cambaridae	TN.
3C—Conchas crayfish	*Orconectes deanae*	Cambaridae	NM.
2—Louisville crayfish	*Orconectes jeffersoni*	Cambaridae	KY.
2—Nashville crayfish	*Orconectes shoupi*	Cambaridae	TN.
2—Palm Springs Cave crayfish	*Procambarus acherontis*	Cambaridae	FL.
2—Pee Dee lotic crayfish	*Procambarus lepidodactylus*	Cambaridae	NC, SC.
2—(No common name)	*Procambarus connus*	Cambaridae	MS.
2—Texas cave shrimp	*Palaemonetes antrorum*	Palaemonidae	TX.
1—Squirrel Chimney cave shrimp	*Palaemonetes cummingi*	Palaemonidae	FL.
SPIDERS (Arachnids, Order Aranea)			
2—Dolloff Cave spider	*Meta dolloff*	Araneidae	CA.
2—Torreya trap-door spider	*Cyclocosmia torreya*	Ctenizidae	FL.
2—Key gnaphosid spider	*Cesonia irvingi*	Gnaphosidae	FL.
2—Kauai cave wolf spider (pe'e pe'e maka 'ole)	*Adelocosa anops*	Lycosidae	HI.
2—Rosemary wolf spider	*Lycosa ericeticola*	Lycosidae	FL.
2—Lake Placid funnel wolf spider	*Sosippus placidus*	Lycosidae	FL.
2—Santa Cruz teleman spider	*Telema* sp. (undescribed)	Telemidae	CA.
PSEUDOSCORPIONS (Arachnids, Order Pseudoscorpiones)			
2—Empire Cave pseudoscorpion	*Microcreagris imperialis*	Neobisiidae	CA.
ROCKHOPPERS AND BRISTLETAILS (Insects, Order Archeognatha)			
2—Hawaiian long-palp bristletail	*Machiloides heteropus*	Machilidae	HI.
2—Perkin's club-palp bristletail	*Machiloides perkinsi*	Machilidae	HI.
MAYFLIES (Insects, Order Ephemeroptera)			
2—Berner's two-winged mayfly	*Heterocleon berneri*	Baetidae	GA.
2—American sand-burrowing mayfly	*Dolania americana*	Behningiidae	FL, GA, SC, NC.
2*—Yellow brachycercus mayfly	*Brachycercus flavus*	Caenidae	LA*.
2*—Frison's ceratellan mayfly	*Ceratella frisoni*	Ephemerellidae	AL*, IL*.
2*—Spiculose ceratellan mayfly	*Ceratella spiculosa*	Ephemerellidae	TN*, NC*.
2—Argo ephemerellan mayfly	*Ephemerella argo*	Ephemerellidae	IL, IN.
2*—Colorado burrowing mayfly	*Ephemera compar*	Ephemeridae	CO*.
2*—West Virginia burrowing mayfly	*Ephemera triplex*	Ephemeridae	WV*.
3A—Robust pentagenian burrowing mayfly	*Pentagenia robusta*	Ephemeridae	OH*.
2—Meridion blackwater mayfly	*Pseudirion meridionalis*	Heptageniidae	FL, GA.

Category and common name	Scientific name	Family	Distribution
2—Cahaba sand-filtering mayfly	*Homoeoneuria cahabensis*	Oligoneuridae	AL, MS.
2—Blackwater sand-filtering mayfly	*Homoeoneuria dolani*	Oligoneuridae	FL, GA, SC.
3A—Pecatonica River mayfly	*Acanthomotropus pecatonica*	Siphlonuridae	IL*.
2—False ameletus mayfly	*Ameletus falsus*	Siphlonuridae	AZ*.
2*—Diverse isonychian mayfly	*Isonychia diversa*	Siphlonuridae	TN*.
DRAGONFLIES AND DAMSELFLIES (Insects, Order Odonata)			
2—Barrens bluet damselfly	*Enallagma recurvatum*	Coenagrionidae	MA, NY, NJ.
1—San Francisco forktail damselfly	*Ischnura gemina*	Coenagrionidae	CA.
2—Adytum megalagrion damselfly	*Megalagrion adytum*	Coenagrionidae	HI.
2*—Fallax megalagrion damselfly	*Megalagrion amaurodytum fallax*	Coenagrionidae	HI*.
2*—Pele megalagrion damselfly	*Megalagrion amaurodytum peles*	Coenagrionidae	HI*.
2*—Waianae megalagrion damselfly	*Megalagrion amaurodytum waianaenum*	Coenagrionidae	HI*.
3A—Jugorum megalagrion damselfly	*Megalagrion jugorum*	Coenagrionidae	HI*.
2—Leptodemas megalagrion damselfly	*Megalagrion leptodemus*	Coenagrionidae	HI.
2—Molokai megalagrion damselfly	*Megalagrion molokaiense*	Coenagrionidae	HI.
3A—Nesiotes megalagrion damselfly	*Megalagrion nesiotes*	Coenagrionidae	HI*.
2—Nigrohamatum megalagrion damselfly	*Megalagrion nigrohamatum*	Coenagrionidae	HI.
2—Blackline megalagrion damselfly	*Megalagrion nigrolineatum*	Coenagrionidae	HI.
2—Oahu megalagrion damselfly	*Megalagrion oahuensis*	Coenagrionidae	HI.
2—Oceanic megalagrion damselfly	*Megalagrion oceanicum*	Coenagrionidae	HI.
2—Pacific megalagrion damselfly	*Megalagrion pacificum*	Coenagrionidae	HI.
2—Orange-black megalagrion damselfly	*Megalagrion xanthomelas*	Coenagrionidae	HI.
1—Say's spiketail dragonfly	*Cordulegaster sayi*	Cordulegastridae	FL, GA.
2—Apalichicola twilight skimmer dragonfly	*Neurocordulia clara*	Corduliidae	AI, FL.
2*—Ohio emerald dragonfly	*Somatochlora hineana*	Corduliidae	OH*, IN*.
2—Big Thicket emerald dragonfly	*Somatochlora margarita*	Corduliidae	TX.
2—Banded bog skimmer dragonfly	*Williamsonia fintneri*	Corduliidae	NY, NJ, MA, RI, NH.
2—Sandhills clubtail dragonfly	*Gomphus (=Hylogomphus) carolinus*	Gomphidae	NC, SC.
3B—Riffle clubtail (syn.)	*Gomphus adelphus (=G. brevis)*	Gomphidae	MA, NY.
2—Cherokee clubtail dragonfly	*Gomphus consanguis*	Gomphidae	SC, AL, NC, TN, VA.
2—Tennessee clubtail dragonfly	*Gomphus sandrius*	Gomphidae	TN.
2—Septima's clubtail dragonfly	*Gomphus septima*	Gomphidae	AI, NC.
2—Bronze clubtail dragonfly	*Gomphus townesi*	Gomphidae	FL, AL, SC, NC, TN.
2*—Edmund's snaketail dragonfly	*Ophiogomphus edmundo*	Gomphidae	NC*.
2—Midget snaketail dragonfly	*Ophiogomphus howei*	Gomphidae	MA*, NY, PA, VA, KY, NC, TN.
2—Alleghany snaketail dragonfly	*Ophiogomphus incurvatus alleghaniensis*	Gomphidae	WV, VA, AL, TN?.
2—Variegated clubtail dragonfly	*Progomphus bellei*	Gomphidae	FL, NC.
2—Wabash belted skimmer dragonfly	*Macromia wabashensis*	Macromiidae	OH*, IN* TX.
STONEFLIES (Insects, Order Plecoptera)			
2—Lake Tahoe benthic stonefly	*Capnia lacustra*	Capniidae	CA, NV.
3A—Robert's alloperlan stonefly	*Alloperla roberti*	Chloroperlidae	IL*.
2—Schoolhouse Springs leuctran stonefly	*Leuctra szczytkoi*	Leuctridae	LA.
2—Meltwater lednian stonefly	*Lednia tumana*	Nemouridae	MT.
2—Wahkeena Falls flightless stonefly	*Nemoura wahkeena*	Nemouridae	OR.
2—Fender's soliperlan stonefly	*Soliperla fenderi*	Peltoperlidae	WA.
2—Georgia beloneurian stonefly	*Beloneuria georgiana*	Perlidae	GA, NC.
2—Cheaha beloneurian stonefly	*Beloneuria jamesae*	Perlidae	AL.
2—Hanson's appalachian stonefly	*Hansonoperla appalachia*	Perlidae	TN, MA.
2—Leon River taeniopteryx stonefly	*Taeniopteryx starki*	Taeniopterygidae	TX.
GRASSHOPPERS, CRICKETS AND KATYDIDS (Insects, Order Orthoptera)			
2—Idaho point-headed grasshopper	*Acrolophitus pulchellus*	Acrididae	ID.
2—Michigan bog grasshopper	*Appalachia arcana*	Acrididae	MI
2—Siskiyou chloealtis grasshopper	*Chloealtis aspasma*	Acrididae	OR.
2*—Superb spharagemon grasshopper	*Spharagemon superbum*	Acrididae	TX*, OK*
2—Pinaleno monkey grasshopper	*Eumorsea pinaleno*	Eumastacidae	AZ.
2—Desert monkey grasshopper	*Psychomastix deserticola*	Eumastacidae	CA/NV.
2—Howarth's cave cricket	*Caconemobius howarthi*	Gryllidae	HI
2—Schauinsland's bush cricket	*Caconemobius schauinslandi*	Gryllidae	HI.
2—Kaumana Cave cricket	*Caconemobius varius*	Gryllidae	HI
2—Keys scaly cricket	*Cycloptilum irregularis*	Gryllidae	FL
2*—Prairie mole cricket	*Gryllotalpa major*	Gryllidae	KS*, IL*, MO*, MS*, OK*.
2—Oahu deceptor bush cricket	*Leptogryllus deceptor*	Gryllidae	HI.
2—Laricis tree cricket	*Oecanthus laricis*	Gryllidae	MI/OH.
2—Volcanoes cave cricket	*Thaumatogryllus cavicola*	Gryllidae	HI.
2—Kauai thin-footed bush cricket	*Thaumatogryllus variegatus*	Gryllidae	HI.
2—Arizona giant sand treader cricket	*Daihinibaenetes arizonensis*	Rhaphidophoridae	AZ.
2—Kelso giant sand treader cricket	*Macrobaenetes kelsoensis*	Rhaphidophoridae	CA.
2—Coachella giant sand treader cricket	*Macrobaenetes valgum*	Rhaphidophoridae	CA.
2—Samwell Cave cricket	*Pristoceuthophilus* sp.	Rhaphidophoridae	CA.
2—Tanner's black camel cricket	*Utabaenetes tanneri*	Rhaphidophoridae	UT.
2—Kelso Jerusalem cricket	*Ammopelmatus kelsoensis*	Stenopelmatidae	CA
2—Port Conception Jerusalem cricket	*Ammopelmatus muwu*	Stenopelmatidae	CA.
2—Coachella Valley Jerusalem cricket	*Stenopelmatus cahuilaensis*	Stenopelmatidae	CA.
2—Navajo Jerusalem cricket	*Stenopelmatus navajo*	Stenopelmatidae	AZ.
2—Sierra pygmy grasshopper	*Tetrix sierrana*	Tetrigidae	CA.
2—Torreya pygmy grasshopper	*Tettigidea empedonapia*	Tetrigidae	FL.
2—Nihoa banza conehead katydid	*Banza nihoae*	Tettigoniidae	HI.
2—Big Pine Key conehead katydid	*Belocephalus micanopy*	Tettigoniidae	FL.
2—Keys short-winged conehead katydid	*Belocephalus sleighti*	Tettigoniidae	FL.
3A—Remote conehead katydid	*Conocephaloides remotus*	Tettigoniidae	HI*.
2—Middlekauf's shieldback katydid	*Idiostatus middlekauffi*	Tettigoniidae	CA.
3A—Antioch Dunes shieldback katydid	*Neduba extincta*	Tettigoniidae	CA*.
2—Santa Monica shieldback katydid	*Neduba longipennis*	Tettigoniidae	CA.
COCKROACHES (Insects, Order Blattodes)			
2—Tuna cave roach	*Aspiduchus cavernicola*	Blattidae	PR.
ZOROAPTERANS (Insects, Order Zoroaptera)			
2—Swezey's zoroapteran	*Zorotypus swezeyi*	Zorotypidae	HI.

Category and common name	Scientific name	Family	Distribution
TRUE BUGS (Insects, Order Hemiptera)			
2—Saratoga Springs belostoman bug	*Belostoma saratogae*	Belostomatide	CA.
2—Mauna Loa metrargan seed bug	*Metrarga obscura*	Lygaeidae	HI.
2—Kauai band-legged neseis seed bug	*Neseis alternatus*	Lygaeidae	HI.
2—Mt. Haleakala neseis seed bug	*Neseis haleakalae*	Lygaeidae	HI.
2—Villosan flightless seed bug	*Nesocryptias villosa*	Lygaeidae	HI.
2—French Frigate Shoal nysius seed bug	*Nysius frigatensis*	Lygaeidae	HI.
2—Fullaway's nysius seed bug	*Nysius fullawayi*	Lygaeidae	HI.
2—Necker gooseloot nysius seed bug	*Nysius neckerensis*	Lygaeidae	HI.
2—Nihoa nysius seed bug	*Nysius nihoae*	Lygaeidae	HI.
2—Necker bunchgrass nysius seed bug	*Nysius suffusus*	Lygaeidae	HI.
2—Bryan's oceanides seed bug	*Oceanides bryani*	Lygaeidae	HI.
2—Perkins' oceanides seed bug	*Oceanides perkinsi*	Lygaeidae	HI.
2—Rough-headed oceanides seed bug	*Oceanides rugosiceps*	Lygaeidae	HI.
2—Dry Creek cliff strider bug	*Oravelia pege*	Macroveliidae	CA.
2—Aaa water treader bug	*Cavaticovelia aaa*	Mesoveliidae	HI.
3A—Phyllostegian leaf bug	*Cyrtopeltis* (=*Engytatus*) *phyllostegiae*	Miridae	HI.
2—Lanai kalanian leaf bug	*Kalania hawaiiensis*	Miridae	HI.
2—Oahu kalanian leaf bug	*Kalania* sp. (undescribed)	Miridae	HI.
1—Ash Meadows naucorid bug	*Ambrysus amargosus*	Naucoridae	NV.
2—Amargosa naucorid bug	*Pelocoris shoshone*	Naucoridae	CA, NV.
2—Pulchrus thread bug	*Empicoris pulchrus*	Reduviidae	HI.
2—Ana wingless thread bug	*Nesidiolestes ana*	Reduviidae	HI.
2—Mt. Tantalus wingless thread bug	*Nesidiolestes insularis*	Reduviidae	HI.
2—Robert's wingless thread bug	*Nesidiolestes roberti*	Reduviidae	HI.
2—Selium wingless thread bug	*Nesidiolestes selium*	Reduviidae	HI.
2—Smith's sicelian reduviid bug	*Siacella smithi*	Reduviidae	HI.
2—Annectans rhopalid bug	*Ithamar annectans*	Rhopalidae	HI.
2—Hawiian rhopalid bug	*Ithamar hawaiiense*	Rhopalidae	HI.
CICADAS AND ALLES (Insects, Order Homoptera)			
3A—Red-veined prairie leafhopper	*Felexamia rubranura*	Cicadellidae	IL*.
2—Kauai parti-colored oliarus planthopper	*Oliarus consimilis*	Cixiidae	HI.
2—Oliarus wild cotton planthopper	*Oliarus discrepans*	Cixiidae	HI.
2—Lanai oliarus planthopper	*Oliarus lanaiensis*	Cixiidae	HI.
2—Lihue oliarus planthopper	*Oliarus lihue*	Cixiidae	HI.
2—Barber's Point oliarus planthopper	*Oliarus myoporicola*	Cixiidae	HI.
2—Priolan oliarus planthopper	*Oliarus priola*	Cixiidae	HI.
2—Mt. Tantalus short-wing fern planthopper	*Nesorestias filicicola*	Delphacidae	HI.
2—Iao Valley nesosydne planthopper	*Nesosydne acuta*	Dphacidae	HI.
2—Bridewell's nesosydne planthopper	*Nesosydne bridwelli*	Dphacidae	HI.
2—Nahiku nesosydne planthopper	*Nesosydne cyrtandrae*	Dphacidae	HI.
2—Glenwood nesosydne planthopper	*Nesosydne cyrtandricola*	Dphacidae	HI.
2—Kusche's nesosydne planthopper	*Nesosydne kuschei*	Dphacidae	HI.
2—Diamond Head nesosydne planthopper	*Nesosydne leahi*	Dphacidae	HI.
2—Long-footed nesosydne planthopper	*Nesosydne longipes*	Dphacidae	HI.
2—Keanae nesosydne planthopper	*Nesosydne sulcata*	Dphacidae	HI.
LACEWINGS AND ALLIES (Insects, Order Neuroptera)			
2—Haleakala nesothauman spongillafly	*Nesothauma haleakalae*	Hemerobiidae	HI.
2—Cookes's pseudopsectran spongillafly	*Pseudopsectra cookeorum*	Hemerobiidae	HI.
2—Lobe-wing pseudopsectran spongillafly	*Pseudopsectra lobipennis*	Hemerobiidae	HI.
2—Swezey's pseudopsectran spongillafly	*Pseudopsectra swezeyi*	Hemerobiidae	HI.
2—Usinger's pseudopsectran spongillafly	*Pseudopsectra usingeri*	Hemerobiidae	HI.
2—(No common Name)	*Oliarces clara*	Ithonidae	CA.
2—Molokai antlion	*Eidoleon perjurus*	Myrmeleontidae	HI.
BEETLES (Insects, Order Coleoptera)			
2—Piko anobiid beetle	*Holcobius pikoensis*	Anobiidae	HI.
2—Antioch Dunes anthicid beetle	*Anthicus antiochensis*	Anthicidae	CA.
2—Sacrameto anthicid beetle	*Anthicus sacramento*	Anthicidae	CA.
2—Beller's ground beetle	*Agonum belleri*	Carabidae	WA.
2—Schaum's Blue Ridge ground beetle	*Sphaeroderus schaumi shenandoah*	Carabidae	VA.
3C—Mojave rabbitbrush longhorn beetle	*Crossidius mojavensis mojavensis*	Cerambycidae	CA.
2—Six-banded longhorn beetle	*Dryobius sexnotatus*	Cerambycidae	MD, MS, OH, PA, AL*, AR*, IN*, KS*, KY*, LA*, MI*, MO*, TN*, VA*.
2—Rude's longhorn beetle	*Necydalis rudei*	Cerambycidae	CA.
2—Hawaiian *Plagithymysus* longhorn beetles	*Plagithymysus* (Genus, about 43 spp.)	Cerambycidae	HI.
2*—Bog idol leaf beetle	*Donacia idola*	Chrysomelidae	WA*.
2—Idaho dunes tiger beetle	*Cicindela arenicola*	Cicindelidae	ID.
2*—Cazier's tiger beetle	*Cicindela cazieri*	Cicindelidae	TX*.
2*—Smyth's tiger beetle	*Cicindela chlorocephala smythi*	Cicindelidae	TX*.
2—Columbia River tiger beetle	*Cicindela columbica*	Cicindelidae	ID, WA, OR*.
2—Northeastern beach tiger beetle	*Cicindela dorsalis dorsalis*	Cicindelidae	MA, MD, NY, NJ, RI, PA*.
2*—Oblivious tiger beetle	*Cicindela latesignata obliviosa*	Cicindelidae	CA*.
2—Coral Pink Dunes tiger beetle	*Cicindela limbata albissima*	Cicindelidae	UT.
2—Cobblestone tiger beetle	*Cicindela marginipennis*	Cicindelidae	NH, VT, NY, NJ, OH, PA, WV*, MS.
2—Los Olmos tiger beetle	*Cicindela nevadica olmosa*	Cicindelidae	TX, NM, Mexico?.
2*—Subtropical blue-black tiger beetle	*Circindela nigrocoerula subtropica*	Cicindelidae	TX*.
2*—Neojuvenile tiger beetle	*Cicindela obsoleta neojuvenalis*	Cicindelidae	TX*.
2—Puritan tiger beetle	*Cicindela puritana*	Cicindelidae	MD, CT? MA*, NH*, NH*, VT.
2—Greenest tiger beetle	*Cicindela tranquebarica viridissima*	Cicindelidae	CA.
2—Oahu nesiotes weevil	*Dainocossonus nesiotes*	Curculionidae	HI.
3C—Antioch Dune weevil	*Dysticheus rotundicollis*	Curculionidae	CA.
2—Oahu heteramphus fern weevil	*Heteramphus filicum*	Curculionidae	HI.
2—Nelson's miloderes weevil	*Miloderes nelsoni*	Curculionidae	CA.
2—Rulien's miloderes weevil	*Miloderes rulieni*	Curculionidae	NV.
2—Gifford's nesotocus weevil	*Nesotocus giffordi*	Curculionidae	HI.
2*—Kauai nesotocus weevil	*Nesotocus kauaiensis*	Curculionidae	HI*.
2—Munro's nesotocus weevil	*Nesotocus munroi*	Curculionidae	HI.
2—Lange's El Segundo Dune weevil	*Onchobarus langei*	Curculionidae	CA.
2—Windward Chain *Oodemas* weevils	*Oodemas*, 4 spp.	Curculionidae	HI.
2—Blackburn's pentarthrum weevil	*Pentarthrum blackburni*	Curculionidae	HI.

Category and common name	Scientific name	Family	Distribution
2—Obscure pentarthrum weevil	*Pentarthrum obscura*	Curculionidae	HI.
2—Hawaiian *Rhyncogonus* snout beetles	*Rhyncogonus* (Genus, 23 spp.)	Curculionidae	HI.
2—Nihoa stenotrupis weevil	*Stenotrupis pritchardiae*	Curculionidae	HI.
2*—Brown-tassel trigonoscuta weevil	*Trigonoscuta brunnotesselata*	Curculionidae	CA*.
2—Dorothy's El Segundo Dune weevil	*Trigonoscuta dorothea dorothea*	Curculionidae	CA.
1—Doyen's trigonoscuta dune weevil	*Trigonoscuta doyeni*	Curculionidae	CA.
3A—Fort Ross trigonoscuta weevil	*Trigonoscuta rossi*	Curculionidae	CA*.
3A—Yorba Linda trigonoscuta weevil	*Trigonoscuta yorbalindae*	Curculionidae	CA*.
2—Death Valley agabus diving beetle	*Agabus rumppi*	Dytiscidae	CA, NV?
2*—Fig seed diving beetle	*Desmopachria cenchramis*	Dytiscidae	FL*.
2—Texas cave dytiscid beetle	*Haideoporus texanus*	Dytiscidae	TX.
2*—Elusive hydroporus diving beetle	*Hydroporus elusivus*	Dytiscidae	NH*.
2—Folkerts' hydroporus diving beetle	*Hydroporus folkertsi*	Dytiscidae	AL.
2—Wooly hydroporus diving beetle	*Hydroporus hirsutus*	Dytiscidae	CA.
2—Leech's skyline diving beetle	*Hydroporus leechi*	Dytiscidae	CA.
2—Simple hydroporus diving beetle	*Hydroporus simplex*	Dytiscidae	CA.
2—Spangler's hydroporus diving beetle	*Hydroporus spanglerl*	Dytiscidae	UT.
2*—Sulphur Springs hydroporus diving beetle	*Hydroporus sulphurius*	Dytiscidae	AR*.
2—Utah hydroporus diving beetle	*Hydroporus utahensis*	Dytiscidae	UT.
3A—Mono Lake hygrotus diving beetle	*Hygrotus artus*	Dytiscidae	CA*.
2—Curved-foot hygrotus diving beetle	*Hygrotus curvipes*	Dytiscidae	CA.
2—Narrow-foot hygrotus diving beetle	*Hygrotus diversipes*	Dytiscidae	WY.
2—Travertine band-thigh diving beetle	*Hygrotus fontinalis*	Dytiscidae	CA.
2—Sylvan hygrotus diving beetle	*Hygrotus sylvanus*	Dytiscidae	MN, NY*.
2—Hatch's click beetle	*Earus hatchi*	Elateridae	WA, Canada?
2—Hawaiian *Eopenthes* click beetles	*Eopanthes* (Genus, 17 spp.)	Elateridae	HI.
2—Necker *Itodacnus* click beetles	*Itodacnus*, 2 spp.	Eleteridae	HI.
2—Wawona riffle beetle	*Atractelmis wawona*	Elmidae	CA.
2—Parker's cylloepus riffle beetle	*Cylloepus parkeri*	Elmidae	AZ.
2—Brownish dubiraphian riffle beetle	*Dubiraphia brunnescens*	Elmidae	CA.
2—Giuliani's dubiraphian riffle beetle	*Dubiraphia giulianii*	Elmidae	CA.
2—Little dubiraphian riffle beetle	*Dubiraphia parva*	Elmidae	OK, LA.
2—Robust dubiraphian riffle beetle	*Dubiraphia robusta*	Elmidae	WI.
2—Dubiraphian riffle beetle (undescribed)	*Dubiraphia* sp. (undescribed)	Elmidae	ME.
2—Stephan's heterelmis riffle beetle	*Heterelmis stepheni*	Elmidae	AZ.
2—Marron's San Carlos riffle beitle	*Huleechius marroni carolus*	Elmidae	AZ.
2—Brown's microcylloepus riffle beetle	*Microcylloepus browni*	Elmidae	MT.
2—Brown's optioservus riffle beetle	*Optioservus browni*	Elmidae	AR.
2—Pinnacles optioservus riffle beetle	*Optioservus canus*	Elmidae	CA.
2—Scott optioservus riffle beetle	*Optioservus phaeus*	Elmidae	KS.
2—Devil's Hole warm spring riffle beetle	*Stenelmis calida calida*	Elmidae	NV.
2—Moapa warm springs riffle beetle	*Stenelmis calida moapa*	Elmidae	NV.
2—Douglas stenelmis riffle beetle	*Stenelmis douglasensis*	Elmidae	MI.
2—Gammon's stenelmis riffle beetle	*Stenelmis gammoni*	Elmidae	NC.
2*—Warm spring zaitzevan riffle beetle	*Zaitzeva thermae*	Elmidae	MT*.
2—Beer's false water penny beetle	*Acneus beeri*	Eubriidae	OR.
2—Burnell's false water penny beetle	*Acneus burnelli*	Eubriidae	OR
2—Stark's false water penny beetle	*Alabameubria starki*	Eubriidae	AL.
2—Variegated false water penny beetle	*Dicranopselaphus variegatus*	Eubriidae	IL.
2*—Dohrn's elegant eucnemid beetle	*Palaeoxenus dohrni*	Eucnemidae	CA*.
2—Red Hills unique whirligig betle	*Spanglerogyrus albiventris*	Gyrinidae	AL.
2—Hungerford's crawling water beetle	*Brychius hungerfordi*	Haliplidae	MI.
2*—Disjunct crawling water beetle	*Haliplus nitens*	Haliplidae	TX*, Canada*.
2—Maureen's gymnocthebius minute moss beetle	*Gymnocthebius maureenae*	Hydraenidae	MS.
2—Maureen's hydraenan minute moss beetle	*Hydraena maureenae*	Hydraenidae	VA.
2—Animas limnebius minute moss beetle	*Limnebius aridus*	Hydraenidae	NM.
2—Texas limnebius minute moss beetle	*Limnebius texanus*	Hydraenidae	TX.
2—Utah Limnebius minute moss beetle	*Limnebius utahensis*	Hydraenidae	UT.
2—Wing-shoulder minute moss beetle	*Ochthebius crassalus*	Hydraenidae	CA.
2—Indiana ochthebius minute moss beetle	*Ochthebius putnamensis*	Hydraenidae	IN.
2—Wilbur Springs minute moss beetle	*Ochthebius reticulatus*	Hydraenidae	CA.
2—Leech's chaetarthria water scavenger beetle	*Chaetarthria leechi*	Hydrophilidae	CA.
2—Utah chaetarthrian water scavenger beetle	*Chaetarthria utahensis*	Hydrophilidae	UT.
2—Arizona cymbiodytan water scavenger beetle	*Cymbiodyta arizonica*	Hydrophilidae	AZ.
2—Ricksecker's water scavenger beetle	*Hydrochara ricksecker!*	Hydrophilidae	CA.
2—Seclusive water scavenger beetle	*Paracymus seclusus*	Hydrophilidae	MS.
2—Florida intertidal firefly	*Micronaspis floridana*	Lampyridae	FL.
2—Everglades brownwing firefly	*Photuris brunnipennis floridana*	Lampyridae	FL.
2—Turtle Mound firefly	*Photuris* sp. (undescribed)	Lampyrida	FL.
2—Blind cave leiodid beetle	*Glacicavicola bathysciodes*	Leiodidae	ID.
2—Kauai flightless stag beetle	*Apterocyrchus honoluluensis*	Lucanidae	HI.
2—Hopping's blister beetle	*Lytta hoppingi*	Meloidae	CA.
2*—Mojave Desert blister beetle	*Lytta inseperata*	Meloidae	CA*.
2—Anthony blister beetle	*Lytta minifica*	Meloidae	NM*, Mexico.
2*—Moestan blister beetle	*Lytta moesta*	Meloidae	CA*.
2—Molestan blister beetle	*Lytta molesta*	Meloidae	CA.
2—Morrison's blister beetle	*Lytta morrisoni*	Meloidae	CA.
2—Hawaiian proterhinid beetles	*Proterhinus* (Genus, 72 spp.)	Proterhinidae	HI.
2—Arizona water penny beetle	*Psephenus arizonensis*	Psephenidae	AZ.
2—White Mountains water penny beetle	*Psephenus montanus*	Psephenidae	AZ.
2—Ciervo aegialian scarab beetle	*Aegialia concinna*	Scarabaeidae	CA.
2—Crescent-Dune aegialian scarab beetle	*Aegialia crescens*	Scarabaeidae	NV.
2—Hardy's aegialian scarab beetle	*Aegialia hardyi*	Scarabaeidae	NV.
2—Large aegialian scarab beetle	*Aegialia magnifica*	Scarabaeidae	NV.
2*—Exiguous anomala scarab beetle	*Anomala exigua*	Scarabaeidae	FL*.
2—Archbold anomala scarab beetle	*Anomala eximia*	Scarabaeidae	FL.
2*—Tibial anomala scarab beetle	*Anomala tibialis*	Scarabaeidae	TX*.
2—Ford's aphodius scarab beetle	*Aphodius fordi*	Scarabaeidae	GA.
2—Aphodius tortoise commensal scarab beetle	*Aphodius troglodytes*	Scarabaeidae	FL, SC.
2—Big Pine Key ataenius dung beetle	*Ataenius superficialis*	Scarabaeidae	FL.
2—Woodruff's ataenius dung beetle	*Ataenius woodruffi*	Scarabaeidae	FL.
2—Copris tortoise commensal scarab beetle	*Copris gopheri*	Scarabaeidae	FL.
2*—Miami roundhead scarab beetle	*Cyclocephala miamiensis*	Scarabaeidae	FL*.
2—Kelso Dune glaresis scarab beetle	*Glaresis arenata*	Scarabaeidae	CA.

Category and common name	Scientific name	Family	Distribution
2—Spiny Florida sandhill scarab beetle	*Gronocarus multispinosus*	Scarabaeidae	FL.
2—White sand bear scarab beetle	*Lichnanthe albopilosa*	Scarabaeidae	CA.
2—Pacific sand bear scarab beetle	*Lichnanthe ursina*	Scarabaeidae	CA.
2—Scrub Island burrowing scarab beetle	*Mycotrupes pedester*	Scarabaeidae	FL.
2—Onthophagus tortoise commensal scarab beetle	*Onthophagus polyphemi*	Scarabaeidae	SC, GA, FL, AL, MS.
2—Ocala burrowing scarab beetle	*Peltotrupes youngi*	Scarabaeidae	FL.
2—Wooly Gulf dune scarab beetle	*Polylamina pubescens*	Scarabaeidae	FL.
2—Saline Valley snow-front scarab beetle	*Polyphylla anteronivea*	Scarabaeidae	CA.
2—Spotted Warner Valley Dunes scarab beetle	*Polyphylla avittata*	Scarabaeidae	UT.
2—Barbate polyphyllan scarab beetle	*Polyphylla barbata*	Scarabaeidae	CA.
2—Atascodero polyphyllan scarab beetle	*Polyphylla nubila*	Scarabaeidae	CA.
2—Andrews' dune scarab beetle	*Pseudocotalpa andrewsi*	Scarabaeidae	CA, Mexico.
2—Giuliani's dune scarab beetle	*Pseudocotalpa giulianii*	Scarabaeidae	NV.
2—Frost's spring serican scarab beetle	*Serica frosti*	Scarabaeidae	FL.
2*—Tantula serican scarab beetle	*Serica tantula*	Scarabaeidae	FL.
2—Scrub palmetto flower scarab beetle	*Trigonopelastes floridana*	Scarabaeidae	FL.
2—Caracara commensal scarab beetle	*Trox howelli*	Scarabaeidae	FL.
2—American burying beetle	*Nicrophorus americanus*	Silphidae	KY, IN, MI, MO, RI, Canada, AL*, AR*, CT*, DC*, FL*, GA*, IA*, IL*, KS*, LA*, MD*, MA*, MN*, MS*, NH*, NJ*, NY*, NC*, OH*, PA*, SC*, SD*, TN*, TX*, VA*, WI*.
2—Black lordithon rove beetle	*Lordithon niger*	Staphylinidae	MO, Canada, AR*, CT*, DC*, GA*, IL*, KS*, KY*, MI*, NY*, NC*, OH*, PA*, TX*, VA*, WV*.
2—Globose dune beetle	*Coelus globosus*	Tenebrinoidae	CA, Mexico.
2—San Joaquin dune beetle	*Coelus gracilis*	Tenebrionidae	CA.
FLIES (Insects, Order Diptera)			
2—Mary Alice's small-headed fly	*Eulonchus marialiciae*	Acroceridae	NC.
3A—Valley mydas fly	*Raphiomydas trochilus*	Apioceratidae	CA*.
2*—Antioch cophuran robberfly	*Cophura hurdi*	Asilidae	CA*.
2—Antioch efferian robberfly	*Efferia antiochi*	Asilidae	CA.
2—Hurd's metapogon robberfly	*Metapogon hurdi*	Asilidae	CA.
2—Nihoa two-spotted asteriid fly	*Bryania bipunctata*	Asteriidae	HI.
3A—Ko'olau spurwing long-legged fly	*Campsicnemus mirabilis*	Dolichopodidae	HI*.
3A—Lanai pomace fly	*Drosophila lanaiensis*	Drosophilidae	HI*.
3A—Hawaiian chersodromian dance fly	*Chersodromia hawaiiensis*	Empididae	HI*.
2—Wilber Springs shore fly	*Paracoenia calida*	Ephydridae	CA.
2—Sugarfoot moth fly	*Nemopalpus nearcticus*	Psychodidae	FL.
2—Delong's mixogaster flower fly	*Mixogaster delongi*	Syrphidae	FL.
2*—Ross's apatalestes tabanid fly	*Apatalestes rossi*	Tabanidae	CA*.
2—Florida asaphomyian tabanid fly	*Asaphomyia floridensis*	Tabanidae	FL.
2*—Texas asaphomyian tabanid fly	*Asaphomyia texanus*	Tabanidae	TX*.
2—Belkin's dune tabanid fly	*Brennania belkini*	Tabanidae	CA, Mexico.
2—Brown merycomyian tabanid fly	*Merycomyia brunnea*	Tabanidae	FL.
3A—Volutine stonemyian tabanid fly	*Stonemyia volutina*	Tabanidae	CA*.
BUTTERFLIES AND MOTHS (Insects, Order Lepidoptera)			
3A—Chestnut ermine moth	*Argyresthia castaneela*	Argyresthiidae	NH* VT*.
2—Green heterocrossan carposinid moth	*Heterocrossa viridis*	Carposinidae	HI.
3A—Chestnut case-bearer moth	*Coleophora leucochrysella*	Coleophoridae	PA*.
2—Ioxanthan looper moth	*Fletcherana ioxantha*	Geometridae	HI.
3A—Kona giant looper moth	*Scotorythra megalophylla*	Geometridae	HI*.
3A—Ko'olau giant looper moth	*Scotorythra nesiotes*	Geometridae	HI*.
3A—Hawaiian hopseed looper moth	*Scotorythra paratactis*	Geometridae	HI*.
3A—'Ola'a peppered looper moth	*Tritocleis microphylla*	Geometridae	HI*.
2—Necker petrochroan leaf miner moth	*Petrochroa neckerensis*	Gracilariidae	HI*.
2—Dakota skipper butterfly	*Hesperia dacotae*	Hesperiidae	MN, IA, SD, ND, IL*, Canda.
1—North Platte montane skipper butterfly	*Hesperia leonardus* (=*pawnee*) *montana*	Hesperiidae	CO.
2—Salt marsh skipper butterfly	*Panoquina panoquinoides errans*	Hesperiidae	CA, Mexico.
2—Rare skipper	*Problema bulenta*	Hesperiidae	MD, VA, NC. SC. GA.
2—Wandering skipper	*Psaudocopaeodes eunus eunus*	Hesperiidae	CA, NV?, AZ?, Mexico?.
2—Atala butterfly	*Eumaeus atala florida*	Lycaenidae	FL.
2—Comstock's blue butterfly	*Euphilotes* (=*Shijimiaeoides* =*Philotes*) *battoides comstocki.*	Lycaenidae	CA.
2—Langston's blue butterfly	*Euphilotes* (=*Shijimiaeoides*) *langstoni langstoni*	Lycaenidae	CA.
2—Mattoni's blue butterfly	*Euphilotes* (=*Shijimiaeoides*) *rita mattonii*	Lycaenidae	NV.
3A—Xerces blue butterfly	*Glaucopsyche xerces*	Lycaenidae	CA*.
2—Miami blue butterfly	*Hemiargus thomasi bethune-bakeri*	Lycaenidae	FL.
2—Moro Bay blue butterfly	*Icaricia icarioides moroensis*	Lycaenidae	CA.
3A—Pheres blue butterfly	*Icaricia icarioides pheres*	Lycaenidae	CA*.
3C—Bog elfin butterfly	*Incisalia* (=*Callophrys* =*Mitoura*) *lanoraieenisis*	Lycaenidae	CA.
3C—Wind's elfin butterfly	*Incisalia* (=*Callophrys* =*Mitora*) *mossi windi*	Lycaenidae	CA.
3C—Doudoroff's elfin butterfly	*Incisalia* (=*Callophrys* =*Mitoura*) *mossi doudoroffi*	Lycaenidae	CA.
2—Karner blue butterfly	*Lycaeides melissa samuelis*	Lycaenidae	NY, NH, IN, MI, WI, MA*, PA*.
3C—Clouded tailed copper butterfly	*Lycaena arota nubila*	Lycaenidae	CA.
2—Clayton's copper butterfly	*Lycaena dorcas claytoni*	Lycaenidae	ME.
2—Hermes copper butterfly	*Lycaena hermes*	Lycaenidae	CA, MEX.
3C—Hessel's hairstreak butterfly	*Mitoura* (=*Callophrys*) *hesseli*	Lycaenidae	NH, MA, NJ, MD, VA, NC, GA, FL.
2—Boharts' blue butterfly	*Philotiella* (=*Zizeeria*) *speciosa bohartorum*	Lycaenidae	CA.
2—San Emigdio blue butterfly	*Plebulina* (=*Plebejus*) *emigdionis*	Lycaenidae	CA.
2—Bartram's hairstreak butterfly	*Strymon acis bartrami*	Lycaenidae	FL.
3C—Hawaiian hairstreak butterfly	*Vaga blackburni*	Lycaenidae	HI.
3C—Kendall's yucca skipper butterfly	*Magathymus coloradensis kendalli*	Magathymidae	TX.
2—Maculated manfreda skipper butterfly	*Stallingsia maculosus*	Magathymidae	TX.
3A—American chestnut nepticulid moth	*Ectodemia castaneae*	Nepticulidae	MD*.
3A—Phleophagan chestnut nepticulid moth	*Ectodemia phleophaga*	Nepticulidae	MD*.
2—Albarufan dagger moth	*Acronicta albarufa*	Noctuidae	MA*, GA*, NJ*, CT*, NY*, PA*, OH*, CO*, NM*, Canada*.
3A—"Poko" noctuid moth	*Agrotis crinigera*	Noctuidae	HI*.
3A—Midway agrotis noctuid moth	*Agrotis fasciata*	Noctuidae	HI*.
3A—Kerr's agrotis noctuid moth	*Agrotis kerri*	Noctuidae	HI*.
3A—Laysan agrotis noctuid moth	*Agrotis laysanensis*	Noctuidae	HI*.
3A—Procellaris agrotis noctuid moth	*Agrotis procellaris*	Noctuidae	HI*.

Category and common name	Scientific name	Family	Distribution
2—Marbled underwing moth	*Catocala marmorata*	Noctuidae	NC, SC, VT*, NY*, NJ*, PA*, VA*, KY*, IN*, IL*, MO*.
2—Precious underwing moth	*Catocala pretiosa*	Noctuidae	NJ, NH*, CT*, MA*, NY*, PA*, MD*, VA*, TN*.
2—Hebard's noctuid moth	*Erythroecia hebardi*	Noctuidae	NJ, VA.
3A—Confused helicoverpan noctuid moth	*Helicoverpa confusa*	Noctuidae	HI*.
3A—Minute helicoverpan noctuid moth	*Helicoverpa minuta*	Noctuidae	HI*.
3A—Laysan dropseed noctuid moth	*Hypena laysanensis*	Noctuidae	HI*.
3A—Hilo hypenan noctuid moth	*Hypena newelli*	Noctuidae	HI*.
3A—Lovegrass noctuid moth	*Hypena plagiota*	Noctuidae	HI*.
3A—Kahoiamano noctuid moth	*Hypena senicula*	Noctuidae	HI*.
2—Lemmer's noctuid moth	*Lithophane lemmeri*	Noctuidae	CT, NJ, NC, SC.
2—Ceromatic noctuid moth	*Pyrrelena ceromatica*	Noctuidae	FL, SC, ME, AL, IN, Canada.
2—Florida leafwing butterfly	*Anaea floridalis*	Nymphalidae	FL.
1—Uncompahgre fritillary butterfly	*Boloria acrocnema*	Nymphalidae	CO.
3C—Alamosa satyr butterfly	*Cercyonis meadi alamosa*	Nymphalidae	CO.
3A—Sthenele wood nymph butterfly	*Cercyonis sthenele sthenele*	Nymphalidae	CA*.
1—Bay checkerspot butterfly	*Euphydryas editha bayensis*	Nymphalidae	CA.
2—Mono checkerspot butterfly	*Euphydryas editha monoensis*	Nymphalidae	CA/NV.
3C—Wright's checkerspot butterfly	*Euphydryas editha wrighti*	Nymphalidae	CA.
3C—Obsolete viceroy butterfly	*Limenitis archippus obsoletus*	Nymphalidae	AZ, CA, NM, NV, Mexico.
3C—Mitchell satyr butterfly	*Neonympha (=Euptychia) mitchellii*	Nymphalidae	MI, NJ, OH*.
3C—Chryxus arctic butterfly	*Oeneis chryxus valerata*	Nymphalidae	WA.
2—Tawny crescent butterfly	*Phyciodes batesi*	Nymphalidae	NC, VA, NY, OH, MI, WI, ND, SD, CO, MN, Canada, GA*, WV*, PA*, NJ*.
3C—Minute checkerspot butterfly	*Poladryas minuta*	Nymphalidae	TX.
2—Smoky eyed brown butterfly	*Satyrodes eurydice fumosa*	Nymphalidae	IL, IA, NE, CO*.
3C—Unsilvered fritillary butterfly	*Speyeria adiaste adiaste*	Nymphalidae	CA.
3A—Atossa fritillary butterfly	*Speyeria adiaste atossa*	Nymphalidae	CA*.
3C—Clemence's fritillary butterfly	*Speyeria adiaste clemencei*	Nymphalidae	CA.
2—Calippe silverspot butterfly	*Speyeria callipe callipe*	Nymphalidae	CA.
3C—Tehachapi Mountain silverspot butterfly	*Speyeria egleis tehachapina*	Nymphalidae	CA.
2*—Hydaspe fritillary butterfly	*Speyeria hydaspe conquista*	Nymphalidae	CO, NM.
2—Regal fritillary butterfly	*Speyeria idalia*	Nymphalidae	ME*, NH*, MA, RI, NY, NJ, MD, DE, VA, NC*, WV, PA, OH, IN, MI, IL, MO, MN, WI, IA, OK, KS, NE, SD, ND, CO, MT, Canada.
3C—Apache silverspot butterfly	*Speyeria nokomis apacheana*	Nymphalidae	CA/NV.
2—Blue silverspot butterfly	*Speyeria nokomis caerulescens*	Nymphalidae	AZ*, Mexico.
3B—Blue-black silverspot butterfly	*Speyeria nokomis nigrocaerulea*	Nymphalidae	AZ, NM.
3C—Mountain silverspot butterfly	*Speyeria nokomis nitocris*	Nymphalidae	AZ, NM, CO.
2—Great basin silverspot butterfly	*Speyeria nokomis nokomis*	Nymphalidae	CO, UT.
2—Behren's silverspot butterfly	*Speyeria zerene behrensii*	Nymphalidae	CA.
2—Myrtle's silverspot butterfly	*Speyeria zerene myrtleae*	Nymphalidae	CA.
2—Henne's eucosman moth	*Eucosma hennei*	Olethreutidae	CA.
2—San Francisco tree lupine moth	*Grapholita edwardsiana*	Olethreutidae	CA.
3A—Strohbeen's parnassian butterfly	*Parnassius clodius strohbeeni*	Papilionidae	CA*.
2—Busk's gall moth	*Carolella busckana*	Phaloniidae	CA.
3C—Catalina orange tip butterfly	*Anthocharis cethura cataline*	Pieridae	CA.
2—Andrew's marble butterfly	*Euchloe hyantis andrewsi*	Pieridae	CA.
3C—Helios yellow butterfly	*Eurema dina helios*	Pieridae	PR, Caribbean.
2*—Molokai sedge hedyleptan moth	*Hedylepta anastrepta*	Pyralidae	HI*.
2—Kohala Mountain sedge hedyleptan moth	*Hedylepta anastreptoides*	Pyralidae	HI.
2*—'Ohe hedyleptan moth	*Hedylepta asaphombra*	Pyralidae	HI*.
3A—Oahu swamp hedyleptan moth	*Hedylepta epicentra*	Pyralidae	HI*.
2*—Ola'a banana hedeleptan moth	*Hedylepta euryprora*	Pyralidae	HI*.
2*—Fullaway's banana hedyleptan moth	*Hedylepta fullawayi*	Pyralidae	HI*.
2*—Giffard's 'ohe hedyleptan moth	*Hedylepta giffardi*	Pyralidae	HI*.
2*—Kilauea pa'iniu hedyleptan moth	*Hedylepta iridias*	Pyralidae	HI*.
3A—Laysan hedyleptan moth	*Hedylepta laysanensis*	Pyralidae	HI*.
2*—Meyrick's banana hedyleptan moth	*Hedylepta meyricki*	Pyralidae	HI*.
2*—Hawaiian bean leafroller moth	*Hedylepta monogona*	Pyralidae	HI*.
2*—Maui banana hedyleptan moth	*Hedylepta musicola*	Pyralidae	HI*.
2*—Hawaiian lo'ulu hedeleptan moth	*Hedylepta pritchardii*	Pyralidae	HI*.
3A—Telegraphic hedyleptan moth	*Hedylepta telegrapha*	Pyralidae	HI*.
2—Blue margaronian moth	*Margaronia cyanomichla*	Pyralidae	HI.
2—Green margaronian moth	*Margaronia exaula*	Pyralidae	HI.
2—'Ohenaupaka oeobian moth	*Oeoblia dryadopa*	Pyralidae	HI.
2*—Chestnut clearwing moth	*Synanthedon castaneae*	Sesiidae	VA*, PA*, SC*, ME*, MS*, NY*.
1—Weist's sphinx moth	*Euproserpinus wiesti*	Sphingidae	CO, NM*.
3A—Blackburn's sphinx moth	*Manduca blackburni*	Sphingidae	HI*.
3A—Fabulous green sphinx of Kauai	*Tinostoma smaragditis*	Sphingidae	HI*.
3A—Chestnut leaf miner moth	*Tischeria perplexa*	Tischeriidae	VA*.
2—'Ohe'ohe leaf roller moth	*Spheterista oheoheana*	Tortricidae	HI.
2—Green-banded 'ohe'ohe leaf-roller moth	*Spheterista ptarotropiana*	Tortricidae	HI.
2—Wailupe leaf-roller moth	*Spheterista reynoldsiana*	Tortricidae	HI.
CADDISFLIES (Insects, Order Trichoptera)			
2—Mt. Hood primitive brachycentrid caddisfly	*Eobrachycentrus gelidae*	Brachycentridae	OR.
2—Artesian agapetus caddisfly	*Agapetus artesus*	Glossosomatidae	MO.
2*—Denning's agapetus caddisfly	*Agapetus denningi*	Glossosomatidae	OR*.
2—Arkansas agapetus caddisfly	*Agapetus medicus*	Glossosomatidae	AR.
2—San Marcos protoptilan caddisfly	*Protoptila arca*	Glossosomatidae	TX.
2—Flint's cheumatopsyche caddisfly	*Cheumatopsyche flinti*	Hydropsychidae	TX.
2—Helma's cheumatopsyche caddisfly	*Cheumatopsyche helma*	Hydropsychidae	TN.
2—Vannote's cheumatopsyche caddisfly	*Cheumatopsyche vannotei*	Hydropsychidae	PA.
2—California diplectronan caddisfly	*Diplectrona californica*	Hydropsychidae	CA.
2—Schuh's homoplectran caddisfly	*Homoplectra schuhi*	Hydropsychidae	OR.
2—Buffalo Springs caddisfly	*Hydropsyche etnieri*	Hydropsychidae	TN.
2—Abellan hydropsyche caddisfly	*Hydropsyche reiseni*	Hydropsychidae	OR.
2—Reisen's hydropsyche caddisfly	*Hydropsyche reiseni*	Hydropsychidae	OK.
2*—King's Creek parapsyche caddisfly	*Parapsyche extensa*	Hydropsychidae	CA*.
2—Knoxville hydroptilan micro caddisfly	*Hydroptila dacia*	Hydroptilidae	TN.
2—Kite's neotrichian micro caddisfly	*Neotrichia kitae*	Hydroptilidae	MO.
2—Alsea ochrotrichian micro caddisfly	*Ochrotrichia alsea*	Hydroptilidae	OR.
2—Contorted ochrotrichian micro caddisfly	*Ochrotrichia contorta*	Hydroptilidae	MO, AR.

Category and common name	Scientific name	Family	Distribution
2—Deschutes ochrotrichian micro caddisfly	*Ochrotrichia phenosa*	Hydroptilidae	OR*, CA.
2—Provost's ochrotrichian micro caddisfly	*Ochrotrichia provosti*	Hydroptilidae	FL.
2—Vertrees's ochrotrichian micro caddisfly	*Ochrotrichia vertreesi*	Hydroptilidae	OR, CA.
2—Florida oxyethiran micro caddisfly	*Oxyethira florida*	Hydroptilidae	FL.
2—Fischer's lepidostoman caddisfly	*Lepidostoma fischeri*	Lepidostomatidae	OR.
2—Goeden's lepidostoman caddisfly	*Lepidostoma goedeni*	Lepidostomatidae	OR.
2—Vertrees's ceraclean caddisfly	*Ceraclea (=Athripsodes) vertreesi*	Leptoceridae	OR.
2*—Florida ceraclean longhorn caddisfly	*Ceraclea floridana*	Leptoceridae	FL*.
2*—Little oecetis longhorn caddisfly	*Oecetis parva*	Leptoceridae	FL*.
3A—Athens triaenodes caddisfly	*Triaenodes phalacris*	Leptoceridae	OH*.
2*—Three-tooth triaenodes caddisfly	*Triaenodes tridonta*	Leptoceridae	OK*, FL*.
2—Cascades apatanian caddisfly	*Apatania (=Radema) tavala*	Limnephilidae	OR.
2—Kings Canyon cryptochian caddisfly	*Cryptochia excella*	Lemnephilidae	CA.
2—Blue Mountains cryptochian caddisfly	*Cryptochia neosa*	Limnephilidae	OR.
2—King's Creek ecclisomyian caddisfly	*Ecclisomyia bilera*	Limnephilidae	CA.
2*—Green Springs Mountain farulan caddisfly	*Farula davisi*	Limnephilidae	OR*.
2—Mt. Hood farulan caddisfly	*Farula jewetti*	Limnephilidae	OR.
2—Tombstone Prairie farulan caddisfly	*Farula reaperi*	Limnephilidae	OR.
2—Missouri Glyphopsyche caddisfly	*Glyphopsyche missouri*	Limnephilidae	MO.
2—Klamath limnephilan caddisfly	*Limnephilus alconura*	Limnephilidae	OR.
2—Fort Dick limnephilus caddisfly	*Limnephilus stercus*	Limnephilidae	CA, OR.
2—Columbia gorge neothremman caddisfly	*Neothremma andersoni*	Limnephilidae	OR.
2—Tombstone Prairie oligophlebodes caddisfly	*Oligophlabodes mostbento*	Limnephilidae	OR.
2*—Clatsop philocascan caddisfly	*Philocasca oron*	Limnephilidae	OR*.
3B—(No common name)	*Psilotreta hansoni*	Odontoceridae	MA.
2—Oregon dolophilodes caddisfly	*Dolophilodes (=Sortosa) oregona*	Philoptamidae	OR.
2—Carlson's polycentropus caddisfly	*Polycentropus carlsoni*	Polycentropodidae	SC.
2—Nearctic paduniellan caddisfly	*Paduniella nearctica*	Psychomyidae	AR.
2—Siskiyou caddisfly	*Tinodes siskiyou*	Psychomyiidae	OR.
2—Alexander's rhyacophilan caddisfly	*Rhyacophila alexanderi*	Rhyacophilidae	MT.
3A—Castle Lake rhyacophilan caddisfly	*Rhyacophila amabilis*	Rhyacophilidae	CA*.
2—Obrien rhyacophilan caddisfly	*Rhyacophila colonus*	Rhyacophilidae	OR.
2—Fender's rhyacophilan caddisfly	*Rhyacophila fenderi*	Rhyacophilidae	OR.
2—Haddock's rhyacophilan caddisfly	*Rhyacophila haddocki*	Rhyacophilidae	OR.
2—Castle Crags rhyacophilan caddisfly	*Rhyacophila lineata*	Rhyacophilidae	CA.
2—Bilobed rhyacophilan caddisfly	*Rhyacophila mosana*	Rhyacophilidae	CA.
2—Spiny rhyacophilan caddisfly	*Rhyacophila spinata*	Rhyacophilidae	CA.
2—One-spot rhyacophilan caddisfly	*Rhyacophila unipunctata*	Rhyacophilidae	OR.
2—Zigzag blackwater caddisfly	*Agarodes ziczac*	Sericostomatidae	FL.
ANTS, BEES AND WASPS (Insects, Order Hymenoptera)			
2*—Yellow-banded andrenid bee	*Perdita hirticeps luteocincta*	Andrenidae	CA*.
2—Antioch andrenid bee	*Perdita scitula antiochensis*	Andrenidae	CA.
2—Nihoa sclerodermus wasp	*Sclerodermus nihoaensis*	Bethylidae	HI.
2—Nihoa eupelmus wasp	*Eupelmus nihoaensis*	Eupelmidae	HI.
2*—Assimulans yellow-faced bee	*Nesoprosophis assimulans*	Hylaeidae	HI*.
2*—Andrenoid yellow-faced bee	*Nesoprosopis andrenoides*	Hylaeidae	HI*.
3A—Lanai yellow-faced bee	*Nesoprosopis angustula*	Hylaeidae	HI*.
2—Anomalous yellow-faced bee	*Nesoprosopis anomala*	Hylaeidae	HI.
2*—Anthricinan yellow-faced bee	*Nesoprosopis anthricina*	Hylaeidae	HI*.
3A—Blackburn's yellow-faced bee	*Nesoprosopis blackburni*	Hylaeidae	HI*.
2*—Bluewing yellow-faced bee	*Nesoprosopis caeruleipennis*	Hylaeidae	HI*.
2*—Chlorostictan yellow-faced bee	*Nesoprosopis chlorosticata*	Hylaeidae	HI*.
2*—Comes yellow-faced bee	*Nesoprosopis comes*	Hylaeidae	HI*.
2*—Conehead yellow-faced bee	*Nesoprosopis coniceps*	Hylaeidae	HI*.
3A—Connected yellow-faced bee	*Nesoprosopis connectens*	Hylaeidae	HI*.
2*—Crabronoid yellow-faced bee	*Nesoprosopis crabronoides*	Hylaeidae	HI*.
2*—Difficult yellow-faced bee	*Nesoprosopis difficilis*	Hylaeidae	HI*.
2*—Dimidiatan yellow-faced bee	*Nesoprosopis dimidiata*	Hylaeidae	HI*.
3A—Erythrodeme yellow-faced bee	*Nesoprosopis erythrodemas*	Hylaeidae	HI*.
2*—Easy yellow-faced bee	*Nesoprosopis facilis*	Hylaeidae	HI*.
2*—Fern yellow-faced bee	*Nesoprosopis filicum*	Hylaeidae	HI*.
3A—Finitiman yellow-faced bee	*Nesoprosopis finitima*	Hylaeidae	HI*.
2—Very yellow-faced bee	*Nesoprosopis flavifrons*	Hylaeidae	HI.
2*—Yellow-foot yellow-faced bee	*Nesoprosopis flavipes*	Hylaeidae	HI*.
2—Darkwing yellow-faced bee	*Nesoprosopis fuscipennis*	Hylaeidae	HI.
2*—Shadowfoot darkwing yellow-faced bee	*Nesoprosopis fuscipennis obscuripes*	Hylaeidae	HI*.
2*—Haleakala yellow-faced bee	*Nesoprosopis haleakalae*	Hylaeidae	HI*.
3A—Hilaris yellow-faced bee	*Nesoprosopis hilaris*	Hylaeidae	HI*.
2*—Hirsute yellow-faced bee	*Nesoprosopis hirsutula*	Hylaeidae	HI*.
3A—Monocolor yellow-faced bee	*Nesoprosopis homeochroma*	Hylaeidae	HI*.
2*—Hostile yellow-faced bee	*Nesoprosopis hostilis*	Hylaeidae	HI*.
2*—Hulan yellow-faced bee	*Nesoprosopis hula*	Hylaeidae	HI*.
2*—Insignis yellow-faced bee	*Nesoprosopis insignis*	Hylaeidae	HI*.
2*—Kauai yellow-faced bee	*Nesoprosopis kauaiensis*	Hylaeidae	HI*.
2*—Koa yellow-faced bee	*Nesoprosopis koae*	Hylaeidae	HI*.
2*—Kona yellow-faced bee	*Nesoprosopis kona*	Hylaeidae	HI*.
2*—Laetan yellow-faced bee	*Nesoprosopis laeta*	Hylaeidae	HI*.
3A—Broadhead yellow-faced bee	*Nesoprosopis laticeps*	Hylaeidae	HI*.
2*—Longhead yellow-faced bee	*Nesoprosopis longiceps*	Hylaeidae	HI*.
3A —Maui yellow-faced bee	*Nesoprosopis mauiensis*	Hylaeidae	HI*.
3A—Melanothix yellow-faced bee	*Nesoprosopis melanothrix*	Hylaeidae	HI*.
3A—Mutatan yellow-faced bee	*Nesoprosopis mutata*	Hylaeidae	HI*.
3A—Molokai yellow-faced bee	*Nesoprosopis neglecta*	Hylaeidae	HI*.
3A—Snowy yellow-faced bee	*Nesoprosopis nivalis*	Hylaeidae	HI*.
2*—Obscuratan yellow-faced bee	*Nesoprosopis obscurata*	Hylaeidae	HI*.
2*—Ombrias yellow-faced bee	*Nesoprosopis ombrias*	Hylaeidae	HI*.
3A—Pele yellow-faced bee	*Nesoprosopis pele*	Hylaeidae	HI*.
2—Perkin's yellow-faced bee	*Nesoprosopis perkinsiana*	Hylaeidae	HI*.
3A—Perspicuan yellow-faced bee	*Nesoprosopis perspicua*	Hylaeidae	HI*.
3A—Psammobian yellow-faced bee	*Nesoprosopis psammobia*	Hylaeidae	HI*.
2*—Furry yellow-faced bee	*Nesoprosopis pubescens*	Hylaeidae	HI*.
2*—Redtail yellow-faced bee	*Nesoprosopis rubrocaudatus*	Hylaeidae	HI*.

Category and common name	Scientific name	Family	Distribution
3A—Rugulose yellow-faced bee	*Nesoprosopis rugulosa*	Hylaeidae	HI*.
2*—Satellus yellow-faced bee	*Nesoprosopis satellus*	Hylaeidae	HI*.
2*—Bristlefront yellow-faced bee	*Nesoprosopis setosifrons*	Hylaeidae	HI*.
2*—Simple yellow-faced bee	*Nesoprosopis simplex*	Hylaeidae	HI*.
2*—Specular yellow-faced bee	*Nesoprosopis specularis*	Hylaeidae	HI*.
2*—Sphecodoid yellow-faced bee	*Nasoprosopis sphecodoides*	Hylaeidae	HI*.
2*—Unique yellow-faced bee	*Nesoprosopis unica*	Hylaeidae	HI*.
2*—Vicinan yellow-faced bee	*Nesoprosopis vicina*	Hylaeidae	HI*.
2—Volatile yellow-faced bee	*Nesoprosopis volatilis*	Hylaeidae	HI*.
2—Anticoh mutillid wasp	*Myrmosula (Myrmosa) pacifica*	Multillidae	CA.
2—Hawaiian deinomimesan sphecid wasp	*Deinomimesa hawaiiensis*	Shpecidae	HI.
2—Puna deinomimesan sphecid wasp	*Deinomimesa punae*	Sphecidae	HI.
2—Giffard's ectemnius sphecid wasp	*Ectemnius (=Nesocrabo) giffardi*	Sphecidae	HI.
2—Short-foot ectemnius sphecid wasp	*Ectemnius (=Oreocrabro) curtipes*	Sphecidae	HI.
2—Haleakala ecteminus sphecid wasp	*Ectemnius (=Oreocrabro) haleakalae*	Sphecidae	HI.
2—Brown cross ectemnius sphecid wasp	*Ectemnius (=Orocrabro) fulvicrus*	Sphecidae	HI.
2—Bidecoratus sphecid wasp	*Ectemnius nesocrabo bidecoratus*	Sphecidae	HI.
2—Redheaded sphecid wasp	*Eucerceris ruficeps*	Sphecidae	CA*, NV.
2—Kauai nesomimesan sphecid wasp	*Nesomimesa kauaiensis*	Sphecidae	HI.
2—Shade-winged nesomimesan sphecid wasp	*Nesomimesa scioptoryx*	Sphecidae	HI.
2*—Antioch sphecid wasp	*Philanthus nasalis*	Sphecidae	CA*.
2—Niihau odynerus vespid wasp	*Odynerus niihauensis*	Vespidae	HI.
2—Soror odynerus vespid wasp	*Odynerus soror*	Vespidae	HI.
SNAILS (Molluscs, Class Gastropoda)			
2—(No common name)	*Valvata utahensis* Call, 1884	Valvatidae	ID, UT.
3B—Newcomb's littorine snail	*Algamorda newcombiana* Hemphill, 1877	Littorinidae	CA, WA, OR.
2—St. George snail	*Amnicola deserta* Pilsbry, 1916	Hydrobiidae	UT.
2—(No common name)	*Aphaostracon asthenes* Thompson, 1968	Hydrobiidae	FL.
2—(No common name)	*Aphaostracon monas* (Pilsbry, 1899)	Hydrobiidae	FL.
2—Compact hydrobe snail	*Aphaostracon pycnus* Thompson, 1968	Hydrobiidae	FL.
2—Fenney Spring hydrobe snail	*Aphaostracon xynoelicius* Thompson, 1968	Hydrobiidae	FL.
2—Helicoid spring snail	*Cincinnatia helicogyra* Thompson, 1968	Hydrobiidae	FL.
2—(No common name)	*Cincinnatia mica* Thompson, 1968	Hydrobiidae	FL.
2—(No common name)	*Cincinnatia monroensis* (Dall, 1885)	Hydrobiidae	FL.
2—(No common name)	*Cincinnatia parva* Thompson, 1968	Hydrobiidae	FL.
2—Ponderous spring snail	*Cincinnatia ponderosa* Thompson, 1968	Hydrobiidae	FL.
2—Seminole Spring snail	*Cincinnatia vanhyningi* (Vanatta, 1934)	Hydrobiidae	FL.
2—Wekiwa Spring snail	*Cincinnatia wekiwae* Thompson, 1968	Hydrobiidae	FL.
2—Phantom cave snail	*Cochlicpa texana* Pilsbry, 1935	Hydrobiidae	TX.
2—Muddy Valley turban snail	*Fluminicola avernalis* Pilsbry, 1935	Hydrobiidae	NV.
1—Point of Rocks Spring snail	*Fluminicola erythropoma* Pilsbry, 1899	Hydrobiidae	NV.
2—Pahranagat Valley turban snail	*Fluminicola merriami* Pilsbry and Belcher, 1892	Hydrobiidae	NV.
2—Longstreet Spring snail	*"Fluminicola"* sp.	Hydrobiidae	NV.
1—Median-gland Nevada spring snail	*"Fluminicola"* sp.	Hydrobiidae	NV.
1—Large-gland Nevada spring snail	*"Fluminicola"* sp.	Hydrobiidae	NV.
3C—(No common name)	*Fontelicella micrococcus* (Pilsbry, 1893)	Hydrobiidae	NV.
1—Socorro spring snail	*Fontelicella* (=*Amnicola*) *neomexicana* (Pilsbry, 1916).	Hydrobiidae	NM.
2—Elk Island snail	*Fontelicella robusta* Walker, 1908	Hydrobiidae	WY.
1—Chupadera spring snail	*Fontelicella* sp.	Hydrobiidae	NM.
1—Roswell spring snail	*Fontelicella* sp.	Hydrobiidae	NM.
2—Great Columbia River spire snail	*Lithoglyphus columbianus* (Pilsbry, 1899)	Hydrobiidae	ID, OR, WA.
2—(No common name)	*Marstonia agarhecta* Thompson, 1977	Hydrobiidae	GA.
2—(No common name)	*Marstonia castor* Thompson, 1977	Hydrobiidae	GA.
2—Obese Marstonia snail	*Marstonia ogmoraphe* Thompson, 1977	Hydrobiidae	TN.
2—Thick-shelled Marstonia snail	*Marstonia pachyta* Thompson, 1977	Hydrobiidae	AL.
2—(No common name)	*Somatogyrus catanotus* Thompson, 1974	Hydrobiidae	GA.
2—(No common name)	*Somatogyrus parvulus* Tryon, 1865	Hydrobiidae	TN.
2—(No common name)	*Somatogyrus tenax* Thompson, 1969	Hydrobiidae	GA.
2—(No common name)	*Stiobia nana* Thompson, 1978	Hydrobiidae	AL.
1—Virile Amargosa snail	Genus and species undescribed	Hydrobiidae	NV.
1—Bliss Rapids snail	Genus and species undescribed	Hydrobiidae	ID.
1—Bruneau Hot Spring snail	Genus and species undescribed	Hydrobiidae	ID.
2—Cheatum's snail	*Tryonia cheatumi* (Pilsbry, 1935)	Littoridinidae	TX.
2—White River snail	*Tryonia clathrata* Stimpson, 1865	Littoridinidae	NV.
2—California brackish water snail	*Tryonia imitator* (Pilsbry, 1899)	Littoridinidae	CA.
1—Point of Rocks Tryonia snail	*Tryonia* sp.	Littoridinidae	NV.
1—Sportinggoods Tryonia snail	*Tryonia* sp.	Littoridinidae	NV.
1—Small solid Tryonia snail	*Tryonia* sp.	Littoridinidae	NV.
1—Minute slender Tryonia snail	*Tryonia* sp.	Littoridinidae	NV.
2—Amargosa Tryonia snail	*Tryonia* sp.	Littoridinidae	NV.
1—Alamosa spring snail	*Tryonia* sp.	Littoridinidae	NM.
2—Badwater snail	*Assiminea infima* Berry, 1947	Assimineidae	CA.
1—Pecos assiminea snail	*Assiminea* sp.	Assimineidae	NM, TX.
2—Anthony's river snail	*Athearnia anthonyi* (Redfield, 1854)	Pleuroceridae	TN.
2—Crass River snail	*Athearnia crassa* (Haldeman, 1841)	Pleuroceridae	GA, TN.
2—Albany snail	*Goniobasis albanyensis* Lea, 1864	Pleuroceridae	AL, FL, GA.
3B—Indiana river snail	*Goniobasis, semicarinata indianensis* Pilsbry, 1903	Pleuroceridae	IN.
1—Spiny river snail	*Io fluvialis* (Say, 1834)	Pleuroceridae	TN, VA.
2—Mainstream river snail	*Leptoxis praerosa* (Say, 1824)	Pleuroceridae	TN.
3B—Umbilicate river snail	*Leptoxis subglobosa umbilicata* (Weatherby, 1876)	Pleuroceridae	TN.
2—Armigerous river snail	*Lithasia armigera* (Say, 1821)	Pleuroceridae	KY.
2—Dutton's river snail	*Lithasia duttoniana* (Lea, 1841)	Pleuroceridae	TN.
2—Geniculate River snail	*Lithasia geniculata* Haldeman, 1840	Pleuroceridae	TN.
2—Jay's river snail	*Lithasia jayana* (Lea, 1841)	Pleuroceridae	TN.
2—Elk River file snail	*Lithasia lima* (Conrad, 1834)	Pleuroceridae	TN, AL.
3C—Small geniculate river snail	*Lithasia pinguis* (Lea, 1852)	Pleuroceridae	TN.
2—Rugged river snail	*Lithasia salebrosa* (Conrad, 1834)	Pleuroceridae	TN.
2—Verrucose file snail	*Lithasia verrucosa* (Rafinesque, 1820)	Pleuroceridae	TN
2—Giant Columbia River limpet	*Fisherola nuttalli* (Haldeman, 1841)	Lancidae	ID, OR, WA.
2—Utah band snail	*Lymnaea kingii* Meek, 1877 (=*Stagnicola utahensis* Call, 1844).	Lymnaeidae	UT.
2—Fish Springs pond snail	*Stagnicola pilsbryi* (Hemphill, 1890)	Lymnaeidae	UT.

Category and common name	Scientific name	Family	Distribution
2—Cape Fear ramshorn snail	*Helisoma magnificum* (Pilsbry, 1903)	Planorbidae	NC.
2—Jackson Lake snail	*Helisoma* (=*Carinifex*) *jacksonense* Henderson, 1932.	Planorbidae	WY.
2—Greenfield ramshorn snail	*Taphius eucosmius eucosmius* Bartsch, 1908	Planoribdae	NC.
1—New Mexico ramshorn snail	Genus and Species undescribed	Planorbidae	NM.
2—Wyoming cave snail	*Physa spelunca* (Turner & Clench, 1974)	Physidae	WY.
2—Utah bubble snail	*Physa utahensis* Clench, 1925	Physidae	UT.
3B—Diamond-Y pond snail	*Physa virgata bottomeri* Clench, 1924	Physidae	TX.
2—Zion Canyon snail	*Physa zionis* Pilsbry, 1905	Physidae	UT.
1—Snake River physa snail	*Physa* sp.	Physidae	ID.
2—Fish Lake snail	*Stenophysa* (=*Aplexa*) *microstriata* (Chamberlain & Berry, 1930).	Physidae	UT.
2—Short Samoan tree snail	*Somoana abbreviata* (Mousson, 1869)	Partulidae	American Samoa.
3A—(No common name)	*Carelia* (all species)	Amastridae	HI.
2—San Clemente Island blunt-top snail	*Sterkia clementina* (Sterki, 1890)	Pupillidae	CA.
2—(No common name)	*Vertigo alabamensis* Clapp, 1915	Pupillidss	AL.
2—(No common name)	*Vertigo hebardi* Vanatta, 1912	Pupillidae	FL.
2—Kanab amber snail	*Oxyloma haydeni kanabensis* Pilsbry, 1948	Succineidae	UT.
3C—Florida tree snail	*Liguus fasciatus* (Muller, 1774)	Bulimulidae	FL.
2—(No common name)	*Helicodiscus diadema* Grimm, 1967	Helicodiscidae	VA.
2—(No common name)	*Helicodiscus hexodon* Hubricht, 1966	Helicodiscidae	TN.
2—(No common name)	*Discus marmorensis* (H. B. Baker, 1932)	Discidae	ID.
1—Slug snail	*Binneya notabilis* Cooper, 1863	Arionidae	CA.
2—(No common name)	*Glyphyalinia pecki* Hubricht, 1966	Zonitidae	AL.
2—(No common name)	*Paravitrea clappi* (Pilsbry, 1898)	Zonitidae	NC, TN.
2—Mt. Matafao different snail	*Diastole matafaoi* Baker, 1938	Helicarionidae	American Samoa.
2—Yate's snail	*Ammonitella yatesi* Cooper, 1868	Ammonitellidae	CA.
2—(No common name)	*Ashmunella pasonis* (Drake, 1951)	Polygyridae	TX.
2—Archer's toothed land snail	*Mesodon archeri* Pilsbry, 1940	Polygyridae	TN.
2—Clench's middle-toothed land snail	*Mesodon clenchi* (Rehder, 1932)	Polygyridae	AR.
2—(No common name)	*Mesodon clausus trossulus* Hubricht, 1966	Polygyridae	AL.
3C—Jones' middle-toothed land snail	*Mesodon jonesianus* (Archer, 1938)	Polygyridae	NC.
2—Magazine Mountain middle-toothed snail	*Mesodon magazinensis* (Pilsbry and Ferris, 1906)	Polygyridae	AR.
2—(No common name)	*Polygyra hippocrepis* (Pfeiffer, 1848)	Polygyridae	TX.
2—Strange many-whorled land snail	*Polygyra peregrina* Rehder, 1932	Polygyridae	AR.
2—(No common name)	*Stenotrema leai cheatumi* Fullington, 1974	Polygyridae	TX.
2—(No common name)	*Stenotrema hubrichti* Pilsbry, 1940	Polygyridae	IL.
2—Pilsbry's narrow-apertured land snail	*Stenotrema pilsbryi* (Ferris, 1900)	Polygyridae	AR, OK.
2—(No common name)	*Triodopsis mullani magnidentata* (Pilsbry, 1940)	Polygyridae	ID.
2—Western three-toothed land snail	*Triodopsis occidentalis* (Pilsbry and Ferris, 1907)	Polygyridae	AR.
1—Karok Indian snail	*Vespericola karokorum* Talmage, 1962	Polygyridae	CA.
2—(No common name)	*Oreohelix avalonensis* Pilsbry, 1905	Oreohelicidae	CA.
2—Carinated striate banded mountain snail	*Oreohelix strigosa goniogyra* Pilsbry, 1933	Oreohelicidae	ID.
2—Idaho banded mountain snail	*Oreohelix idahoensis idahoensis* Newcomb, 1866	Oreohelicidae	ID.
2—(No common name)	*Oreohelix jugalis jugalis* (Hemphill, 1980)	Oreohelicidae	ID.
2—Vortex banded mountain snail	*Oreohelix jugalis vortex* Berry, 1932	Oreohelicidae	ID.
2—Walton's banded mountain snail	*Oreohelix waltoni* Solem, 1975	Oreohelicidae	ID.
2—Coalville mountain snail	*Oreohelix peripherica weberiana* Pilsbry, 1939	Oreohelicidae	UT.
2—Allyn Smith's banded snail	*Helminthoglypta allynsmithi* Pilsbry, 1939	Helminthoglyptidae	CA.
3B—Cape Mendocino snail	*Helminthoglypta arrosa mattolensis* A. G. Smith, 1938.	Helminthoglyptidae	CA.
3B—Dented Peninsula snail	*Helminthoglypta arrosa miwoka* (Bartsch, 1919)	Helminthoglyptidae	CA.
2—(No common name)	*Helminthoglypta arrosa pomoensis* A. G. Smith, 1938.	Helminthoglyptidae	CA.
2—(No common name)	*Helminthoglypta arrosa williamsi* A. G. Smith, 1938	Helminthoglyptidae	CA.
2—(No common name)	*Helminthoglypta callistoderma* (Pilsbry & Ferris, 1918).	Helminthoglyptidae	CA.
2—(No common name)	*Helminthoglypta mohaveana* Berry, 1927	Helminthoglyptidae	CA.
2—Nicklin's peninsula snail	*Helminthoglypta nickliniana awania* (Bartsch, 1919)	Helminthoglyptidae	CA.
2—(No common name)	*Helminthoglypta nickliniana bridgesi* (Newcomb, 1861).	Helminthoglyptidae	CA.
2—(No common name)	*Helminthoglypta sequoicola consors* (Berry, 1838)	Helminthoglyptidae	CA.
2—(No common name)	*Helminthoglypta traski coelata* (Bartsch, 1916)	Helminthoglyptidae	CA.
1—Banded dune snail	*Helminthoglypta walkeriana* (Hemphill, 1911)	Helminthoglyptidae	CA.
1—Concentrated snail	*Micrarionta facta* (Newcomb, 1864)	Helminthoglyptidae	CA.
2—Fraternal snail	*Micrarionta feralis* (Hemphill, 1901)	Helminthoglyptidae	CA.
2—Gabb's snail	*Micrarionta gabbi* (Newcomb, 1864)	Helminthoglyptidae	CA.
3B—Cathedral snail	*Micrarionta indioensis cathedralis* Willet, 1930	Helminthoglyptidae	CA.
2—(No common name)	*Micrarionta rowelli bakerensis* Pilsbry and Lowe, 1934.	Helminthoglyptidae	CA.
2—California McCoy snail	*Micrarionta rowelli mccoiana* Willet, 1935	Helminthoglyptidae	CA.
2—(No common name)	*Micrarionta immaculata* Willet, 1937	Helminthoglyptidae	CA.
3C—Horseshoe snail	*Micrarionta intercisa* (W. G. Binney, 1857)	Helminthoglyptidae	CA.
2—Colorado desert snail	*Micrarionta morongoana* Berry, 1929	Helminthoglyptidae	CA.
2—Prickly pear snail	*Micrarionta opuntia* Roth, 1975	Helminthoglyptidae	CA.
3C—Wreathed island snail	*Micrarionta redimita* (W. G. Binney, 1858)	Helminthoglyptidae	CA.
3C—Tryon's snail	*Micrarionta tryoni* (Newcomb, 1864)	Helminthoglyptidae	CA.
2—(No common name)	*Monadenia circumcarinata* (Stearns, 1879)	Helminthoglyptidae	CA.
2—(No common name)	*Monadenia fidelis minor* (W. G. Binney, 1865)	Helminthoglyptidae	OR.
2—Rocky coast snail	*Monadenia fidelis pronotis* Berry, 1931	Helminthoglyptidae	CA.
2—Indian Yosemite snail	*Monadenia hillebrandi yosemitensis* (Lowe, 1916)	Helminthoglyptidae	CA.
2—(No common name)	*Monadenia mormonum buttoni* (Pilsbry, 1900)	Helminthoglyptidae	CA.
2—(No common name)	*Monadenia mormonum hirsuta* Pilsbry, 1927	Helminthoglyptidae	CA.
2—(No common name)	*Monadenia troglodytes* Hanna and Smith, 1933	Helminthoglyptidae	CA.
2—Trinity bristle snail (=California northern river snail).	*Monadenia setosa* Talmadge, 1952	Helminthoglyptidae	CA.
2—(No common name)	*Sonorella aremita* Pilsbry and Ferris, 1915	Helminthoglyptidae	AZ.
2—(No common name)	*Sonorella metcalfi* Miller, 1976	Helminthoglyptidae	TX.
CLAMS AND MUSSELS (Molluscs, Class Bivalvia)			
2—Spectacle case pearly mussel	*Cumberlandia monodonta* (Say, 1829)	Margaritiferidae	IN, IL, KY, MO, NE, OH, TN, VA.
2—Alabama pearl shell	*Margaritifera marrianae* Johnson, 1983	Margaritiferidae	AL.
2—(No common name)	*Alasmidonta arcula* (Lea, 1830)	Unionidae	GA.
2—(No common name)	*Alasmidonta atropurpurea* (Rafinesque, 1831)	Unionidae	KY, TN.

Category and common name	Scientific name	Family	Distribution
2—Dwarf wedge mussel	*Alasmidonta heterodon* (Lea, 1830)	Unionidae	MA, MD, NC, NH, NJ, PA, VA, VT, Canada.
3A—(No common name)	*Alasmidonta mccordi* Athearn, 1964	Unionidae	GA.
2—(No common name)	*Alasmidonta raveneliana* (Lea, 1834)	Unionidae	NC, TN.
2—(No common name)	*Alasmidonta robusta* Clarke, 1981	Unionidae	NC, SC.
2—(No common name)	*Alasmidonta wrightiana* Walker, 1901	Unionidae	FL.
2—Wheeler's pearly mussel	*Arkansia whealeri* Ortmann and Walker, 1912	Unionidae	AR, OK.
2—Virginia spiny mussel	*Fusconaia collina* (Conrad, 1837)	Unionidae	VA.
1—Tar River spiny mussel	*Elliptio* (*Canthyria*) *steinstansana* Johnson and Clarke, 1983.	Unionidae	NC.
2—Georgia spiny mussel	*Elliptio* (*Canthyria*) *spinosa* (Lea, 1836)	Unionidae	GA.
2—Savannah shore mussel	*Carunculina pulla* (Conrad, 1838)	Unionidae	GA, NC, SC.
2—Western fan-shell pearly mussel	*Cyprogenia aberti* (Conrad, 1838)	Unionidae	AR, KS, MO, OK.
2—Eastern fan-shell pearly mussel	*Cyprogenia irrorata* (Lea, 1830)	Unionidae	AL, TN, KY, VA.
2—Cape Fear spike pearly mussel	*Elliptio marsupiobesa* Fuller, 1972	Unionidae	NC.
2—Waccamaw lance pearly mussel	*Elliptio* sp.	Unionidae	NC.
3A—Recovery pearly mussel	*Elliptio nigella* (Lea, 1852)	Unionidae	GA.
2—Waccamaw spike	*Elliptio waccamawensis* (Lea, 1863)	Unionidae	NC.
3A—Arc-form pearly mussel	*Epioblasma* (=*Dysnomia*) *arcaeformis* (Lea, 1831)	Unionidae	AL, TN.
3A—(No common name)	*Epioblasma* (=*Dysnomia*) *biemarginata* (Lea, 1857)	Unionidae	AL, TN.
2—(No common name)	*Epioblasma* (=*Dysnomia*) *brevidens* (Lea, 1831)	Unionidae	AL, KY, TN, VA.
2—(No common name)	*Epioblasma* (=*Dysnomia*) *capsaeformis* (Lea, 1834)	Unionidae	AL, TN, KY, VA.
3A—Arcuate pearly mussel	*Epioblasma* (=*Dysnomia*) *flexuosa* (Rafinesque, 1820).	Unionidae	AL, TN.
3A—Acorn pearly mussel	*Epioblasma* (=*Dysnomia*) *haysiana* (Lea, 1834)	Unionidae	AL, TN, VA.
3A—Lefevre's pearly mussel	*Epioblasma* (=*Dysnomia*) *lefevrei* (Utterback, 1915)	Unionidae	AR, MO.
3A—Stones pearly mussel	*Epioblasma* (=*Dysnomia*) *lenior* (Lea, 1843)	Unionidae	AL, TN.
3A—Lewis' pearly mussel	*Epioblasma* (=*Dysnomia*) *lewisi* (Walker, 1910)	Unionidae	AL, TN, KY.
1—Penitent mussel	*Epioblasma* (=*Dysnomia*) *penita* (Conrad, 1834)	Unionidae	AL, MS.
3A—Fine-rayed pearly mussel	*Epioblasma* (=*Dysnomia*) *personata* (Say, 1829)	Unionidae	AL, TN.
3A—Nearby pearly mussel	*Epioblasma* (=*Dysnomia*) *propinqua* (Lea, 1857)	Unionidae	AL, TN.
3A—Steward's pearly mussel	*Epioblasma* (=*Dysnomia*) *stewardsoni* (Lea, 1852)	Unionidae	AL, TN.
2—Purple cat's paw pearly mussel	*Epioblasma* (=*Dysnomia*) *sulcata sulcata* (Lea, 1824).	Unionidae	AL, TN, KY.
2—Cracking pearly mussel	*Hemistena* (=*Lastena*) *lata* (Rafinesque, 1820)	Unionidae	KY, TN, VA.
2—(No common name)	*Lampsilis perovalis* (Conrad, 1834)	Unionidae	AL, MS.
2—Neosho pearly mussel	*Lampsilis rafinesqueana* Frierson, 1927	Unionidae	KS, MO, OK.
2—(No common name)	*Lampsilis streckeri* Frierson, 1927	Unionidae	AR TX.
2—(No common name)	*Lasmigona holstonia* (Lea, 1838)	Unionidae	AL, TN, VA.
2—Scale shell	*Leptodea leptodon* (Rafinesque, 1820)	Unionidae	AR, MO, OK.
2—Slab-side pearly mussel	*Lexingtonia dolabelloides* (Lea, 1840)	Unionidae	AL, TN, VA.
2—Golf stick pearly mussel	*Obovaria retusa* (Lamarck, 1819)	Unionidae	AL, TN, KY.
2—Little-winged pearly mussel	*Pegias fabula* (Lea, 1836)	Unionidae	AL, KY, VA.
2—Northern club shell	*Pleurobema clava* (Lamarck, 1819)	Unionidae	AL, IN, KY, MI, OH, TN.
1—Curtus' mussel	*Pleurobema curtum* (Lea, 1859)	Unionidae	AL, MS.
1—Marshall's mussel	*Pleurobema marshalli* Frierson, 1927	Unionidae	AL, MS.
2—(No common name)	*Pleurobema oviforme* (Conrad, 1834)	Unionidae	TN, VA.
2—(No common name)	*Pleurobema rubrum* (Rafinesque, 1820)	Unionidae	AL, KY, TN.
1—Judge Tait's mussel	*Pleurobema taitianum* (Lea, 1834)	Unionidae	AL, MS.
2—(No common name)	*Potamilus inflatus* (Lea, 1831)	Unionidae	AL, MS.
2—Rough rabbit's foot pearly mussel	*Quadrula cylindrica strigillata* (Wright, 1898)	Unionidae	AR, OH, TN, VA.
2—Rough maple leaf pearly mussel	*Quadrula fragosa* (Conrad, 1836)	Unionidae	OK.
1—Stirrup shell	*Quadrula stapes* (Lea, 1831)	Unionidae	AL, MS.
2—Salamander mussel	*Simpsoniconcha* (=*Simpsonaias*) *ambigua* (Say, 1825).	Unionidae	IA, IL, IN, KY, MI, MO, OH, TN, WI.
2—Choctaw pearly mussel (Athearn's Villosa pearly mussel).	*Villosa choctawensis* (Athearn, 1964)	Unionidae	AL, FL.
2—(No common name)	*Villosa* (=*Micromya*) *fabalis* (Lea, 1831)	Unionidae	KY, MI, OH, TN, VA.
2—Ortmann's pearly mussel	*Villosa* (=*Micromya*) *ortmanni* (Walker, 1925)	Unionidae	KY.
2—Fine-rayed purple pearly mussel	*Villosa* (=*Micromya*) *perpurpurea* (Lea, 1861	Unionidae	VA.
2—(No common name)	*Pisidium ultramontanum* Prime, 1865	Sphaeriidae	CA, OR.

[FR Doc. 84-13661 Filed 5-21-84: 8:45 am]
BILLING CODE 4310-55-M

Federal Register

Tuesday
May 22, 1984

Part IV

Evironmental Protection Agency

40 CFR Part 271

State Hazardous Waste Programs; Procedures for Revision of State RCRA Programs; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 271

[SW-FRL-2558-2]

State Hazardous Waste Programs; Procedures for Revision of State RCRA Programs

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: EPA is today promulgating amendments to its requirements under 40 CFR 271.21(e) for the approval and revision of authorized State hazardous waste programs. One purpose is to ensure that States applying for final authorization under the Resource Conservation and Recovery Act of 1976, as amended (RCRA), do not have to revise their programs and applications to respond to Federal regulatory changes occurring while the States' applications are being prepared or processed. The second purpose is to provide authorized States sufficient time to amend their programs to conform to Federal program changes. The final rule establishes deadlines for making changes and provides a time extension for those States that can demonstrate its necessity.

DATES: These regulations shall be promulgated for purposes of judicial review at 1:00 p.m. eastern time on June 5, 1984. These regulations shall become effective on June 5, 1984.

FOR FURTHER INFORMATION CONTACT: The RCA Hotline at (800) 424–9346, or in Washington, D.C., 382–3000; or Denise Hawkins, Office of Solid Waste, U.S. Environmental Protection Agency, Washington, D.C. 20460, (202) 382–2210.

SUPPLEMENTARY INFORMATION:

I. Background

Section 3006(b) of the Resource Conservation and Recovery Act of 1976 (RCRA) requires EPA to grant final authorization to State hazardous waste programs that: (1) Are equivalent to the Federal hazardous waste program (40 CFR Parts 124, 260–266 and 270); (2) are consistent with the Federal program and other State programs which have received final authorization; and (3) provide adequate enforcement. In addition, Section 3009 of RCRA provides that State programs may not impose any requirements "less stringent" than the Federal requirements. The effect of final authorization is that a State operates its State hazardous waste management program in lieu of EPA's operating the Federal hazardous waste management program in the State. Regulations which govern the granting of final authorization are set forth in 40 CFR Part 271, Subpart A.

Section 271.21(e) requires that State programs comply with the Federal regulations immediately upon approval (authorization). This section also requires States which have received final authorization to make any necessary changes to their programs when the Federal regulations change. The latter requirement assures that State programs remain equivalent to and no less stringent than the Federal program. Currently, the regulation provides that program revisions after authorization must be made within one year of the date of promulgation of the modified Federal regulations (or two years if a State must revise its statutes).

The States, through the National Governors' Association and the Association of State and Territorial Solid Waste Management Officials (ASTSWMO), asserted that this regulation presented problems both for States applying for final authorization and for States which are already authorized.

A. States Applying for Final Authorization

Section 271.21(e) currently provides that State programs must be judged against the Federal requirements in effect at the time of approval. Thus, while a State is preparing its application, the State must be concerned with new EPA regulations which may become effective by the time the State program is approved. This requirement could result in substantial delay as a State would be required to amend its program, provide for public participation and revise its application should a Federal regulation become effective during the application review process. This could also result in reversion of interim-authorized State programs to EPA if the delay resulted in an interim-authorized State being unable to achieve final authorization by January 26, 1985, the date all interim authorizations expire.

To reduce the likelihood of such reversions and to resolve the uncertainty about what Federal requirements the States must meet to receive final authorization, EPA proposed on August 25, 1983 (48 FR 38722–38725), a different basis for assessment of State programs. EPA proposed that the Federal regulations in effect one year prior to submission of the State's official application or the Federal regulations in effect on January 26, 1983, whichever is later, would be the Federal program against which a State program would be measured for the purpose of receiving final authorization.

B. States With Final Authorization

In meetings with the Agency, the National Governors' Association and the Association of State and Territorial Solid Waste Management Officials expressed concern about the time periods allowed for modification of authorized State programs after promulgation of amendments to the Federal regulations. They asserted that the amount of time provided by § 271.21(e) does not allow adequate leeway for State regulatory or legislative schedules. In the August 25 proposal, EPA proposed to extend by six months the time period allowed for making such modifications. For modifications in States which must submit their regulations for review by State legislatures or legislative committees, the Agency also proposed to allow the same amount of time as allowed for modifications requiring State statutory amendments.

In the preamble to the proposal, EPA specifically stated that public comments on the proposal would be critical. Although the State associations believed the time frames to be a problem, there was little specific documentation available to EPA which demonstrated the number of States which would have difficulty meeting the deadlines or which would justify an appropriate alternative time frame. EPA explained that comments would be used to confirm whether there was a real need for the proposed amendments and to determine whether the time frames proposed by EPA were appropriate.

EPA's resolutions of the issues discussed above, embodied in this final rule, are discussed below.

II. Provisions of the Final Rule

A. States With Final Authorization

The State commentors uniformly supported the proposal to extend the amount of time allowed for States to modify their programs in response to Federal program changes. However, comments received from the States during the public comment period did not persuasively demonstrate a widespread need to amend the deadlines in the existing requirements. In fact, a survey taken by ASTSWMO showed only a small number of States for which the existing deadlines would pose a problem. Of 42 States responding to this portion of the ASTSWMO poll, 30 indicated that they could make regulatory changes within one year.

While seventeen States commented during the public comment period on this aspect of the proposal, the comments were quite general. Only three States provided specific explanations demonstrating that the one year time period for regulatory amendments would not be adequate.

Comments on time frames for statutory amendments were similar. Of 41 States responding to this portion of the ASTSWMO survey, 25 indicated that amendments could be passed within 24 months. Six additional States gave only minimum time frames which ranged from six to 12 months, well within the 24 months allowed by the existing regulation. Ten States indicated that they would require more than 24 months. Four States indicated that they had biennial legislatures which may be unable to meet the 2-year time frame, depending on the timing of the amended Federal regulation.

Comments also did not demonstrate the need to allow the same amount of time for regulatory amendments which require action by State legislatures as is allowed for statutory amendments. No State provided data that demonstrated that legislative review would require it to exceed the one-year time frame although, depending on the timing of rule development, this situation could possibly occur.

Some commenters opposed the proposed extension, believing that there was insufficient evidence that a large number of States did, indeed, require more time than was currently provided to modify their programs. They also believed that the speed with which States upgrade their programs to reflect changes to the Federal regulations is critical to effecting actual implementation of these changes.

Although individual States did indicate that there may be difficulty in meeting the time frames, the comments received indicated that most States do not need more time to make program modifications. The Agency, therefore, has decided to retain the existing deadlines for modifying State programs, but to allow a limited extension of these deadlines in certain situations. Therefore, in general, States will have 12 months from the date of promulgation of Federal regulations to modify their programs and 24 months if a statutory amendment is required. However, where States are unable to meet these deadlines due to the legitimate constraints of their legislative or rulemaking processes, a case-by-case extension of the deadlines for up to six months will be allowed. Examples of legitimate reasons for extending the deadlines may include, but are not limited to:

—States with biennial legislatures,
—States with lengthy public participation requirements, and
—States which require legislative review of regulations.

The fact that these situations exist, however, will not guarantee an extension in every case. The extension may only be granted by the Regional Administrator where the State has made a good faith effort to meet the deadline and can demonstrate that exigencies of the legislative or rulemaking process render the deadline impossible to meet. The extension, however, cannot exceed six months.

The rule also addresses modification of State programs in response to potential Congressional amendments to RCRA. The Act is currently being considered by Congress for reauthorization. The Agency cannot predict precisely the timing or content of the new legislation. However, unlike the current Act, the bills under consideration contain provisions which will automatically take effect in both authorized and nonauthorized States. If these statutory provisions, commonly referred to as "self-implementing", take effect in this manner, they immediately become part of "the Federal program". The proposed amendments to this rule addressed only Federal regulatory changes; however, in the event Congress enacts such legislation and the self-implementing provisions actually take effect, authorized States must also develop State analogs to these Federal statutory requirements in order to remain equivalent to the Federal program. (Until the States revise their programs, EPA will implement the Federal statutory requirements in authorized States.) The final rule, therefore, provides that States have one year (or two years if statutory revisions are required) in which to modify their programs, commencing on the effective date of the particular self-implementing statutory provision.

While EPA did not explicitly deal with Federal legislative changes in the proposed regulation, the issues are exactly the same as for Federal regulatory changes. Therefore, additional notice and comment is not necessary. Including Federal legislative changes in the final rule simply clarifies the obvious point that the "Federal program" to which programs must remain equivalent includes Federal statutory, as well as regulatory, provisions.

There is one aspect of this rule which requires clarification. The rule addresses the length of time States have to "modify" their programs. The proposed rule used the term "revise". In the proposed rule, in all conversations with the State associations and in all comments received on the proposal, all parties have apparently interpreted "revise" to mean the length of time required for the States to make appropriate statutory, regulatory or other program changes. That was also EPA's intent. However, the actual process of revision, as described in 40 CFR 271.21(a)–(d), includes not only State actions, but the EPA actions required to approve such changes as well. The final rule, therefore, uses the term "modify" to clarify that paragraph (e) of this section refers only to completion of the State process to adopt or amend statutes and/or regulations or other State actions necessary to respond to amendments in the Federal program. Subsequent Federal actions which are required to approve such State modifications are not included in the time frames provided in this final rule, but are addressed in paragraph (b) of 40 CFR 271.21. To ensure that State program modifications are submitted to EPA in a timely manner in order to complete the revision process, the final rule provides that the documentation described in paragraph (b) must be submitted to EPA within 30 days of completion of any State program modification.

B. States Applying for Final Authorization

The proposed amendment would have required that States submitting applications for final authorization demonstrate equivalence with the Federal program in effect one year prior to the submission of their official applications or the program in effect on January 26, 1983, whichever is later. Most Federal regulations under RCRA become effective six months after promulgation. Therefore, this proposal allowed a State 18 months from the date of promulgation of Federal regulations to prepare and submit a complete application, and was consistent with the 18 months allowed in the proposal for authorized States to revise their programs.

Commentors supported the idea of using a time (e.g., date of submission of the official application) to specify the Federal program against which a State's program would be judged for final authorization. However, there is no reason to provide more time prior to final authorization for States to modify their programs than is provided after final authorization. It is important to

ensure that States modify their programs in a timely manner in order to provide the intended level of public health and environmental protection, and it is desirable to maintain consistency between the two parts of this regulation. Therefore, the final rule provides that State applications for final authorization will be assessed on the basis of the Federal regulations that were promulgated 12 months prior to the submission of the official application. It is possible for Federal regulations to become effective sooner than six months after promulgation. However, by calculating the time from the date of promulgation rather than the effective date, EPA is assuring that States will actually have at least 12 months in which to make corresponding changes in their programs prior to submitting their applications.

The previous section discussed the situation where certain authorized States may require more than 12 months to make program modifications. Similarly, some State programs may, for like reasons, need more than 12 months in which to acquire the State authority (i.e., adopt the statutes and regulations) necessary to obtain final authorization in the first place. Therefore, the final rule provides that a State may request more time where the State is unable, after a good faith effort and for reasons such as those discussed earlier, to address in its application all the Federal regulations promulgated 12 months previously. In such cases, States may on a case-by-case basis, seek to receive approval to have the application assessed on the basis of the Federal regulations that were promulgated up to 18 months prior to the submission of its official application.

Where the Federal program is changed (e.g., revised Federal regulations are promulgated) during the 12 months prior to submission of the official application or during the period between submission of the official application and receipt of authorization, the State will not be required to amend its official application for final authorization. Nevertheless, the State must use the same time period to adopt State analogs to the new Federal requirements with the one year/two year schedule prescribed in 40 CFR 271.21(e)(1)(C). However, because the State will be proceeding on two separate schedules— one to obtain final authorization and one to incorporate State analogs to the most recent Federal amendments—it is possible that the one-year deadline for making State regulatory changes could expire before the State receives final authorization. To avoid the unintended result of requiring a State to modify its program before it has an authorized program to modify, the final rule provides that the State can modify its program either by 12 (or 24) months from the promulgation date of the Federal program change or by the time of authorization, whichever is later.

Under the proposed rule, the following situation could occur. Were a State to submit an official application in January 1986, it would be judged against the Federal regulations promulgated as of January 1985. If EPA promulgates a rule in February 1985 which will become effective in August 1985, the State would not have to address that rule in its application for final authorization. It would, however, have only until February 1986 (that is, one year from the February 1985 Federal promulgation) to modify its program to include an analogous State requirement. The State most likely would not receive authorization until July 1986, six months after it submitted its official application. In that case, even before it received final authorization to administer the RCRA program, the State would be in violation of the requirement to modify its program to conform to Federal program changes. This change is intended to prevent that situation, while ensuring that State analogs to Federal amendments are developed in a timely manner.

This amendment was not in the proposed rule, but we do not believe there is a need for further notice and comment. The change is designed to remedy an unanticipated and illogical timing problem arising from the "time window" provided for preparation and submission of the official application.

The proposed rule provided that State programs applying for final authorization would be assessed on the basis of the Federal regulations that are in effect one year prior to submission of the official application or in effect on January 26, 1983, whichever is later. The latter date was not retained in the final rule since January 26, 1984 has passed. In all cases, therefore, one year prior to submission of the official application will be later than January 26, 1983.

The proposed rule also requested comments on whether to assess official applications on the basis of the Federal program in effect one year prior to submission of the official application or one year prior to the effective date of this regulation, whichever is later. Comments were divided on this option. We have chosen to assess the official application on the basis of the Federal program promulgated one year prior to submission of the official application. Only one regulation is affected by this choice: on February 10, 1984, EPA expanded the scope of the Federal program by adding a new listing, 49 FR 5308–5312. Many States have submitted or are within a few months of submitting official applications. Requiring these States to include analogs to this new listing in their official applications would seriously jeopardize the ability of many of these States to receive final authorization prior to January 26, 1985. This would defeat the entire purpose of this "moving target" amendment by imposing, at the last minute, a new requirement. Therefore, the final rule allows this new listing to be treated as a program revision for States submitting their official applications prior to February 10, 1985. Of course, States that are able to do so are not precluded from including and receiving authorization for this listing.

Finally, as discussed in the previous section, the final rule clarifies that States applying for final authorization must have provisions equivalent to Federal statutory, as well as, regulatory provisions. The final rule, therefore, provides that official applications from States applying for final authorization will be assessed on the bases of Federal self-implementing statutory provisions in effect 12 months prior to submission of the official application and Federal regulations promulgated 12 months prior to submission of the official application.

III. Response to Comments

The explanation in the previous section gives the EPA's reasons for rejecting the comments supporting the proposed amendments. Other commentor criticized aspect of the proposal which EPA is not adopting; therefore, there is no need to respond to them. The following responds to the remaining comments.

A. States With Authorization

Comment: EPA encourages inaction and delay by the States by providing more time than necessary for them to make the requisite changes in their regulatory programs. If any modification to § 271.21(e) is required, it must provide additional time to only those States which truly require more time.

Response: EPA agrees that there is insufficient evidence to demonstrate that a large number of States would be unable to meet the existing time frame. The final rule has been modified, as suggested by the commentor, to allow a State an extension only upon demonstration that its rulemaking procedures render the deadline impossible to meet.

B. States Applying for Authorization

Comment: There is constant contact between EPA and the States which includes informing the States about upcoming Federal regulations. The time between proposal and promulgation of a regulation combined with the six months between the promulgation date and effective date should be sufficient for States to plan their rulemaking and submit applications for authorization.

Response: The commentor's observation is correct insofar as the notice of proposed rulemaking puts the public on notice of upcoming regulations. However, as EPA evlauates and responds to public comments, final rules promolugated by EPA are very often different from the proposed rules. Thus States cannot know the precise content of a final rule before it is promulgated.

Comment: Where Federal rules become effective during review of a State's authorization application, language should be required in the Memorandum of Agreement (MOA) between the State and EPA that would provide for "cross-referencing" of Federal rules until necessary changes can be made in the State's rules or statutes.

Response: RCA provides that an authorized State program operates "in lieu of" the Federal program. Therefore, once a State is authorized, Federal rules do not apply in that State. Certain States may have broad enough authority in existing statutes or regulations to implement new Federal requirements. However, State due process requirements will ordinarily require that the public be given notice and opportunity for comment before new requirements are imposed. MOA agreements have limited value as a substitute for State regulations.

Comment: EPA has not taken the six months between promulgation date and effective date into account in computing the one-year grace period for States applying for final authorization.

Response: EPA did consider the period between promulgation and effective dates. The proposal reflected our intent to allow States 18 months to amend their regulations prior to submitting an official application (that is, one year prior to the date of submission of an official application six months between the promulgation and effective date). This was consistent with the second part of the proposal which allowed authorized States 18 months from the date of promulgation to amend their programs in response to changes in the Federal program. As described previously, the final rule was changed.

Comment: Judging a State's program against Federal regulations in effect does not provide sufficient flexibility. States should have the option of including certain proposed Federal regulations under certain circumstances.

Response: RCRA does not allow EPA to adopt the approach recommended by the commentor. Section 3006(b) provides that the Administrator must assess the equivalence of State programs based on "the Federal program under this subtitle." The Federal program only includes promulgated rules and, therefore, proposed rules cannot be considered when reviewing a State's program for authorization. In addition, proposals do not represent final Agency decisions.

Comment: At the time EPA promulgates its revised definition of solid waste and related standards for recycle/reuse activities, EPA should make clear that these regulatory requirements must be adopted by States wishing to achieve or maintain equivalency for purposes of Section 3006 of RCRA.

Response: This rulemaking pertains to the length of time States should be allowed to modify their programs in response to Federal program changes, while the comment pertains to what portions of a specific Federal regulation States should be required to adopt. At the time EPA promulgates the revised definition, the Agency will announce the changes States must make in order to maintain equivalence to the Federal program.

IV. Effective Date

In its August 25, 1983, proposal (48 FR 38722–38725) to amend this regulation, EPA explained its intent to make the amendment immediately effective. The Agency received no comments opposing this intention. The Agency believes that the effect of moving target for authorization would be confusing and disruptive for the States, the public and the regulated community. For these reasons, the Agency believes there is good cause for making this rule effective immediately.

IV. Executive order 12291

Under Executive Order 12291 (46 FR 12193, February 19, 1981), EPA must judge whether a regulation is "major" and, therefore, subject to the requirement of a Regulatory Impact Analysis. A major rule is defined as a regulation which is likely to result in:

—An annual effect on the economy of $100 million of more;

—A major increase in costs or prices for consumers, individual industries, Federal, State or local government agencies or geographic regions; or

—Significant adverse effects on competition, employment, investment, productivity, innovation or on the ability of United States-based enterprises to compete foreign-based enterprises in domestic or export markets.

The regulation is not major because it will not result in an effect on the economy of $100 million or more, an increase in costs or prices, or any of the adverse effects mentioned in the Executive Order. Because this proposed amendment is not a major regulation, no Regulatory Impact Analysis is being prepared.

This proposed amendment was submitted to the Office of Management and Budget for review as required by Executive Order 12291. Any comments from OMB to EPA and any EPA response to those comments are available for public inspection at the Office of Solid Waste Docket, Room S–269, U.S. EPA, 401 M Street, SW., Washington, D.C. 20460.

VI. Regulatory Flexibility Act

Pursuant to the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, EPA is required to determine whether a regulation will have significant impact on a substantial number of small entities so as to require a regulatory flexibility analysis. No regulatory flexibility analysis is required where the head of the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities.

The amendments promulgated here merely add flexibility to procedural requirements for the modification of State hazardous waste programs and do not affect the compliance burdens of the regulated community. Therefore, pursuant to 5 U.S.C. § 605(b), I certify that this regulation does not have a significant economic impact on a substantial number of small entities.

VII. Paperwork Reduction Act

Under the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.*, EPA must estimate the paperwork burden created by any information collection requests contained in a proposed or final rule. Because there are no information collection activities created by this rulemaking, the requirements of the Paperwork Reduction Act do not apply.

Information collection requirements contained elsewhere in 40 CFR Part 271 have been approved by the Office of Management and Budget (OMB) under the provisions of the Paperwork

Reduction Act and have been assigned OMB control number 2000–0387.

List of Subjects in 40 CFR Part 271

Hazardous materials, Indian lands, Reporting and recordkeeping requirements, Waste treatment and disposal, Water pollution control, Water supply, Intergovernmental relations, Penalties, and Confidential business information.

Dated: May 15, 1984.

William D. Ruckelshaus,

Administrator.

PART 271—STATE PROGRAM REQUIREMENTS

Title 40 of the Code of Federal Regulations is amended as follows:

1. The authority for Part 271 reads as follows:

Authority: Secs. 1006, 2002(a) and 3006 of the Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act, 42 U.S.C. 6901 *et seq.*

2. Section 271.21(e) is revised to read as follows:

§ 271.21 Procedures for revision of State programs.

* * * * *

(e)(1)(i) Official State applications for final authorization shall be reviewed on the bases of Federal self-implementing statutory provisions that were in effect 12 months prior to the State's submission of its official application and the regulations in 40 CFR Parts 124, 260–266, 270 and 271 that were promulgated 12 months prior to the State's submission of its official application. Where a State program meets the requirements of section 3006(b) of RCRA and this Subpart it may receive final authorization for any provision of its program corresponding to a Federal provision in effect on the date of the State's authorization.

(ii) The Regional Administrator may decide to allow the official State application to be reviewed on the bases of Federal self-implementing statutory provisions that were in effect up to 18 months prior to the submission of its official application and the Federal regulations in 40 CFR Parts 124, 260–266, 270 and 271 that were promulgated up to 18 months prior to the submission of its official application. This decision may be made upon an adequate demonstration by a State that it has made a good faith effort to meet the 12-month deadline in paragraph (e)(1)(ii) of this section and that its legislative or rulemaking procedures render the State unable to do so.

(iii) A State must modify its program to comply with any Federal program changes which occur during the time period provided for in paragraphs (e)(1)(i) and (ii) of this section and during the period between submission of its official application and authorization of its program. These State program modifications must be completed within one year of the date of promulgation of the Federal regulation (or within one year of the effective date of a self-implementing Federal statutory amendment) or on the date of final authorization, whichever is later. If a State must amend or enact a statute to make the required changes, such modification shall take place within two years.

(2) Any authorized State program which requires revision because of a Federal program change to this part or to 40 CFR Parts 124, 260–266 or 270 shall be modified within one year (or two years if a State statutory amendment is required) of the date of promulgation of the Federal regulation. Authorized States shall one year (two years if a statutory amendment is required) from the effective date of self-implementing RCRA statutory amendments to modify their programs.

(3) The deadlines in paragraphs (e)(1)(iii) and (e)(2) of this section may be extended by the Regional Administrator upon an adequate demonstration by a State that it has made a good faith effort to meet these deadlines and that its legislative or rulemaking procedures render the State unable to do so. No such extension shall exceed six months or shall be granted when the date of authorization occurs more than 18 months after promulgation of the Federal regulation or 18 months after the effective date of a self-implementing Federal statutory amendment.

(4) The State must submit the documentation described in paragraph (b) of this section to revise its program within 30 days of the completion of the State program modification.

[FR Doc. 84–13680 Filed 5–21–84; 8:45 am]

BILLING CODE 6560–50–M

federal register

Tuesday
May 22, 1984

Part V

Office of Management and Budget

Notice of Cumulative Report on Rescissions and Deferrals

OFFICE OF MANAGEMENT AND BUDGET

Cumulative Report on Rescissions and Deferrals

May 1, 1984.

This report is submitted in fulfillment of the requirements of Section 1014(e) of the Impoundment Control Act of 1974 (Pub. L. 93–344). Section 1014(e) provides for a monthly report listing all budget authority for this fiscal year with respect to which, as of the first day of the month, a special message has been transmitted to the Congress.

This report gives the status as of May 1, 1984 of nine rescission proposals and 59 deferrals contained in the first eight special messages of FY 1984. These messages were transmitted to the Congress on October 3, November 17, December 14 and December 21, 1983; and January 12, February 1 and 22, and March 26, 1984.

Rescissions (Table A and Attachment A)

As of May 1, 1984, there were no rescission proposals pending before the Congress. Attachment A shows the history and status of the nine rescissions proposed by the President in 1984.

Deferrals (Table B and Attachment B)

As of May 1, 1984, $4,056.3 million in 1984 budget authority was being deferred from obligation and $11,000 in 1984 outlays was being deferred from expenditure. Attachment B shows the history and status of each deferral reported during FY 1984.

Information from Special Messages

The special messages containing information on the rescission proposal and deferrals covered by this cumulative report are printed in the **Federal Registers** listed below:

Vol. 48, FR p. 45730, Thursday, October 6, 1983
Vol. 48, FR p. 53060, Wednesday, November 23, 1983
Vol. 48, FR p. 56720, Thursday, December 22, 1983
Vol. 48, FR p. 57098, Tuesday, December 27, 1983
Vol. 49, FR p. 2076, Tuesday, January 17, 1984
Vol. 49, FR p. 4692, Tuesday, February 7, 1984
Vol. 49, FR p. 7342, Tuesday, February 28, 1984
Vol. 49, FR p. 13096, Monday, April 2, 1984.

David Stockman,
Director, Office of Management and Budget.

BILLING CODE 3110-01-M

TABLE A

STATUS OF 1984 RESCISSIONS

	Amount (In millions of dollars)
Rescissions proposed by the President	$ 636.4
Accepted by the Congress	-0-
Rejected by the Congress	-636.4
Pending before the Congress	$ -0-

****

TABLE B

STATUS OF 1984 DEFERRALS

	Amount (In millions of dollars)
Deferrals proposed by the President	$ 7,304.2
Routine Executive releases through May 1, 1984 (OMB/Agency Releases of $3,315.1 million and cumulative adjustments of -$69.3 million)	-3,245.8
Overturned by the Congress	-2.0
Currently before the Congress	$ 4,056.3 a/

a/ This amount includes $11,000 in outlays for a Department of the Treasury deferral (D84-16).

Attachments

Attachment A - Status of Rescissions - Fiscal Year 1984

As of May 1, 1984 Amounts in Thousands of Dollars Agency/Bureau/Account	Rescission Number	Amount Previously Considered by Congress	Amount Currently before Congress	Date of Message	Amount Rescinded	Amount Made Available	Date Made Available
DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT							
Public and Indian Housing Programs							
Payment for operation of low-income housing	R84-2		331,431	2-1-84		331,431	3-28-84
DEPARTMENT OF THE INTERIOR							
National Park Service							
Land acquisition	R84-3		30,000	2-1-84		30,000	3-28-84
DEPARTMENT OF LABOR							
Occupational Safety and Health Administration	R84-1		1,700	12-21-83		1,700	3-19-84
OTHER INDEPENDENT AGENCIES							
Corporation for Public Broadcasting							
Public broadcasting fund	R84-9		20,000	2-1-84		20,000	3-28-84
Delaware and Susquehana River Basin Commissions							
Salaries and expenses, Delaware River Basin Commission	R84-4		19	2-1-84		19	3-28-84
Salaries and expenses, Susquehana River Basin Commission	R84-5		24	2-1-84		24	3-28-84
Panama Canal Commission							
Operating expenses	R84-6A		17,750	2-1-84		17,750	3-28-84
Capital outlay	R84-6B		7,625	2-1-84		7,625	3-28-84
OFF-BUDGET FEDERAL ENTITIES							
DEPARTMENT OF AGRICULTURE							
Rural Electrification Administration							
Rural electrification and telephone revolving fund	R84-7		197,862	2-1-84		197,862	3-28-84
Rural telephone bank	R84-8		30,000	2-1-84		30,000	3-28-84
Rescissions, total BA			636,411			636,411	

Attachment B - Status of Deferrals - Fiscal Year 1984

As of May 1, 1984 Amounts in Thousands of Dollars Agency/Bureau/Account	Deferral Number	Amount Transmitted Original Request	Amount Transmitted Subsequent Change	Date of Message	Cumulative OMB/Agency Releases	Congressionally Required Releases	Congressional Action	Cumulative Adjustments	Amount Deferred as of 5-1-84
FUNDS APPROPRIATED TO THE PRESIDENT									
Appalachian Regional Development Programs									
Appalachian regional development programs..	D84-1	10,000		10-3-83					10,000
International Security Assistance									
Foreign military sales credit.....	D84-30	1,315,000		1-12-84	-187000				1,128,000
Economic support fund.....	D84-24	303,880		12-14-83					
	D84-24A		2,267,691	1-12-84	-1994741				576,830
Military assistance.....	D84-31	426,970		1-12-84	-330030				96,940
DEPARTMENT OF AGRICULTURE									
Soil Conservation Service									
Watershed and flood prevention operations..	D84-49	8,138		2-1-84					8,138
Forest Service									
Construction.....	D84-37	10,814		2-1-84					10,814
Timber salvage sales.....	D84-2	6,211		10-3-83					
	D84-2A		9,210	1-12-84					15,421
Expenses, brush disposal.....	D84-3	42,674		10-3-83					
	D84-3A		12,398	1-12-84					55,072
DEPARTMENT OF COMMERCE									
International Trade Administration									
Participation in U.S. expositions.....	D84-32	550		1-12-84					550
National Oceanic & Atmospheric Administration									
Promote and develop fishery products and research pertaining to American fisheries.	D84-4	33,600		10-3-83	-33600				0
DEPARTMENT OF DEFENSE - MILITARY									
Operation and Maintenance									
Environmental restoration, defense.....	D84-33	75,000		1-12-84	-75000				0
Military Construction									
Military construction, all services.....	D84-5	414,597		10-3-83					
	D84-5A		488,340	12-14-83	-417561			125,198	610,574

As of May 1, 1984 Amounts in Thousands of Dollars Agency/Bureau/Account	Deferral Number	Amount Transmitted Original Request	Amount Transmitted Subsequent Change	Date of Message	Cumulative OMB/Agency Releases	Congressionally Required Releases	Congressional Action	Cumulative Adjustments	Amount Deferred as of 5-1-84
Family Housing, Defense									
Family housing, Air Force	D84-6	53,000		10-3-83					
	D84-6A		20,131	12-14-83	-73131				0
DEPARTMENT OF DEFENSE - CIVIL									
Wildlife Conservation, Military Reservations									
Wildlife conservation	D84-7	777		10-3-83					
	D84-7A		385	1-12-84					1,162
DEPARTMENT OF EDUCATION									
Office of Postsecondary Education									
Higher education	D84-38	500		2-1-84					500
DEPARTMENT OF ENERGY									
Energy Programs									
Energy supply, research & development activities	D84-39	10,052		2-1-84					10,052
Uranium supply and enrichment activities	D84-8	130,000		10-3-83					130,000
Fossil energy research and development	D84-21	20,326		11-17-83	-20326				
	D84-21A		500	12-14-83					
	D84-21B		8,993	2-1-84					9,493
Fossil energy construction	D84-25	38,038	1,962	12-14-83				-26000	
	D84-25A		23,196	2-1-84					37,196
Naval petroleum and oil shale reserves	D84-40	41,500		2-1-84					41,500
Energy conservation	D84-41	10,077		2-1-84					10,077
Strategic petroleum reserve	D84-26	12,707		12-14-83					
	D84-26A		256	2-1-84					12,963
Alternative fuels production	D84-22	13,800		11-17-83					
	D84-22A		4,300	2-1-84	-12300				5,800
Power Marketing Administrations									
Operation and maintenance, Southwestern Power Administration	D84-42	7,000		2-1-84					7,000
Departmental Administration									
Departmental administration	D84-43	29,053		2-1-84					29,053

As of May 1, 1984
Amounts in Thousands of Dollars

Agency/Bureau/Account	Deferral Number	Amount Transmitted Original Request	Amount Transmitted Subsequent Change	Date of Message	Cumulative OMB/Agency Releases	Congressionally Required Releases	Congressional Action	Cumulative Adjustments	Amount Deferred as of 5-1-84
DEPARTMENT OF HEALTH AND HUMAN SERVICES									
Centers for Disease Control									
Disease control	D84-27	15,560		12-14-83					15,560
Office of Assistant Secretary for Health									
Scientific activities overseas (special foreign currency program)	D84-9	6,463		10-3-83					
	D84-9A		571	1-12-84					7,034
Social Security Administration									
Limitation on administrative expenses (construction)	D84-10	10,571		10-3-83					
	D84-10A		10,491	12-21-83	-14				21,048
DEPARTMENT OF THE INTERIOR									
Minerals Management Service									
Payments for proceeds, sale of water, Mineral Leasing Act of 1920	D84-11	48		10-3-83					48
Bureau of the Mines									
Mines and minerals	D84-44	1,667		2-1-84					1,667
National Park Service									
Land acquisition and state assistance (contract authority)	D84-23	30,000		11-17-83					
	D84-23A		2,700	2-1-84				-30000	2,700
Construction (trust fund)	D84-50	14,000		2-22-84					14,000
Office of the Secretary									
Office of Water Policy	D84-51	300		2-22-84					300
DEPARTMENT OF JUSTICE									
Interagency Law Enforcement									
Organized crime drug enforcement	D84-57	272		3-26-84					272
Federal Bureau of Investigation									
Salaries and expenses	D84-58	42,000		3-26-84					42,000
Federal Prison System									
Buildings and facilities	D84-28	22,025		12-14-83					
	D84-28A		23,752						45,777
Office of Justice Assistance, Research and Statistics									
Law enforcement assistance	D84-52	296		2-22-84					296

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DEPARTMENT OF STATE									
International Organizations and Conferences									
Contributions to international organizations	D84-46	4,723		2-1-84					4,723
Contributions for international peacekeeping activities	D84-45	10,879		2-1-84					10,879
United States emergency refugee and migration assistance fund	D84-12	37,928		10-3-83					
	D84-12A		192	1-2-84					38,120
United States bilateral science and technology agreements	D84-13	2,000		10-3-83					2,000
DEPARTMENT OF TRANSPORTATION									
Federal Railroad Administration									
Railroad research and development	D84-53	578		2-22-84					578
Federal Aviation Administration									
Facilities, engineering and development	D84-59	360		3-26-84					360
Construction, Washington Metropolitan Airports	D84-54	277		2-22-84					277
Facilities and equipment (airport and airway trust)	D84-14	1,083,268		10-3-83	-153063				930,205
U.S. Coast Guard									
Retired pay	D84-55	13,350		2-22-84					13.350
Maritime Administration									
Ship construction	D84-47	7,000		2-1-84					7,000
Office of the Secretary									
Transportation planning, research and development	D84-56	160		2-22-84					160
DEPARTMENT OF THE TREASURY									
Office of Revenue Sharing									
State and local government fiscal assistance trust fund	D84-15	56,068		10-3-83	-2866			111	53,313
	D84-16	15,209		10-3-83	-15198				11
Bureau of the Mint									
Expansion and improvements	D84-29	256		12-14-83	-256				

As of May 1, 1984 Amounts in Thousands of Dollars Agency/Bureau/Account	Deferral Number	Amount Transmitted Original Request	Amount Transmitted Subsequent Change	Date of Message	Cumulative OMB/Agency Releases	Congressionally Required Releases	Congressional Action	Cumulative Adjustments	Amount Deferred as of 5-1-84
OTHER INDEPENDENT AGENCIES									
Pennsylvania Avenue Development Corporation									
Land acquisition and development fund	D84-17	13,148		10-3-83					13,148
Railroad Retirement Board									
Milwaukee Railroad restructuring, administration	D84-18	85		10-3-83					
	D84-18A		147	12-14-83					232
Tennessee Valley Authority									
Tennessee Valley Authority fund	D84-19	7,000		10-3-83					7,000
	D84-48	2,192		2-1-84					2,192
United States Information Agency									
Salaries and expenses	D84-34	2,400		1-12-84					2,400
Salaries and expenses (special foreign currency program)	D84-35	2,900		1-12-84					2,900
Acquisition and construction of radio facilities	D84-36	9,645		1-12-84					9,645
United States Railway Association									
Administrative expenses	D84-20	2,050		10-3-83		-2050	98-181		
TOTAL, DEFERRALS		4,428,942	2,875,215		-3,315,087	-2,050		69,309	4,056,330

Notes: Deferral D84-25 was reported as part of D84-21 in the second special message. In the third special message the deferral was reported separately and adjusted upward slightly.

Of the amount deferred as D84-25, $26 million was transferred to Fossil energy research and development pursuant to the 1984 Interior and Related Agencies Appropriations Act.

All of the above amounts represent budget authority except one general revenue sharing deferral (D84-16) of outlays only.

[FR Doc. 84-13817 Filed 5-18-84; 8:45 am]
BILLING CODE 3110-01-C

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Tuesday, May 22, 1984

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This is a continuing list of public bills from the current session of Congress which have become Federal laws. The text of laws is not published in the **Federal Register** but may be ordered in individual pamphlet form (referred to as "slip laws") from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402 (phone 202-275-3030).

H.R. 3240 / Pub. L. 98-285

To authorize the President of the United States to present on behalf of Congress a specially struck medal to the widow of Roy Wilkins. (May 17, 1984; 98 Stat. 186)
Price: $1.50

S.J. Res. 220 / Pub. L. 98-286

To designate the week of May 20, 1984, through May 26, 1984, as "National Arts With the Handicapped Week". (May 17, 1984; 98 Stat. 187)
Price: $1.50.