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The following agencies have agreed to publish all documents on two assigned days of the week (Monday/Thursday or Tuesday/Friday). This is a voluntary program. (See OFR notice 41 FR 32914, August 6, 1976.)

Monday	Tuesday	Wednesday	Thursday	Friday
DOT/COAST GUARD	USDA/ASCS		DOT/COAST GUARD	USDA/ASCS
DOT/NHTSA	USDA/APHIS		DOT/NHTSA	USDA/APHIS
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CSA	MSPB*/OPM*		CSA	MSPB*/OPM*
	LABOR			LABOR
	HEW/FDA			HEW/FDA

Documents normally scheduled for publication on a day that will be a Federal holiday will be published the next work day following the holiday.

Comments on this program are still invited. Comments should be submitted to the Day-of-the-Week Program Coordinator, Office of the Federal Register, National Archives and Records Service, General Services Administration, Washington, D.C. 20408.

***NOTE: As of January 1, 1979, the Merit Systems Protection Board (MSPB) and the Office of Personnel Management (OPM) will publish on the Tuesday/Friday schedule. (MSPB and OPM are successor agencies to the Civil Service Commission.)**

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[6325-01-M]

Title 5—Administrative Personnel

CHAPTER I—OFFICE OF PERSONNEL MANAGEMENT

PART 451—INCENTIVE AWARDS

AGENCY: Office of Personnel Management.

ACTION: Final rule.

SUMMARY: Part 451 is amended to conform with applicable provisions of the Civil Service Reform Act of 1978 (P.L. 95-454) which provide additional incentives designed to encourage high quality performance by Federal employees.

EFFECTIVE DATE: March 16, 1979.

FOR FURTHER INFORMATION CONTACT:

Richard P. Brengel, Incentive Awards Branch, WED Office of Personnel Management, 202/632-5568.

SUPPLEMENTARY INFORMATION: The following specific changes have been made to Part 451:

(1) Sections 451.101(b), 451.103(c)(1), and 451.203 have been changed to include paperwork reduction as a recognizable achievement (P.L. 95-454, Section 502).

(2) Sections 451.102, 451.103(b), 451.201 (a) and (c)(4), 451.202(a), 451.206, 451.302, 451.308 (b) and (c), 451.309 (a) and (b), and (c) (2) and (3), are changed to reflect the organizational change from the Civil Service Commission to the Office of Personnel Management (P.L. 95-454, Section 503).

(3) Sections 451.103(h) and 451.306 have been changed to reflect the addition of Presidential awarding of Ranks in the Senior Executive Service (P.L. 95-454, Section 407).

(4) Sections 451.103(c)(2), 451.303(b), 451.305(c) and 451.309 (a) and (c), have been changed to correct gender-specific terminology.

(5) Section 451.206 has been changed to reflect the new date of November 15 for submission of agency annual reports, to coincide with the new fiscal year reporting cycle.

(6) Section 451.302 has been changed to reflect an increase from $5,000 to $10,000 in authority delegated to agency heads to approve awards (P.L. 95-454, Section 502).

(7) Section 451.306 has been changed to reflect the provisions of E.O. 12014 which abolished the Distinguished Civilian Service Awards Board and delegated authority to the Director, Office of Personnel Management, to advise and assist the President in selecting persons to receive this award.

Accordingly, 5 CFR Part 451, as revised, reads as follows:

PART 451—INCENTIVE AWARDS

Subpart A—General Provisions

Sec.

451.101 Purpose.
451.102 Policy.
451.103 Definitions.

Subpart B—Agency Plans

451.201 Agency plans.
451.202 Awards, promotions, and recognition.
451.203 Stimulating participation.
451.204 Prompt action on contributions.
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Subpart C—Awards

451.301 Basic requirements.
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451.308 Interagency referral.
451.309 Award by other benefiting agency.

AUTHORITY: 5 U.S.C. 4506.

Subpart A—General Provisions

§ 451.101 Purpose.

The Government Employees' Incentive Awards Program is established to improve Government operations and to recognize civilian employees by incentive awards. Awards under this program are designed to:

(a) Encourage employees to participate in improving the efficiency and economy of Government operations;

(b) Recognize and reward employees, individually or in groups, for their suggestions, inventions, superior accomplishments, or other personal efforts that contribute to efficiency, economy, or other improvements in Government operations, or achieve a significant reduction in paperwork; and

(c) Recognize and reward employees, individually or in groups, who perform special acts or services in the public interest in connection with or related to their official employment.

§ 451.102 Policy.

The policy of the Office of Personnel Management in administering chapter 45 of title 5, United States Code, is to:

(a) Establish broad principles and standards for the administration of the Incentive Awards Program;

(b) Delegate to heads of agencies authority to establish and operate incentive awards plans consistent with these principles and standards;

(c) Help agency officials develop effective programs;

(d) Encourage exchange of contributions among agencies; and

(e) Review operation of agency plans to strengthen the Government Employees' Incentive Awards Program.

§ 451.103 Definitions.

In this part:

(a) "Agency," "employee," and "Government" have the meanings given to these terms by section 4501 of title 5, United States Code.

(b) "Plan" means a written statement giving effect to chapter 45 of title 5, United States Code, this part, and the instructions of the Office concerning the incentive awards program, which has been approved by the head of an agency issuing the plan.

(c) "Contribution" means:

(1) An employee's suggestion, invention, superior accomplishment, or other personal effort contributing to the efficiency, economy, or other improvement of Government operations, or achieving a significant reduction in paperwork; and

(2) An employee's special act or service in the public interest, connected with or related to official employment.

(d) "Incentive award or award" means either a cash award, an honorary award, or both.

(e) "Honorary award" means an incentive award granted by the head of an agency in the form of a certificate, emblem, pin, or other item the employee can wear or display.

(f) "Agency award" means an incentive award granted by the head of an agency for an approved contribution from an employee of that agency.

(g) "Interagency award" means an incentive award granted by the head

of an agency for an approved contribution from an employee or employees of another agency.

(h) "Presidential award" means an award granted by the President under sections 4504 and 4507 of title 5, United States Code.

Subpart B—Agency Plans

§ 451.201 Agency plans.

(a) *Establishment and change.* The head of each agency shall establish and operate an incentive award plan, and shall submit any new plan or a change in a plan to the Office within 30 days of the effective date of the plan or the change.

(b) *Authority for awards.* The head of an agency may grant an agency or interagency award for a contribution, to an employee, a former employee, or the estate of a deceased employee.

(c) *Agency administration.* Each plan must provide for:

(1) Central administrative direction and review;

(2) Delegation to bureaus, offices, and field units, of authority and responsibility adequate to ensure maximum compliance with the purposes of chapter 45 of title 5, United States Code, and with this part;

(3) Consideration of the applicability of employee contributions throughout the agency; and

(4) Referral to the appropriate agency or to the Office of contributions that may apply to other agencies;

(5) Use of the normal management review processes for identification of program areas with superior results that warrant award consideration, and use of this data by management to obtain award recommendations for employees who have made a significant contribution to program success.

[33 FR 12444, Sept. 4, 1968, as amended at 34 FR 8193, May 27, 1969; 38 FR 18446, July 11, 1973; 38 FR 26601, Sept. 24, 1973]

§ 451.202 Awards, promotions, and recognition.

The head of each agency shall provide that:

(a) Due weight be given to incentive awards granted under the Incentive Awards Program when qualifying and selecting for promotion employees who meet the Office's requirements for promotion; and

(b) Recognition be given to supervisors for the extent of their success in motivating their employees' interests and participation in the Incentive Awards Program.

§ 451.203 Simulating participation.

To obtain maximum value from the Incentive Awards Program, the head of each agency shall emphasize to supervisors and employees the need for their active participation in improving Government operations and reducing paperwork.

§ 451.204 Prompt action on contributions.

The head of each agency shall provide for prompt action on contributions to encourage maximum employee participation, and to obtain all possible benefit to the Government.

§ 451.205 Documentation of action.

The head of each agency shall provide that action on a contribution be adequately documented.

§ 451.206 Report.

The head of each agency shall submit to the Office by November 15 of each year a report on the operation of the agency's Incentive Awards Program during the preceding fiscal year.

Subpart C—Awards

SOURCE: 38 FR 18446, July 11, 1973; 38 FR 22535, Aug. 22, 1973; 38 FR 26601, Sept. 24, 1973, unless otherwise noted.

§ 451.301 Basic requirements.

An agency may not grant an incentive award before the contribution has been approved by the benefiting agency. The contribution must have been made while the contributor was a Government employee, and must be described in writing.

§ 451.302 Award over $10,000.

An agency head may not grant a cash award above $10,000 without prior approval of the Office. The maximum award is $25,000.

§ 451.303 Effect of an award on pay.

(a) *Pay.* A cash award under this part is in addition to the regular pay of the recipient.

(b) *Further claim.* The acceptance of a cash award under this part constitutes an agreement that the use by the Government of a contribution, idea, method or device for which an incentive award is made does not form the basis of a further claim of any nature against the Government by the employee, his or her heirs, or assigns.

§ 451.304 Honorary award.

An agency may grant an honorary award for a contribution. An honorary award may be granted in addition to a cash award.

§ 451.305 Group awards.

(a) *The award.* When a contribution is made by more than one employee, each contributing employee, including a supervisor, may share in the award.

(b) *Cash award shares.* An agency may grant the employees a cash award in equal shares, or in shares proportionate to each employee's participation in the contribution.

(c) *Amount of cash award.* The total amount of a cash award to a group may not exceed the amount that would be authorized if the contribution has been made by one individual, except that an agency head for special reasons may decide a different amount is justified. Reasons in support of the different amount must be documented.

§ 451.306 Presidential awards.

Each agency shall submit any recommendation for a Presidential award in accordance with instructions issued by the Director, Office of Personnel Management.

§ 451.307 Interagency award.

The head of an agency in which a contribution originates may grant an incentive award for a contribution that also may benefit another agency. The initial award is based on the benefit to the originating agency before consideration of additional benefits to another agency.

§ 451.308 Interagency referral.

(a) *Originating agency.* The head of each agency in which a contribution originates shall establish a procedure that requires that the contribution be referred to other agencies which may benefit from it. The referral to other agencies shall be made only after consideration of the applicability of the contribution in the originating agency.

(b) *Referral to one agency.* When the agency in which a contribution originates determines that only one other agency is responsible for acting on the contribution, it shall refer the contribution to that agency. The agency to which the contribution is referred shall notify the originating agency of the action on the contribution and shall send a copy of the notification to the Office.

(c) *Referral to Office.* When the originating agency determines that more than one other agency is responsible for acting on the contribution, it shall refer the file to the Office, with information on the activities in other agencies that may benefit from the contribution.

§ 451.309 Award by other benefiting agency.

(a) *Contribution approved.* When the head of an agency approves a contribution which originated in another agency, approval shall be reported to either the originating agency or the Office, whichever referred the contribution.

(b) *The report.* The approving agency shall report its approval as soon as possible and not later than six months after receipt of the referral except that the report may be made at a later date with prior approval of the

Office. The report shall state the estimated first year net tangible benefits, if any; the intangible benefits, if any; and the incentive award it will grant, under this part.

(c) *Funds for award.* (1) When the head of an agency approves a contribution referred by another agency, arrangements shall be made with the originating agency for transfer of funds necessary to pay the incentive award.

(2) When more than one agency benefits from a contribution, the Office shall determine the total interagency first year net measurable benefits, and the total intangible benefits, and recommended to the appropriate benefiting agencies, their proportionate share of the award.

(3) Within thirty days after receipt of the recommendation referred to in paragraph (c)(2) of this section, each benefiting agency shall notify the Office in writing of its action on the recommendation.

OFFICE OF PERSONNEL MANAGEMENT,
BEVERLY M. JONES,
Issuance System Manager.

[FR Doc. 79-7695 Filed 3-15-79; 8:45 am]

[3410-05-M]

Title 7—Agriculture

CHAPTER VII—AGRICULTURAL STABILIZATION AND CONSERVATION SERVICE (AGRICULTURAL ADJUSTMENT), DEPARTMENT OF AGRICULTURE

SUBCHAPTER B—FARM MARKETING QUOTAS AND ACREAGE ALLOTMENTS

[Amdt. 11]

PART 725—FLUE-CURED TOBACCO

Subpart—Flue-Cured Tobacco Acreage Allotment and Marketing Quota Regulations, 1973-74 and Subsequent Marketing Years

TRANSFER OF FLUE-CURED TOBACCO QUOTA BY LEASE AND OTHER MISCELLANEOUS AMENDMENTS

AGENCY: Agricultural Stabilization and Conservation Service, Department of Agriculture.

ACTION: Final Rule.

SUMMARY: This rule (1) establishes May 1 as the final date to file requests for lease and transfer during the planting season with provisions for approving late-filed request; (2) provides that producers on farms with excess acres will not be eligible to lease and transfer quotas after June 14; (3) requires producers to file reports of tobacco on hand at end at marketing season; (4) expands the reporting requirements for dealers and buyers by requiring them to file supplemental reports to include tobacco acquired by them not previously reported in their seasonal report on February 1; and (5) makes the provisions for storing carryover tobacco through marketing agents inapplicable to the 1979 and subsequent crops of tobacco.

EFFECTIVE DATE: This rule shall become effective March 13, 1979.

FOR FURTHER INFORMATION CONTACT:

Maurice Reddick, Production Adjustment Division, Agricultural Stabilization and Conservation Service, USDA, P. O. Box 2415, Washington, D. C. 20013. (202) 447-7935.

SUPPLEMENTARY INFORMATION: On February 13, 1979, the proposed rule was published in the FEDERAL REGISTER (44 FR 9389). The public was given 15 days to comment on the proposal. A total of 25 comments were received by the Department. Since producers are now transplanting seedlings into fields and need to know the changes provided by this rule, it is hereby found and determined that compliance with the 30-day effective date provisions of 5 U.S.C. 553 and the requirements of Executive Order 12044 is impracticable and contrary to the public interest.

DISCUSSION OF COMMENTS

1. *Make inapplicable the provisions for storing carryover tobacco of the 1979 and subsequent crops through marketing agents.* Thirteen commenters supported eliminating the provision for storing carryover tobacco through marketing agents. Of these, 10 comments were received from producers, 1 from a buying company, 1 from a tobacco auction warehouse group and 1 from a State farm organization. Those favoring the proposal gave no specific reason for their opinion but indicated that the tobacco program needs to be tightened.

Ten commenters opposed eliminating the provision for storing carryover tobacco through marketing agents. Of these, 2 were from producers, 2 represented agencies of State government, 4 were from State farm organizations, 1 from a national farm organization, and 1 from a buying company.

Eight of those who opposed eliminating the carryover provision recommended that it be carried out only through the Flue-Cured Tobacco Cooperative Stabilization Corporation which assists this Department implement the tobacco price support program. Two of the commenters who opposed eliminating the carryover provision stated that some kind of off-farm storage should be provided for carryover tobacco.

Those commenters who favored continuing the carryover provision with the loan association as the sole marketing agent for carryover tobacco, gave the following reasons:

a. Tobacco is a perishable commodity subject to quality deterioration and insect infestation and must be handled and stored under proper conditions.

b. The loan association is grower-owned and operated and growers have confidence that carryover tobacco will be properly handled through the loan association and will not enter trade channels until the following marketing year.

c. The carryover provision prevents tobacco stored on the farm from illegally moving into trade channels without payment of marketing quota penalties and without reduction in future farm quotas.

2. *Establish May 1 as the final date to file request for transfer of quota by lease during the planting season.* Twelve comments—all favorable—were received regarding this proposal. No specific reason was given by those favoring the proposal.

3. *Require producers to file reports of tobacco on hand at end of the marketing season.* Eleven comments were received, all favoring the proposal. No specific reason was given.

4. *Growers with excess acres ineligible to transfer quota by lease after June 14.* Eleven comments were received, all favoring the proposal. No specific reason was given.

5. *Require dealers and buyers to file supplemental reports of tobacco acquired by them.* Eleven comments were received, all favoring the proposal. No specific reason was given.

The opposing comments were limited to the carryover provision. Most commenters who favored continuing the carryover program wanted the loan association to be designated as the sole marketing agent. One commenter, a major buying company, while not opposing elimination of the carryover provision, urged that if the loan association is allowed to handle carryover tobacco, all other interested marketing agents should also be allowed to do so.

The basic purpose of the proposed changes is to discourage growers from deliberately overproducing their farm allotments and marketing quotas. As long as the carryover program exists in any form for handling overproduction, growers will be encouraged to produce higher yields and plant additional acreage knowing that if excess production cannot be disposed of otherwise it can be carried over for marketing in the next marketing year as a last resort. Past experience has shown that once excess tobacco is produced,

properly accounting for its disposition becomes exceedingly difficult. The fact that reported yearly carryover tobacco poundage has climbed steadily from a few hundred thousand pounds in 1973 (the year the carryover provisions were published in the FEDERAL REGISTER) to 26 million pounds of carryover tobacco from the 1978 crop convinces us that the carryover program does contribute toward excess production.

Two commenters stated that government restrictions on tobacco production should be eliminated. Though this comment is beyond the scope of this regulation, it is to be noted that the Agricultural Adjustment Act of 1938, as amended, requires this Department to administer an acreage-poundage program for flue-cured tobacco unless the program is voted down in a referendum of interested growers.

We feel that it is essential for the successful operation of the flue-cured tobacco program that the provisions for storage of carryover tobacco through marketing agents be eliminated effective for the 1979 and subsequent crops.

After giving careful consideration to all comments received, the proposed rule is hereby adopted without change as set forth below. Accordingly, 7 CFR Part 725 is amended to read as follows:

1. In § 725.72, paragraphs (c) (1), (2) and (4) are amended and new subparagraphs (3) (vi) and (vii) are added to read as follows:

§ 725.72 Lease and transfer of tobacco marketing quotas.

* * * * *

(c) *Filing and approval of transfer agreement.*

(1) *General.* The approval or disapproval of an agreement to transfer all or any part of an effective farm marketing quota shall be the responsibility of the county committee, except for late-filed transfers approved under subparagraph (4) of this paragraph. The county committee may redelegate authority to approve transfers to the county executive director or other county office employees.

(2) *Filing transfer agreements.* No lease of any quota under this section shall become effective until a record of transfer, determined by the county committee to be in compliance with the provisions of this section, has been executed on Form ASCS-375 and filed within the time periods prescribed in this section, with the county committee in the county where the farms are administratively located. * * *

(3) *Approval of transfer agreement filed after June 14.* * * *

* * * * *

(vi) Not be made if the record of transfer is filed with the county committee after November 30 of the current crop year.

(vii) Not be made if the planted acreage on the receiving or transferring farm exceeds the effective farm acreage allotment or exceeds 110 percent of the effective farm acreage allotment if the farm is a participant in the program for which the farm operator executes an agreement to destroy four leaves of downstalk tobacco.

(4) *Transfers not to be approved.* Except for transfers filed after June 14 under the conditions prescribed in paragraph (c)(3) of this section, a transfer shall not be approved:

(i) If the record of transfer is filed after May 1 of the current crop year except that a record of transfer filed after May 1 but prior to June 15 shall be considered timely filed if the county committee, with approval of the State committee, finds that (a) the lease was agreed upon no later than May 1 of the current crop year, and (b) the record of transfer was not timely filed with the county committee because of conditions beyond the control of the lessee or lessor.

(ii) If after the transfer the lessee farm acreage allotment, plus the acres obtained by dividing the pounds transferred to the lessee farm by the current year's farm yield for such farm, would exceed 50 percent of the cropland on such farm.

(iii) If it is determined that the primary purpose of the transfer for a farm is to pyramid (leasing to and from the farm for a period of two or more years to maintain the quota with no satisfactory evidence of plans for producing the quota during such period) the quota on the farm.

2. In § 725.98, paragraph (f) is revised by inserting a new sentence immediately after the period in the first sentence and revising the current second sentence as follows:

RECORDS AND REPORTS

§ 725.98 Producer's records and reports.

* * * * *

(f) *Report of production and disposition.* * * *

The operator on each farm or any producer on the farm (even though the harvested acreage does not exceed the acreage allotment or even though no allotment was established for the farm) shall, upon written request from the county committee, furnish on Form MQ-108-1, Report of Unmarketed Tobacco, a written report of the amount and location of tobacco produced on the farm which is unmarketed at the end of the marketing season and the amount of tobacco produced by such operator or producer on any other farm, which is unmarketed at the end of the marketing season and which is stored on the farm, by sending the report to the county committee within 15 days after the request was mailed to such person at his last known address. Failure to file the MQ-108 or MQ-108-1 as requested, the filing of an MQ-108 or MQ-108-1 which is found by the State or county committee to be incomplete or incorrect shall, to the extent that it involves tobacco produced on the farm, constitute failure of the producer to account for disposition of tobacco produced on the farm and the allotment next established for such farm shall be reduced, except that such reduction for any such farm shall not be made if it is established to the satisfaction of the county or State committee that failure to furnish such proof of disposition was unintentional and no producer on such farm could reasonably have been expected to furnish such proof of disposition: *Provided,* That (i) such failure will be construed as intentional unless such proof of disposition is furnished and payment of all additional penalty is made, or (ii) no person connected with such farm for the year for which the quota is being established caused, aided, or acquiesced in the failure to furnish such proof.

* * * * *

3. In § 725.102, paragraph (b) is amended to read as follows:

§ 725.102 Dealers exempt from regular records and reports on MQ-79; and season report for dealers.

* * * * *

(b) For the 1973-74 and subsequent marketing years, each dealer or buyer shall also make a report not later than February 1 of each year to the Director, Production Adjustment Division, showing by States where acquired, source and pounds of all tobacco, in the form normally marketed by producers, purchased at auction or nonauction including tobacco received which was not billed to the dealer or buyer. Any acquisition of tobacco in the form normally marketed by producers by the dealer or buyer during the marketing year (July 1 through June 30) which is not included in the February 1 report shall be reported in like manner no later than the end of the calendar week following the week in which the tobacco was acquired. The report shall show: * * *

* * * * *

4. Section 725.103 paragraph (a) is amended by inserting a new sentence at the beginning.

§ 725.103 Recordkeeping and reporting requirements for processed producer carryover tobacco.

(a) *General.* This section shall not be applicable to 1979 and subsequent crops of tobacco. * * *

* * * * *

5. Section 725.104 paragraph (a) is amended by inserting a new sentence at the beginning.

§ 725.104 Recordkeeping and reporting requirements for unprocessed producer carryover tobacco.

(a) *General.* This section shall not be applicable to 1979 and subsequent crops of tobacco. * * *

* * * * *

AUTHORITY: Section 301, 313, 314, 316, 317, 363, 372-375, 377, 378, 52 Stat. 38, as amended, 47, as amended, 48, as amended, 75 Stat. 469, as amended, 79 Stat. 66, 52 Stat. 63, as amended, 65-66, as amended, 72 Stat. 995; section 401, 63 Stat. 1054, as amended, sections 106, 112, 125, 70 Stat. 191, 195, 198, as amended, section 16(e), 76 Stat. 606; (7 U.S.C. 1301, 1313, 1314, 1314b, 1314c, 1363, 1372-1375, 1377, 1378, 1421, 1813, 1824, 1836), (16 U.S.C. 590p(e)).

NOTE.—A Final Impact Statement will be available from J. A. Wells, Director, Production Adjustment Division, USDA-ASCS, Room 3630-South Building, P.O. Box 2415, Washington, D.C. 20013. Telephone:, 202-447-7641.

NOTE.—This rule has been determined not significant under USDA criteria implementing Executive Order 12044.

Signed at Washington, D.C., on March 13, 1979.

STEWART N. SMITH,
Acting Administrator, Agricultural Stabilization and Conservation Service.

[FR Doc. 79-8030 Filed 3-13-79; 2:29 pm]

[3410-05-M]

[Amdt. 12]

PART 726—BURLEY TOBACCO

Subpart—Burley Tobacco, 1971-72 and Subsequent Marketing Years

TRANSFER OF BURLEY TOBACCO QUOTAS BY LEASE AND OTHER MISCELLANEOUS AMENDMENTS

AGENCY: Agricultural Stabilization and Conservation Service, Department of Agriculture.

ACTION: Final rule.

SUMMARY: This rule (1) makes the provisions for storing carryover tobacco through marketing agents inapplicable to the 1979 and subsequent crops of tobacco, (2) limits transfers of quota by lease or by owners to or from the same farm but not both, except under disaster conditions, (3) expands the reporting requirements for dealers and buyers by requiring them to file supplemental reports to include tobacco acquired by them not previously reported in their seasonal report on April 1; and (4) requires producers to file reports of tobacco on hand at the end of the marketing season.

The new rules are designed to eliminate program abuses brought about by overproduction of farm marketing quotas and to improve the administration of the tobacco program in general.

EFFECTIVE DATE: This rule shall become effective March 13, 1979.

FOR FURTHER INFORMATION CONTACT:

Raymond S. Fleming, Production Adjustment Division, ASCS, USDA, South Building, P.O. Box 2415, Washington, D.C. 20013, (202) 447-7935.

SUPPLEMENTARY INFORMATION: On February 13, 1979, the proposed rule was published in the FEDERAL REGISTER (44 FR 9391). The public was given 15 days to comment on the proposal. A total of 76 comments were received. Sixty-six were from producers, 3 from agencies of State Governments, 2 from burley loan associations, 1 from a State farm organization, 1 from a national farm organization, 1 from a warehouse association, 1 from a bank, and 1 from a tobacco buying company. Since producers are now transplanting seedlings into fields and need to know the changes provided by this rule, it is hereby found and determined that compliance with the 30-day effective date provisions of 5 U.S.C. 553 and the requirements of Executive Order 12044 is impracticable and contrary to the public interest.

DISCUSSION OF COMMENTS

(1) *Makes inapplicable the provisions for storing carryover tobacco of the 1979 and subsequent crops through marketing agents.* Seventy-five comments were received. Fifteen commenters were opposed to this proposal. Generally, they stated that tobacco stored on the farm is subject to quality deterioration and insect infestation and in some crop years yields are unusually high and producers inadvertently produce more than 110 percent of their effective farm quota.

One agency of State government stated that it favors continuing the carryover provisions but wanted delivery of carryover tobacco limited to the burley loan association. The following reasons were given in support of its position: The loan associations are grower-owned and operated and growers have confidence that the carryover program will be properly handled. Also, tobacco will not reach the buyer's inventory until the succeeding marketing year and thus would not serve to depress prices during the current marketing season. One tobacco buying company commented that it did not object to the proposal but it strongly felt that if the carryover provisions are continued, all marketing agents, not just the tobacco loan association, should be allowed to participate. Sixty commenters favored the proposal. These commenters expressed concern that the carryover provisions, which were designed as a convenience to producers with high yields, are resulting in producers deliberately overproducing tobacco far in excess of farm marketing quotas. Such overproduction, they state, circumvents the law, and could ultimately destroy the burley tobacco price support and production control programs. There was also concern that the carryover program depresses prices paid for tobacco during the current marketing season and upsets the normal flow of tobacco in trade channels.

2. *Limit lease and owner transfer to or from the same farm but not both.* All but 4 of the 50 comments received favored the proposal. Those who did not favor the proposal generally were concerned that the restriction against leasing unused quota would cause a hardship on producers who leased in poundage and failed to produce the farm quota. However, the proposal would permit lease and transfer of quota to and from the same farm when production is limited because of conditions beyond the control of the producer.

3. *Require producers to file reports of tobacco on hand at the end of the marketing season.* All but one of the 43 comments received favored the proposal.

4. *Require dealers and buyers to file supplemental reports of tobacco acquired by them.* All but one of the 43 comments received favored the proposal.

The basic purpose of the proposed changes is to discourage growers from deliberately overproducing their farm marketing quotas. As long as the carryover program exists in any form for handling overproduction, growers will be encouraged to produce higher yields and plant additional acreage knowing that if excess production cannot be disposed of otherwise it can be placed into the carryover program as a last resort. Past experience has shown that once excess tobacco is produced, properly accounting for its disposition becomes difficult and sometimes impossible. The fact that reported yearly carryover tobacco poundage has climbed steadily from a few hundred thousand pounds in 1973 (the

year the carryover provisions were promulgated) to over 20 million pounds of carryover tobacco from the 1978 crop convinces us that the carryover program contributes toward excess production.

We feel that it is essential for the successful operation of the burley tobacco program that the provision for storage of carryover tobacco though marketing agents be eliminated effective for the 1979 and subsequent crops.

After giving careful consideration to all comments received the proposed rule is hereby adopted without change, except that the parenthetical statement in 726.92(e) is corrected to read (even though no quota was established for the farm).

Accordingly, 7 CFR Part 726 is amended to read as follows:

1. Section 726.68(n) is revised to read as follows:

§ 726.68 Transfer of Burley Tobacco Farm Marketing Quota by Lease or by Owner.

* * * * *

(n) *Limitation on transfer to and from a farm (subleasing).* The county committee shall not approve any transfer filed for the current year if, after approval, a transfer would be in effect both to and from the same farm, except as follows:

(1) A transfer may be approved if the quota is temporarily transferred from a farm subsequently combined with another farm that is otherwise eligible to receive quota by transfer.

(2) After October 1 a transfer may be approved for a farm that previously received leased quota for the current year provided the producers so certify and the county committee determines that the (i) acreage of burley tobacco planted on the farm was equal to at least 80 percent of the acreage determined by dividing the effective marketing quota by the current farm yield for the farm, and (ii) the production to tobacco was limited to less than the effective farm marketing quota because of conditions beyond control of the producer.

* * * * *

2. Section 726.92 paragraph (e) is amended by inserting a new sentence immediately after the period in the first sentence and revising the current second sentence as follows:

RECORDS AND REPORTS

§ 726.92 Producer records and reports.

* * * * *

(e) *Report of production and disposition.* * * * The operator on each farm or any producer on the farm (even though no quota was established for the farm) shall, upon written request from the county committee, furnish on Form MQ-108-1, Report of Unmarketed Tobacco, a written report of the amount and location of tobacco produced on the farm which is unmarketed at the end of the marketing season and the amount of tobacco produced by such operator or producer on any other farm, which is unmarketed at the end of the marketing season and which is stored on the farm, by sending the report to the county committee within 15 days after the request was mailed to such person at his last known address. Failure to file the MQ-108 or MQ-108-1 as requested, the filing of an MQ-108 or MQ-108-1 which is found by the State or county committee to be incomplete or incorrect shall, to the extent that it involves tobacco produced on the farm, constitute failure of the producer to account for disposition of tobacco produced on the farm and the quota next established for such farm shall be reduced, except that such reduction for any such farm shall not be made if it is established to the satisfaction of the county or State committee that failure to furnish such proof of disposition was unintentional and no producer on such farm could reasonably have been expected to furnish such proof of disposition: *Provided,* That (i) such failure will be construed as intentional unless such proof of disposition is furnished and payment of all additional penalty is made, or (ii) no person connected with such farm for the year for which the quota is being established caused, aided or acquiesced in the failure to furnish such proof.

* * * * *

3. Section 726.95, paragraph (b), is revised as follows;

§ 726.95 Dealers exempt from regular records and reports on MQ-79; and season reports from dealers.

* * * * *

(b) For the 1971-72 and subsequent marketing years, each dealer or buyer shall also make a report not later than April 1 of each year to the Director, Production Adjustment Division, showing by States were acquired, source and pounds of all tobacco, in the form normally marketed by producers, purchased at auction or nonauction including tobacco received which was not billed to the dealer or buyer. Any acquisitions of tobacco in the form normally marketed by producers by the dealer or buyer during the marketing year (October 1 through September 30) which is not included in the April 1 report shall be reported in like manner no later than the end of the calendar week following the week in which the tobacco was acquired. The report shall show * * *

4. Section 726.105, paragraph (a), is amended by inserting a new sentence at the beginning.

§ 726.105 Recordkeeping and reporting requirements for processed producer carryover tobacco.

(a) *General.* This section shall not apply to burley tobacco produced in the 1979 and subsequent crop years. * * *

5. Section 726.106, paragraph (a), is amended by inserting a new sentence at the beginning.

§ 726.106 Recordkeeping and reporting requirements for unprocessed producer carryover tobacco.

(a) *General.* This section shall not apply to burley tobacco produced in the 1979 and subsequent crop years. * * *

* * * * *

AUTHORITY: (Secs. 301, 312, 313, 314, 316, 318, 363, 372-375, 377, 378, 52 Stat. 38, as amended, 46, as amended, 47, as amended, 48, as amended, 75 Stat. 469, as amended, 80 Stat. 120, as amended, 52 Stat. 63, as amended, 65, as amended, 66 as amended, 70 Stat. 206 as amended, 72 Stat. 995, as amended, 7 U.S.C. 1301, 1312, 1314, 1314b, 1314d, 1363, 1372-1375, 1377, 1378, Public Law 92-10 approved April 14, 1971)

NOTE.—A Final Impact Statement will be available from J. A. Wells, Director Production Adjustment Division, USDA-ASCS, Room 3630-South Building, P.O. Box 2415, Washington, D.C. 20013. Telephone: 202-447-7641.

NOTE.—This rule has been determined not significant under USDA criteria implementing Executive Order 12044.

Signed at Washington, D.C., on March 13, 1979.

STEWART N. SMITH,
Acting Administrator, Agricultural Stabilization and Conservation Service.

[FR Doc. 79-8029 Filed 3-13-79; 2:29 pm]

[3410-02-M]

CHAPTER IX—AGRICULTURAL MARKETING SERVICE (MARKETING AGREEMENTS AND ORDERS; FRUITS, VEGETABLES, NUTS), DEPARTMENT OF AGRICULTURE

[Lemon Regulation 190]

PART 910—LEMONS GROWN IN CALIFORNIA AND ARIZONA

Limitation of Handling

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This regulation establishes the quantity of fresh California-Arizona lemons that may be shipped to market during the period March 18–24, 1979. Such action is needed to provide for orderly marketing of fresh lemons for this period due to the marketing situation confronting the lemon industry.

EFFECTIVE DATE: March 18, 1979.

FOR FURTHER INFORMATION CONTACT:

Charles R. Brader, (202) 447-6393.

SUPPLEMENTARY INFORMATION: *Findings.* Pursuant to the marketing agreement, as amended, and Order No. 910, as amended (7 CFR Part 910), regulating the handling of lemons grown in California and Arizona, effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), and upon the basis of the recommendations and information submitted by the Lemon Administrative Committee, and upon other information, it is found that the limitation of handling of lemons, as hereafter provided, will tend to effectuate the declared policy of the act. This regulation has not been determined significant under the USDA criteria for implementing Executive Order 12044.

The committee met on March 13, 1979, to consider supply and market conditions and other factors affecting the need for regulation and recommended a quantity of lemons deemed advisable to be handled during the specified week. The committee reports the demand for lemons continues good.

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 purposes of the act to make these regulatory provisions effective as specified, and handlers have been apprised of such provisions and the effective time.

§ 910.490 Lemon Regulation 190.

Order. (a) The quantity of lemons grown in California and Arizona which may be handled during the period March 18, 1979, through March 24, 1979, is established at 250,000 cartons.

(b) As used in this section, "handled" and "carton(s)" mean the same as defined in the marketing order.

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

Dated: March 14, 1979.

D. S. KURYLOSKI
Acting Deputy Director, Fruit and Vegetable Division, Agricultural Marketing Service.

[FR Doc. 79-8286 Filed 3-15-79; 11:25 am]

[3410-05-M]

CHAPTER XIV—COMMODITY CREDIT CORPORATION

PART 1464—TOBACCO

Subpart A—Tobacco Loan Program

PRICE SUPPORT REGULATIONS

AGENCY: Commodity Credit Corporation, USDA.

ACTION: Final rule.

SUMMARY: This rule amends the tobacco price support regulations to (1) reduce the acreage limitation for flue-cured tobacco when the 4 lower leaves are not harvested, and (2) terminate price support eligibility on 1979 and subsequent crops of flue-cured and burley tobacco which are packed for a producer's account by a loan association and carried over from one marketing year to another. These actions are designed to eliminate abuses of the tobacco program.

DATE: This rule shall become effective March 13, 1979.

ADDRESS: Price Support and Loan Division, ASCS, U.S. Department of Agriculture, 3741-South Building, P.O. Box 2415, Washington, D.C. 20013.

FOR FURTHER INFORMATION CONTACT:

Thomas A. VonGarlem, (202) 447-7954.

SUPPLEMENTARY INFORMATION: On February 13, 1979, notice was published in the FEDERAL REGISTER (44 FR 9393) inviting written comments on proposals to change the conditions of price support by (1) reducing from 120 percent to 110 percent the acreage limitation applicable when the 4 lower leaves are not harvested, and (2) the carryover provision under which price support may be obtained on 1979 and subsequent crops of eligible tobacco packed by a marketing agent in the previous year.

Under current regulations, eligible producers of flue-cured who have entered into an agreement with the local ASC county committee not to harvest the bottom 4 leaves on each stalk of tobacco may plant 120 percent of their allotment and still retain price support eligibility. This allows those producers to raise more flue-cured tobacco from the upper portion of the stalk for which demand is relatively strong while leaving in the field leaves from lower stalk positions for which demand is weak. Eligible producers who do not agree to leave the 4 bottom leaves from each plant are required to plant within 100 percent of their allotment to retain price support eligibility. Under this amendment producers who have entered into an agreement with the local ASC county committee not to harvest the bottom 4 leaves will be required to plant within 110 percent, rather than 120 percent of their acreage allotment in order to retain their eligibility for price support. The 120 percent tolerance is not needed because it encouraged overproduction in that the bottom 4 leaves constitute closer to 10 to 12 percent of the plant rather than 20 percent of the plant.

Under current regulations eligible producers of flue-cured and burley tobacco may obtain price support on eligible tobacco which has been packed for their account by an association and carried over from the previous marketing year to avoid marketing in excess of their farm marketing quota. This provision was designed to provide a convenient means by which a producer could carry over tobacco for marketing the following year if unusually high yields resulted in production in excess of the current year's farm marketing quota. This provision is encouraging some producers to deliberately produce tobacco in excess of their marketing quotas. Such overproduction burdens the marketing facilities and tends to increase the cost of leasing tobacco quotas. Under this amendment, the carryover provision under which price support may be obtained on eligible tobacco which has been packed by a marketing agent and carried over from the previous year is terminated for the 1979 and subsequent crops of tobacco.

DISCUSSION OF COMMENTS

1. 4-LEAF PROGRAM

Comments were received from three producers and five organizations by the close of the comment period, February 28, 1979. None objected to the proposed change.

2. ELIMINATION OF CARRYOVER PROVISIONS

Comments were received from one farmer and four organizations. Three were opposed to the proposed change while two favored the change. Two of the three who opposed the proposal gave no reasons for their opinion while the third felt that tobacco stored in warehouses was handled better than could be done on the farm, thereby preventing disease and possible quota violations. One of those who opposed the change wanted the farmer associations to be the only delivery point for carryover tobacco. After careful consideration of all comments, the proposed rule is hereby adopted without change as set forth below. Accordingly, 7 CFR Part 1464 is amended to read as follows:

FINAL RULE

1. A new sentence is added at the beginning of paragraph (e)(3)(ii) of § 1464.2 as follows:

§ 1464.2 Availability of price support.

* * * * *

(e)(3) * * *

(ii) This paragraph shall not apply to the 1979 and subsequent crops of flue-cured and burley tobacco. Eligible producers of flue-cured and burley tobacco may, subject to the provisions of this subdivision, obtain price support on eligible tobacco which has been packed for their account by the association and carried over from one marketing year to another to avoid marketing in excess of the farm marketing quota. Price support advances obtained on such packed tobacco shall be at the rates in effect at the time of tender for loan, and on the basis of grades and quantities of the tobacco as determined at the time of delivery to the association for packing and carryover. If all the tobacco packed from the tobacco delivered to the association for packing and carryover is not tendered for price support, or if the packed tobacco tendered for price support is commingled tobacco of different producers, the price support advances will be computed as follows: for each packed grade of tobacco, the loan value will be computed on the basis of (a) the total pounds of each green grade used in processing the packed quantity of (b) the grade loan rates applicable to such green grades. Loan advances may be obtained on the quantity of each packed grade tendered for price support in an amount equal to the loan value so determined, multiplied by the percentage which the pounds of the packed grade tendered is of the total packed weight of such grade. An individual producer's share of the loan advance obtained on the tender of any quantity of a packed grade shall be a percentage of such advance equal to the percentage which the loan value of all the tobacco delivered by the producer for packing and carryover is of the loan value of all the tobacco delivered by all producers for packing and carryover. Packed tobacco tendered for price support shall be in sound and merchantable condition and shall have been processed and packed under the standards and specifications which were applied to the tobacco received for price support during the immediately preceding crop year.

Prior to tendering packed tobacco for price support, the association shall determine what percentage of the tobacco which was received for packing and carryover is eligible.

The packed tobacco tendered for price support shall not be a greater percentage of the total quantity packed than the percentage so determined.

* * * * *

2. Subparagraphs (2), (2)(i) and (2)(ii) of § 1464.7(a) are revised as follows:

§ 1464.7 Eligible producers

(a) * * * (2) all the tobacco produced on his/her farm is produced on acreage which does not exceed the acreage allotment, or if flue-cured tobacco, does not exceed: (i) The acreage allotment established for his/her farm; or (ii) 110 percent of the acreage allotment established for his/her farm in instances where the producer has left unharvested the 4 lower leaves, exclusive of plant bed leaves, on each stalk of tobacco produced on his/her farm and has previously entered into an agreement to do so with the local ASC county committee in accordance with procedures to be established by the Deputy Administrator, State and County Operations, ASCS; and (3) * * *.

NOTE.—This proposal has been determined not significant under the USDA criteria implementing Executive Order 12044.

NOTE.—A Final Impact Statement is available from Thomas A. VonGarlem, Acting Director, Price Support and Loan Division, Room 3741-South Building, P.O. Box 2415, Washington, D.C. 20013.

Signed at Washington, D.C. on March 13, 1979.

STEWART N. SMITH,
Acting Administrator, Agricultural Stabilization and Conservation Service.

[FR Doc. 79-8031 Filed 3-13-79; 2:29 pm]

[3410-07-M]

CHAPTER XVIII—FARMERS HOME ADMINISTRATION, DEPARTMENT OF AGRICULTURE

SUBCHAPTER H—PROGRAM REGULATIONS

[FmHA Instruction 1955-D]

PART 1955—PROPERTY MANAGEMENT

Subpart D—Purchasing of Services for Program Property

AMENDMENT

AGENCY: Farmers Home Administration, USDA.

ACTION: Final rule.

SUMMARY: The Farmers Home Administration (FmHA) amends its regulations to incorporate the purchase of services for making and servicing loans. State Office Contracting Officers who have received proper training will be authorized to enter into contracts up to $10,000. The intended effect of the changes is to provide the State Office with contracting authority to enter into contracts with contractors for the writing and servicing of FmHA Emergency Disaster (EM), and Economic Emergency (EE) loans, as well as other required program loan and acquired property services.

EFFECTIVE DATE: March 16, 1979.

FOR FURTHER INFORMATION CONTACT:

Mr. R. M. Yates, 202-447-3752.

SUPPLEMENTARY INFORMATION: The Farmers Home Administration amends Sections 1955.151, 1955.153, 1955.154 and 1955.162 of Subpart D of Part 1955, Subchapter H, Chapter XVIII, Title 7 in the Code of Federal Regulations. This amendment will provide for the use of Contracting Officers (CO) to enter into contracts for the writing and servicing of EM, EL, and EE loan accounts as well as other required program loan and acquired property services. Contracts awarded in the State Office for services, will be limited to $5,000 if solicited orally and reduced to writing and in no event will the Contracting Officer enter into a single contract exceeding $10,000. This authority will be limited to properly trained contracting officers. It is the policy of this Department that rules relating to public property, loans, grants, benefits or contracts shall be published for comment notwithstanding the exemption in 5 U.S.C. 553 with respect to such rules. These amendments, however, are not published for proposed rulemaking since they are administrative and relate solely to agency management and procurement. This determination has been made by Mr. R. M. Yates.

PART 1955 [AMENDED]

Accordingly, 7 CFR Part 1955 is amended as follows:

1. Part 1955 is retitled "Property Management," as set forth above.

2. In Subpart D, § 1955.151 is revised as follows:

§ 1955.151 Purpose

This subpart describes procedures for purchasing goods and services for making and servicing loans, for appraisal, inspection, maintenance, management, repair, and disposal of program property. The monetary limit of a contract signed by a County Supervisor is $2,000. The monetary limit of a contract signed by a State Contracting Officer who has received procurement training is $10,000. The monetary limit of a contract signed by the Director, Property Management Staff is $10,000. Requirements aggregating more than the foregoing limitations shall not be broken down into several purchases which are less than the limiting amount merely for the purpose of utilizing this method of purchase. This information pertains only to the systems of purchasing. Program approval must be first determined in accordance with the delegation of program authority.

3. Paragraphs (a) and (b)(2) of § 1955.153 are revised as follows:

§ 1955.153 Publicizing the requirements.

(a) *Policy.* It is the policy of the Farmers Home Administration (FmHA) to seek maximum competition for all purchases consistent with local conditions and prudent business practices. The sources of potential suppliers will normally not extend beyond a 25-mile radius of the site of work, provided that there are suppliers within the area. Placing orders with small business concerns and minority business enterprises is specifically encouraged. Solicitations will not be limited to only well known suppliers. The area of competition must never be designed to exclude a particular potential supplier. Although adequate competition is sought, excess competition is not particularly desired for small dollar volume work. There is no prescribed number of potential suppliers to be solicited. If only two potential contractors are in the area of work, and both do bid work, solicit both.

(b) * * *

(2) Written solicitations may be used for contracts of any value and must be used for all work when extensive specifications are required. Written solicitations normally will require written quotations. However, lump sum quotations given orally are sufficient in some instances. When oral quotations are acceptable, the solicitation must clearly state this information. Oral quotations, reduced to writing, are limited to solicitations not exceeding $2,000 for award by County Supervisors, and $5,000 for award by other contracting officers (legal requirement).

* * * * *

4. Paragraph (a) of § 1955.154 is revised as follows:

§ 1955.154 Preparation of solicitation.

(a) *Oral solicitations.* Prepare an original and three written copies of Form FmHA 120-10 (Items 1 through 7 specifications—See Exhibit A for typical specifications for repair services. See Exhibit B, C, D, H, I, J, and K for examples of services. Exhibit E shows a request for contract action to be used when the estimated cost exceeds awarding authority of the contracting officer.)

* * * * *

5. Paragraph (c) of § 1955.162 is revised as follows:

§ 1955.162 Control of material and work.

* * * * *

(c) *Government furnished property.* To repair or service Government owned property, the contractor may be required to reinstall or repair certain existing components and, at the same time, may also have to furnish or supply items. The contractor is responsible for the Government property under the contractors control and this responsibility continues until work is completed and accepted by the Government. Obtain a receipt from the contractor at the time Government furnished property is turned over to the Contractor. Certain contracts may permit the contractor to use Government facilities or equipment during the conduct of the contract. The contractor must be notified of his responsibility for Government property being utilized.

NOTE.—This document has been reviewed in accordance with FmHA Instruction 1901-G "nvironmental Impact Statements." It is the determination of FmHA that the 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.

(7 U.S.C. 1989; 5 U.S.C. 301; Sec. 10 Pub. L. 93-357, 88 Stat 392; delegation of authority by the Sec. of Agri., 7 CFR 2.23; delegation of authority by the Asst. Sec. for Rural Development, 7 CFR 2.70)

Dated: March 5, 1979.

GORDON CAVANAUGH,
Administrator,
Farmers Home Administration.

[FR Doc. 79-8095 Filed 3-15-79; 8:45 am]

[3410-07-M]

[FmHA Instruction 1980-A]

PART 1980—GENERAL

Subpart A—General

AMENDMENT

AGENCY: Farmers Home Administration, USDA.

ACTION: Final rule.

SUMMARY: The Farmers Home Administration (FmHA) amends its regulations to add State Program Loan Chiefs as additional Loan Officers authorized to execute FmHA guaranteed loan forms since Program Loan Chiefs attend loan closings but lack authority to execute guaranteed loan forms. The intended effect of this action is to expand signing authority to Program Chiefs which should result in more efficient processing.

EFFECTIVE DATE: March 16, 1979.

FOR FURTHER INFORMATION CONTACT:

Darryl H. Evans, Acting Director, Business Management and Development Division, telephone 202-447-4150.

SUPPLEMENTARY INFORMATION: § 1980.61(g) of Subpart A of Part 1980 of Chapter XVIII, Title 7, Code of Federal Regulations is amended. This change adds State Program Loan Chiefs to those FmHA officials authorized to execute the Lender's Agreement, Loan Note Guarantee, and Assignment Guarantee Agreement. Chiefs many times attend loan closings, but lack signature authority. This amendment will eliminate delays in loan closing.

It is the policy of this Department that rules relating to public property, loans, grants, benefits, or contracts shall be published for comment notwithstanding the exemption in 5 U.S.C. 553 with respect to such rules. This amendment, however, is not published for proposed rulemaking since it is administrative in nature. Therefore, public participation is unnecessary. The official responsible for this determination is Darryl H. Evans.

Accordingly, § 1980.61(g) of Subpart A of Part 1980 is amended and reads as follows:

§ 1980.61 Issuance of lender's agreement, loan note guarantee and assignment guarantee agreement.

* * * * *

(g) *Authorized FmHA representatives to execute forms.* State Directors, District Directors, State Program Loan Chiefs, and County Supervisors are authorized to execute the Lender's

Agreement, Loan Note Guarantee, and Assignment Guarantee Agreement.

* * * * *

NOTE.—This document has been reviewed in accordance with FmHA Instruction 1901-G, "Environmental Impact Statements." It is the determination of FmHA that the 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, an Environmental Impact Statement is not required.

This regulation has not been determined significant under USDA criteria implementing Executive Order 12044.

(7 U.S.C. 1989; 5 U.S.C. 301; Sec 10 Pub. L. 93-357, 88 Stat 392; delegation of authority by the Secretary of Agriculture, 7 CFR 2.23; delegation of authority by the Assistant Secretary for Rural Development, 7 CFR 2.70)

Dated: March 6, 1979.

GORDON CAVANAUGH,
Administrator,
Farmers Home Administration.

[FR Doc. 79-8096 Filed 3-15-79; 8:45 am]

[4410-10-M]

Title 8—Aliens and Nationality

CHAPTER I—IMMIGRATION AND NATURALIZATION SERVICE, DEPARTMENT OF JUSTICE

PART 242—PROCEEDINGS TO DETERMINE DEPORTABILITY OF ALIENS IN THE UNITED STATES: APPREHENSION, CUSTODY, HEARING, AND APPEAL

PART 287—FIELD OFFICERS; POWERS AND DUTIES

Authorization of Officer in Charge, Agana, Guam, To Issue Orders To Show Cause

AGENCY: Immigration and Naturalization Service, Justice.

ACTION: Final rule.

SUMMARY: This final rulemaking order amends the regulations of the Immigration and Naturalization Service to authorize the Officer in Charge at Agana, Guam to issue orders to show cause, notices of hearing and warrants of arrest. It also makes an editorial and conforming amendment to the sentence describing officers having authority to issue orders to show cause and warrants of arrest when such determinations must be made respecting aliens who are arrested without warrant. The first amendment is necessary and intended to strengthen the Service enforcement capability and effectiveness on the island of Guam. The second amendment is needed and intended for the purpose of editorial conformity within Service regulations.

EFFECTIVE DATE: March 16, 1979.

FOR FURTHER INFORMATION CONTACT:

James G. Hoofnagle, Jr., Instructions Officer, Immigration and Naturalization Service. Telephone: (202) 633-3048.

SUPPLEMENTARY INFORMATION: This final rulemaking order amends 8 CFR 242.1(a) and 8 CFR 287.3. 8 CFR 242.1(a) will be amended to authorize the Officer in Charge at Agana, Guam to issue orders to show cause and notices of hearing in order to commence deportation proceedings against aliens who are in the United States in violation of law. This amendment will also authorize that officer to issue warrants of arrest, as provided in 8 CFR 242.2(a).

This amendment is being made to strengthen Service enforcement capability on the island of Guam. Our primary enforcement problem there concerns aliens who were admitted as H-2 temporary workers who are now out of status because their authorized period of stay has expired and they have failed to depart the island or have failed to obtain an authorized extension of stay from the Service. At the present time, the Service has difficulty in dealing with this problem because the Officer in Charge at Agana, Guam must apply to the district director in Honolulu, Hawaii for orders to show cause to institute deportation proceedings against these aliens. By the time the documents arrive in Guam, the alien has absconded and the papers cannot be served nor can the deportation hearings be held. Thus, Service enforcement efforts are hampered because the Officer in Charge at Agana is not in a position to deal with the problem of temporary workers who are not in status immediately and effectively.

Therefore, in order to improve Service enforcement capability on the island of Guam, 8 CFR 242.1(a) will be amended to authorize the Officer in Charge at Agana, Guam to issue orders to show cause, notices of hearing and warrants of arrest.

This order will also amend the final sentence of 8 CFR 287.3. The existing final sentence provides that the case of an alien arrested without a warrant is to be presented promptly to the district director, deputy district director or acting district director for a determination of whether there is prima facie evidence that the arrested alien is in the United States in violation of law, and for the issuance of an order to show cause and warrant of arrest prescribed in 8 CFR 242.

This Amendment will conform the language used in 8 CFR 287.3 to describe the officers having authority to issue orders to show cause and warrants of arrest to that shown in 8 CFR 242.1(a).

The following amendments are hereby prescribed to Chapter I of Title 8 of the Code of Federal Regulations:

In Part 242, § 242.1(a) will be amended by adding Agana, Guam in alphabetical sequence to the list of offices indicated in the third sentence thereof. As amended, the third sentence reads as follows:

§ 242.1 Orders to show cause and notice of hearing.

(a) *Commencement.* * * * Orders to show cause may be issued by district directors, acting district directors, deputy district directors, assistant district directors for investigations, and Officers in Charge at Agana, GU; Albany, NY; Charlotte Amalie, VI; Cincinnati, OH; Hammond, IN; Milwaukee, WI; Norfolk, VA; Oklahoma City, OK; Pittsburgh, PA; Providence, RI; Salt Lake City, UT; St. Louis, MO; Spokane, WA.

* * * * *

In Part 287, the final sentence of § 287.3 is revised to read as follows:

§ 287.3 Disposition of cases of aliens arrested without warrant.

* * * Unless voluntary departure has been granted pursuant to § 242.5 of this chapter, the alien's case shall be presented promptly, and in any event within 24 hours, to the district director, acting district director, deputy district director, assistant district director for investigations, officers in charge at Agana, GU; Albany, NY; Charlotte Amalie, VI; Cincinnati, OH; Hammond, IN; Milwaukee, WI; Norfolk, VA; Oklahoma City, OK; Pittsburgh, PA; Providence, RI; Salt Lake City, UT; St. Louis, MO; Spokane, WA for a determination as to whether there is prima facie evidence that the arrested alien is in the United States in violation of law and for issuance of an order to show cause and warrant of arrest prescribed in Part 242 of this chapter.

* * * * *

(Sec. 103, 242 and 287; 8 U.S.C. 1103, 1252 and 1357.)

These amendments are being published in accordance with section 552 of Title 5 of the United States Code, as amended by Pub. L. 93-502 (88 Stat. 1561), and the authority contained in section 103 of the Immigration and Nationality Act, (8 U.S.C. 1103), 28 CFR 0.105(b), and 8 CFR 2.1.

Compliance with the provisions of section 553 of Title 5 of the United States Code as to notice of proposed rulemaking and delayed effective date is unncessary in this instance because the amendment to 8 CFR 242.1(a) pertains to agency organization and management, and the amendment to 8 CFR 287.3 is editorial in nature.

Effective date: These amendments become effective on March 16, 1979.

Dated: March 12, 1979.

LEONEL J. CASTILLO,
Commissioner of Immigration and Naturalization.

[FR Doc. 79-8015 Filed 3-15-79; 8:45 am]

[3410-34-M]

Title 9—Animals and Animal Products

CHAPTER I—ANIMAL AND PLANT HEALTH INSPECTION SERVICE, DEPARTMENT OF AGRICULTURE

SUBCHAPTER C—INTERSTATE TRANSPORTATION OF ANIMALS (INCLUDING POULTRY) AND ANIMAL PRODUCTS

PART 78—BRUCELLOSIS

Subpart D—Designation of Brucellosis Areas, Specifically Approved Stockyards, and Slaughtering Establishments

BRUCELLOSIS AREAS

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final Rule.

SUMMARY: This amendment adds the counties of San Miguel and Valencia, New Mexico, to the list of Certified Brucellosis-Free Areas and deletes such counties from the list of Modified Certified Brucellosis Areas. It has been determined that these counties qualify to be designated as Certified Brucellosis-Free Areas. The effect of this action will allow for less restrictions on cattle and bison moved interstate from these areas.

EFFECTIVE DATE: March 16, 1979.

FOR FURTHER INFORMATION CONTACT:

Dr. A. D. Robb, USDA, APHIS, VS, Room 805, 6505 Belcrest Road, Hyattsville, MD 20782, 301-436-8713.

SUPPLEMENTARY INFORMATION: A complete list of brucellosis areas was published in the FEDERAL REGISTER (43 FR 60865-60867) effective December 29, 1978. This amendment adds the counties of San Miguel and Valencia, New Mexico, to the list of Certified Brucellosis-Free Areas in § 78.20 and deletes such counties from the list of Modified Certified Brucellosis Areas in § 78.21, because it has been determined that they now come within the definition of a Certified Brucellosis-Free Area contained in § 78.1(1) of the regulations. This list is updated monthly and reflects actions taken under criteria for designating areas according to brucellosis status.

Accordingly, Part 78, Title 9, Code of Federal Regulations, is hereby amended in the following respects:

§ 78.20 [Amended]

1. In § 78.20, paragraph (b) is amended by adding: *New Mexico.* San Miguel and Valencia.

§ 78.21 [Amended]

2. In § 78.21, paragraph (b) is amended by deleting: *New Mexico.* San Miguel and Valencia.

(Secs. 4-7, 23 Stat. 32, as amended; secs. 1 and 2, 32 Stat. 791-792, as amended; sec. 3, 33 Stat. 1265, as amended; sec. 2, 65 Stat. 693; and secs. 3 and 11, 76 Stat. 130, 132; 21 U.S.C. 111-113, 114a-1, 115, 117, 120, 121, 125, 134b, 134f; 37 FR 28464, 28477; 38 FR 19141, 9 CFR 78.25.)

This amendment relieves certain restrictions presently imposed on cattle and bison moved from certain areas in interstate commerce. It should be made effective immediately in order to permit affected persons to move cattle interstate from such areas without unnecessary restrictions. It does not appear that public participation in this rulemaking proceeding would make additional relevant information available to the Department.

Accordingly, under the administrative procedure provisions of 5 U.S.C. 553, it is found upon good cause that notice and other public procedure with respect to the amendment are impracticable and unnecessary, and good cause is found for making them effective upon publication in the FEDERAL REGISTER.

Done at Washington, D.C., this 6th day of March 1979.

NOTE.—This final rulemaking is being published under emergency procedures as authorized by E.O. 12044 and Secretary's Memorandum 1955. It has been determined by Paul Becton, Director, National Brucellosis Eradication Program, APHIS, VS, USDA, that the emergency nature of this action, as indicated above, warrants the publication of this rule without waiting for public comment. This amendment, as well as the complete regulation, will be scheduled for review under provisions of E.O. 12044 and Secretary's Memorandum 1955. The review will include preparation of an Impact Analysis Statement which will be available from Cattle Diseases Staff, Room 805, 6505 Belcrest Road, Federal Building, Hyattsville, Maryland, 20782, 301-436-8713.

NORVAN L. MEYER,
Acting Deputy Administrator, Veterinary Services.

[FR Doc. 79-7955 Filed 3-15-79; 8:45 am]

[3410-34-M]

PART 82—EXOTIC NEWCASTLE DISEASE; AND PSITTACOSIS OR ORNITHOSIS IN POULTRY

Area Quarantined

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: The purpose of this amendment is to quarantine an additional portion of Orange County in California because of the existence of exotic Newcastle disease. Exotic Newcastle disease was confirmed in Orange County, California, on March 6, 1979. Therefore, in order to prevent the dissemination of exotic Newcastle disease it is necessary to quarantine an additional portion of such county.

EFFECTIVE DATE: March 9, 1979.

FOR FURTHER INFORMATION CONTACT:

Dr. M. A. Mixson, USDA, APHIS, VS, Federal Building, Room 748, Hyattsville, Maryland 20782, 301-436-8073.

SUPPLEMENTARY INFORMATION: This amendment quarantines an additional portion of Orange County, California, because of the existence of exotic Newcastle disease in such area. Therefore, the restrictions pertaining to the interstate movement of poultry, mynah, and psittacine birds, and birds of all other species under any form of confinement, and their carcasses and parts thereof, and certain other articles, from quarantined areas, as contained in 9 CFR Part 82, as amended, will apply to the quarantined area.

Accordingly, Part 82, Title 9, Code of Federal Regulations, is hereby amended in the following respect:

In § 82.3(a)(1), relating to the State of California, a new paragraph (ix) relating to Orange County is added to read:

§ 82.3 Areas quarantined.

(a) * * *

* * * * * * *

(1) *California.*

* * * * * * *

(ix) The premises of Tom Friend, 10602 Bolsa Avenue, Garden Grove, Orange County.

* * * * *

(Secs. 4-7, 23 Stat. 32, as amended; secs. 1 and 2, 32 Stat. 791-792, as amended; secs. 1-4, 33 Stat. 1264, 1265, as amended; secs. 3 and 11, 76 Stat. 130, 132 (21 U.S.C. 111-113, 115, 117, 120, 123-126, 134b, 134f); 37 FR 28464, 28477; 38 FR 19141.)

The amendment imposes certain restrictions necessary to prevent the interstate spread of exotic Newcastle disease, a communicable disease of poultry, from the quarantined area, and, therefore, must be made effective immediately to accomplish its purpose in the public interest. It does not appear that public participation in this rulemaking proceeding would make additional relevant information available to the Department.

Accordingly, under the administrative procedure provisions in 5 U.S.C. 553, it is found upon good cause that notice and other public procedure with respect to the amendment are impracticable and contrary to the public interest, and good cause is found for making the amendment effective less than 30 days after publication in the FEDERAL REGISTER.

Done at Washington, D.C., this 9th day of March 1979.

NOTE: This final rulemaking is being published under emergency procedures as authorized by E.O. 12044 and Secretary's Memorandum 1955. It has been determined by M. A. Mixson, Acting Assistant Deputy Administrator, Animal Health Programs, APHIS, VS, USDA, that the possibility of the spread of exotic Newcastle disease into other States or Territories of the United States from the quarantined area is severe enough to constitute an emergency which warrants the publication of this quarantine without waiting for public comment. This amendment, as well as the complete regulations, will be scheduled for review under provisions of E.O. 12044 and Secretary's Memorandum 1955. The review will include preparation of an Impact Analysis Statement which will be available from Program Services Staff, Room 870, Federal Building, 6505 Belcrest Road, Hyattsville, Maryland 20782, 301-436-8695.

E. A. SCHILF,
Acting Deputy Administrator,
Veterinary Services.

[FR Doc. 7954 Filed 3-15-79; 8:45 am]

[3410-34-M]

PART 82—EXOTIC NEWCASTLE DISEASE; AND PSITTACOSIS OR ORNITHOSIS IN POULTRY

Area Quarantined

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: The purpose of this amendment is to quarantine an additional portion of Orange County in California because of the existence of exotic Newcastle disease. Exotic Newcastle disease was confirmed in Orange County, California, on March 3, 1979. Therefore, in order to prevent the dissemination of exotic Newcastle disease it is necessary to quarantine an additional portion of such county.

EFFECTIVE DATE: March 9, 1979.

FOR FURTHER INFORMATION CONTACT:

Dr. M. A. Mixson, USDA, APHIS, VS, Federal Building, Room 748, Hyattsville, Maryland 20782, 301-436-8073.

SUPPLEMENTARY INFORMATION: This amendment quarantines an additional portion of Orange County, California, because of the existence of exotic Newcastle disease in such area. Therefore, the restrictions pertaining to the interstate movement of poultry, mynah, and psittacine birds, and birds of all other species under any form of confinement, and their carcasses and parts thereof, and certain other articles, from quarantined areas, as contained in 9 CFR Part 82, as amended, will apply to the quarantined area.

Accordingly, Part 82, Title 9, Code of Federal Regulations, is hereby amended in the following respect:

In § 82.3(a)(1), relating to the State of California, a new paragraph (viii) relating to Orange County is added to read:

§ 82.3 Areas Quarantined

(a) * * *

* * * * *

(1) *California.*

* * * * *

(viii) The premises of Thomas Johnston, 2273 Columbia Street, Costa Mesa, Orange County.

* * * * *

(Secs. 4-7, 23 Stat. 32, as amended; secs. 1 and 2, 32 Stat. 791-792, as amended; secs. 1-4, 33 Stat. 1264, 1265, as amended; secs. 3 and 11, 76 Stat. 130, 132 (21 U.S.C. 111-113, 115, 117, 120, 123-126, 134b, 134f); 37 FR 28464, 28277; 38 FR 19141.)

The amendment imposes certain restrictions necessary to prevent the interstate spread of exotic Newcastle disease, a communicable disease of poultry, from the quarantined area, and, therefore, must be made effective immediately to accomplish its purpose in the public interest. It does not appear that public participation in this rulemaking proceeding would make additional relevant information available to the Department.

Accordingly, under the administrative procedure provisions in 5 U.S.C. 553, it is found upon good cause that notice and other public procedure with respect to the amendment are impracticable and contrary to the public interest, and good cause is found for making the amendment effective less than 30 days after publication in the FEDERAL REGISTER.

Done at Washington, D.C., this 9th day of March 1979.

NOTE: This final rulemaking is being published under emergency procedures as authorized by E.O. 12044 and Secretary's Memorandum 1955. It has been determined by M. A. Mixson, Acting Assistant Deputy Administrator, Animal Health Programs, APHIS, VS, USDA, that the possibility of the spread of exotic Newcastle disease into other States or Territories of the United States from the quarantined area is severe enough to constitute an emergency which warrants the publication of this quarantine without waiting for public comment. This amendment, as well as the complete regulation, will be scheduled for review under provisions of E.O. 12044 and Secretary's Memorandum 1955. The review will include preparation of an Impact Analysis Statement which will be available from Program Services Staff, Room 870, Federal Building, 6505 Belcrest Road, Hyattsville, Maryland 20782, 301-436-8695.

E. A. SCHILF,
Acting Deputy Administrator,
Veterinary Services.

[FR Doc. 79-7953 Filed 3-15-79; 8:45 am]

[7590-01-M]

Title 10—Energy

CHAPTER I—NUCLEAR REGULATORY COMMISSION

PART 9—PUBLIC RECORDS

Waiver or Reduction of Fees for Searching and Reproduction of Records

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: This rule amends the Commission's regulations "Public Records" by adding a new section "Waiver or Reduction of Fees." These amendments reflect the requirements of the Freedom of Information Act that documents shall be furnished without charge or at a reduced charge where an agency determines that waiver or reduction of the fee for searching and reproduction of records is in the public interest because furnishing the information can be considered as primarily benefiting the general public.

EFFECTIVE DATE: This rule becomes effective on April 16, 1979.

FOR FURTHER INFORMATION CONTACT:

Mr. J. M. Felton, Director, Division of Rules and Records, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555 (telephone 301-492-7211).

SUPPLEMENTARY INFORMATION: On March 31, 1977 the Commission published in the FEDERAL REGISTER (42 FR 17131) proposed amendments to its regulation "Public Records," 10 CFR Part 9, which would add a new § 9.14a, "Waiver or Reduction of Fees." At the request of the Union of Concerned Scientists, the comment period was extended to May 23, 1977.

Comments on the proposed rule were received from the Union of Concerned Scientists (UCS) and the Rochester Gas and Electric Corporation (RG&E).

DISCUSSION OF COMMENTS

1. *Adequacy of Standards for Making Determinations to Waive or Reduce Fees.* Section 9.14a(c) of the proposed rule required a person who requests the NRC to waive or reduce fees to provide information concerning such matters as the intended use of the records, how the information would be disseminated to the public, the size of the public to be benefited, and any financial benefit the requester may receive from the use of the records. The rule repeated the Congressional mandate contained in the FOIA that records shall be furnished without charge or at a reduced charge where the agency determines "that waiver or reduction of the fee is in the public interest because furnishing the information can be considered as primarily benefiting the general public." In making this determination, the proposed rule provided that the NRC would, based upon the information submitted by the requester, balance whether the benefit to the public outweighs the cost to the public.

In their comments, UCS stated that the governing criteria were vague and subject to arbitrary agency determinations, and that the NRC should develop criteria to be applied in specific cases. In response to the comments, paragraph (c) of § 9.14a has been revised to require the requester to show how the intended use of the records is reasonably likely to:

(i) Result in actions to maintain or enhance the public's health, safety, or the quality of the environment;

(ii) Result in improved regulatory processes;

(iii) Reduce the cost of providing a government service;

(iv) Contribute substantially to public debate on an important policy issue; or

(v) Contribute substantially to matters of historical importance. In addition, a new paragraph (d) has been added to § 9.14a which specifies those situations in which a public benefit would not normally result. Finally, a new paragraph (e) has been added which provides that based upon the criteria in paragraph (d) and the information furnished by the requester in response to paragraph (c), the NRC will determine if waiver or reduction of the fee is in the public interest because furnishing the information can be considered as primarily benefiting the general public.

2. *Automatic Waiver of Fees for Public Interest Groups.* UCS proposed that non-profit organizations whose mission is to protect or enhance the public health, safety, and welfare, are automatically entitled to a waiver or reduction of fees. The Commission does not agree, and believes the proper statutory criterion is whether production of the records would primarily benefit the general public; that is, the focus of the decision to waive or reduce fees should be on the intended use of the records, and not the requester's organization affiliation, the organization's tax exempt status, or the purpose of the organization. It is recognized, however, that many non-profit organizations, whose mission is to protect or enhance the public health and safety, would qualify for a waiver or reduction of fees. In hearings before the Senate Subcommittee on Administrative Practice and Procedure in October, 1977, the head of the Freedom of Information Committee and other Department of Justice witnesses indicated in response to questions by Senator Abourezk that, although the decision would have to be made on a case-by-case basis, there would be a presumption that fees should be waived for public interest groups and media representatives. In light of these considerations, a new provision has been added to the proposed effective rule as § 9.14a(f) which provides that the NRC, in absence of a specific request for a waiver or reduction of fees, may waive or reduce the fees if it determines, based upon information furnished by the requester in his request for access to records, that production of the records would primarily benefit the general public. This provision allows the agency to waive or reduce fees where the information provided in the request letter indicates that the requester is likely to use the records in a manner which primarily benefits the general public. It is designed to alleviate the formal showing by requester organizations that they meet the requirements of § 9.14a where it is obvious a fee waiver or fee reduction is justified under the circumstances.

3. *General Waiver Provisions.* With respect to the general waiver provisions set forth in § 9.14a(b) of the proposed rule, the Rochester Gas and Electric Corporation challenges the right of the NRC to waive fees for searches which do not exceed four hours or for reproduction costs which do not exceed $10.00. The basis for the company's claim are that there has been no showing that the general waiver provisions are in the public interest and that it is unfair to assess taxpayers for work done by a public employee for the benefit of a private party. The purpose of the general waiver provisions was to eliminate the costs of billing and processing payments and responding to requests for a waiver of fees when these costs to the government were relatively small in relation to the amount of staff time that would be required to process a fee waiver request or to collect reproduction costs. In view of the NRC's practice of granting access to records by placing copies of the records in NRC Public Document Room or a Local Public Document Room, the provision granting waiver of reproduction costs not in excess of $10.00 has been eliminated from the effective rule. The Commission believes, however, that it is in the public interest to waive the minimal costs encompassed by the search fee waiver provisions, and the effective rule continues to contain this provision. The Rochester Gas and Electric Corporation also challenges the propriety of automatically waiving search fees as provided in § 9.14a(b)(4) of the proposed rule when no documents subject to the request are located or when no documents are located which can be disclosed to the requester. The Commission believes that this situation is now adequately addressed by the revised fee waiver criteria set forth in § 9.14a, and this provision has been eliminated from the effective rule.

4. *Relevancy of Information Required To Be Submitted by a Requester for Waiver or Reduction of Fees.* UCS questions the right of the NRC to require organizations to submit information in order to qualify for a waiver of fees stating that "it is the responsibility of the agency to initially decide whether a primarily public benefit will ensue from the release of the information" and the request "need only raise a substantial question as to whether the release of the information will 'primarily benefit the general public' ". As noted above in item 2, § 9.14a(f) provides that the NRC may waive fees on its own initiative, and the information required by § 9.14a(b) would only have to be submitted when the agency has concluded that the request, on its face, does not automatically warrant waiver or reduction of

fees. Under these circumstances, the Commission believes that the burden of proof properly shifts to the requester to provide NRC with sufficient information to justify that production of the records will primarily benefit the general public. UCS also questions the ability of the requester to comply with certain information requirements § 9.14a(c) of the proposed rule and challenges the relevancy of others. These are discussed as follows:

A. UCS questions the ability of the requester to respond to the requirements in § 9.14a(c)(1) of the proposed rule regarding the "intended use of the records", and states that the exact use cannot be determined until the requested documents are reviewed. The information required by this provision is *intended* use of the records, not *exact* use. Failure of a requester to have some idea in mind as to how the records requested will be used would be persuasive evidence that the requester is on a fishing expedition and that providing the records would not primarily benefit the general public. This provision has been retained in the effective rule.

B. UCS also questions the ability of a requester to respond to the requirement "why all the requested documents are necessary to accomplish the requester's intended use" (§ 9.14a(c)(2) of the proposed rule). UCS points out that in most FOIA cases, "all" the requested documents are never necessary. The Commission agrees with this comment and feels that this information is not necessary. Where an issue is raised regarding the scope of a request, it has been the experience of the Commission that a negotiated resolution can be reached with the requester.

C. UCS questions the requirement to provide information concerning how the documents will be reviewed or analyzed and the results thereof disseminated to the public (§ 9.14a(c)(3) of the proposed rule), and argues that a specific use cannot be meaningfully presented until the documents are read. As stated in item 3.A above, the Commission believes there should be an intended use of the documents at the time a request for waiver is made. Further, the requirement for review and analysis of the documents reinforces that belief, as provided in § 9.14a(d)(5) of the effective rule, that the intent to distribute copies of the records to the public does not, by itself, constitute public benefit.

D. UCS, while questioning the relevancy of the requirement to provide information regarding what financial benefit, if any, the requester will receive from use of the requested records (§ 9.14a(c)(6) of the proposed rule), acknowledges the relevancy of the requirement if direct financial benefit is the only motivating factor in making the request. The ability of the requester to pay for the records also was acknowledged by Congress as being relevant to a determination of whether to waive or reduce fees. The Senate Report on the 1974 Amendments to the FOIA indicated that if a requester was indigent, a waiver or reduction of fee would be in the public interest. The Commission has, however, deleted the requirement regarding the requesters "willingness to pay" for the requested documents.

It should be noted that the specific items of information required to be furnished by requesters is based upon the guidelines contained in the Attorney General's Memorandum on the 1974 Amendments. In the Justice Department's recent testimony before the Abourezk Subcommittee, it was stated that these guidelines were coordinated with both the House and Senate committees responsible for the FOIA legislation.

The Commission believes that in the absence of clear Congressional guidance as to what was the intent of the term "primarily benefiting the general public", and in light of the diversity of requesters and type of records requested, the standards and criteria set forth in § 9.14a of the effective rule are sufficient to assure that the agency makes a fair and equitable determination with respect to any request for a waiver or reduction of fees.

5. *Adequacy of Procedures for Processing Requests for Waiver or Reduction of Fees.* UCS alleges that the proposed rule did not set forth an adequate administrative structure to assure fair and efficient processing of FOIA requests and requests for waiver or reduction of fees. UCS questions whether NRC has the right, if a request for records does not qualify for a waiver of fees, to deem the request not received, for purposes of complying with the ten-day FOIA response deadline, until a deposit equal to the estimated costs is received or the requester has agreed to bear the anticipated costs. UCS also states that requesters should be allowed to initiate fee waiver requests on appeal.

In response to UCS's comments, a new § 9.14b has been added to the effective rule which specifies the procedures which will be followed in processing an FOIA request for a waiver or reduction of fees. The procedures provide that if the request involves more than four hours of search time, and the requester does not qualify for a waiver of fees under § 9.14a(f), the NRC will notify the requester within 10 working days of the estimated costs of complying with the request. Thereafter, the requester may agree to pay for the records or request a waiver or reduction of fees. If the NRC refuses to waive or reduce the fees, it will provide a statement to the requester as to why the request does not meet the requirements of § 9.14a, and this determination may be appealed to the EDO or to the Commission, as appropriate. Where the request does qualify for waiver or reduction of fees, § 9.14b provides that records will be promptly provided.

The Commission believes that the new procedures for processing requests are responsive to UCS's concerns and provide a reasonable balance between the rights of the requester, the resources available to the NRC, and the rights of the general public. The Commission further believes that the NRC has an obligation not to expend public funds to search for records requested under the FOIA when the request does not either qualify for an automatic waiver of fees or the requester does not agree to pay the costs of the search. Congress, in permitting agencies to charge fees to cover costs of searching for records, implied that where production of the records would not primarily benefit the general public, search costs should be assessed. It would be a misuse of public funds to divert the staff from other important activities to conduct a search for records which a requester may never agree to pay for or may never make the showing that waiver of the fees is justified under the circumstances. In view of these considerations, the Commission continues to believe that a request for access to records should not be deemed to have been received until the fee issue is resolved by the requester either agreeing to pay for the records or by qualifying for a waiver or reduction of fees. In addition, the Commission does not agree with UCS's recommendation that documents be made available to the requester at the initial stage and that a requester then be permitted to request a fee waiver on appeal "even though no such initial request was made." The Commission has, however, agreed on a trial basis to provide in § 9.14b(d) that, in those cases where a waiver of fees was requested and denied and the requester agreed to bear the estimated cost, the requester may, within 30 days of receipt of the requested documents, resubmit a request for a waiver or reduction of fees if the receipt of the documents has materially changed the information originally furnished by the requester.

With respect to the waiver or reduction of fees for reproduction costs, the majority of NRC requesters, as a matter of practice, accept access to requested records at the NRC Public Document Room in Washington, D.C. or at a Local Public Document Room in cases where the requested documents pertain to a specific facility.

The requester may then examine the records which have been made available, and make copies of just those records in which he is interested. The Commission believes this procedure is in the public interest and represents a reasonable balance between the rights of the public and the rights of the individual requester. The Commission also believes that this procedure is in accord with the broad purpose of the FOIA by providing general public access to agency records. Under the circumstances when access to records can be provided to a requester at a PDR or LPDR, to also waive reproduction costs would result in a private benefit only to the requester. This practice has now been incorporated into the regulations by adding a sentence to § 9.10(a) of the effective rule that provides that copies of documents disclosed in response to FOIA requests will normally be placed in the NRC PDR or local PDR, and by providing in § 9.14a(g) that the NRC will not waive reproduction costs for documents located in the PDR or LPDR in the absence of a compelling reason to do so. A "compelling reason" could be, for example, if the requester were both indigent and required the documents for intervention in an NRC licensing proceeding.

6. *Charging Professional and Clerical Rates for Searching.* UCS states that the present rule does not adequately indicate when clerical rates or when professional rates for search will be applied, and recommends that professional search charges should only be applied in those instances where it is absolutely essential for professionals to search for documents due to the nature and content of the requested document. The Commission believes that the proposed rule, as published, is adequate, and that this matter is properly left to the discretion of the responsible operating official. Decisions regarding who will conduct the search are dependent upon subject matter of the request, familiarization of staff with subject matter, and the necessity to assure an adequate and timely search within the FOIA statutory deadlines. FOIA requests received by the NRC are normally related to specific technical issues and, in many cases, only a member of the professional staff is capable of assuring that all records within the scope of the request are identified. The diversity of the subject matter of FOIA requests received by NRC would make it virtually impossible to establish general criteria applicable to all requests. It is expected, however, that the responsible operating official will use clerical staff to conduct the search where it is feasible to do so in order not to unnecessarily divert the technical staff from their regulatory functions or to increase costs to the requester.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and sections 552 and 553 of Title 5 of the United States Code, the following amendments to Title 10, Chapter I, Code of Federal Regulations, Part 9 are published as a document subject to codification:

1. Paragraph (b) of § 9.8 is revised to read as follows:

§ 9.8 Requests for records.

* * * * *

(b) All requests for copies of records must reasonably describe the record sought in sufficient detail to permit the identification of the requested record. Where possible, specific information regarding dates, titles, docket numbers, file designations, and other information which may help identify the records should be supplied by the requester. If a request does not reasonably describe the record sought in sufficient detail to permit its identification, the requester will be so informed by the Director, Office of Administration, or his designee, within 10 working days after receipt of the request and requested to submit additional information regarding the request or to meet with appropriate NRC personnel in order to clarify the request. Requests for Waiver or reduction of fees shall be made in accordance with § 9.14a, waiver or reduction of fees, and shall be processed in accordance with § 9.14b, Processing of requests for a waiver or reduction of fees.

2. Sections 9.10, 9.11, and 9.14 are revised to read as follows:

§ 9.10 Form and content of responses.

(a) When a requested record has been identified and is available, the head of the office of which a request has been referred or the Director, Office or Administration, will promptly furnish the record or notify the requester as to where and when the record will be available for inspection and copying. Copies of records disclosed in response to Freedom of Information Act requests will normally be placed in the NRC Public Document Room and, in the case of records relating to nuclear power facility, in the Local Public Document Room established for that facility. The notification will also advise the requester of any applicable fees under § 9.14.

(b) A reply denying a request for a record or denying a request for waiver or reduction of fees filed pursuant to § 9.14a will be in writing signed by the Director, Office of Administration, or his designee, and will include as appropriate:

(1) The reason for the denial;

(2) A reference to the specific exemption under the Freedom of Information Act and the Commission's regulations authorizing the withholding of the record;

(3) The name and title or position of each person responsible for the denial of the request, including the head of the office recommending denial of the request;

(4) A statement as to why the request does not meet the requirements of § 9.14a if the request is for a waiver or reduction of fees; and

(5) A statment that the denial may be appealed within 30 days from the receipt thereof to the Executive Director for Operations.

(c) A copy of each letter granting or denying requested records or denying a request for waiver or reduction of fees will be maintained by or furnished to the Director, Office of Administration, or his designee.

§ 9.11 Appeal from initial determination.

(a) Except as provided in § 9.15, a requester may within 30 days of receipt of a notice of denial of the request for records or denial of a request for waiver or reduction of fees pursuant to this subpart, appeal such denial to the Executive Director for Operations. The appeal shall be in writing, addressed to the Executive Director for Operations, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, and should clearly state on the envelope and in the letter, that it is an "Appeal from Initial FOIA Decision." An appeal that is not so marked will be deemed not to have been received by the NRC until it is actually received by the Executive Director for Operations.

(b) Except as provided in § 9.13, the Executive Director for Operations will make a determination with respect to any appeal pursuant to this section within 20 working days after the receipt of such appeal.

(c)(1) If on appeal the denial of the request for records is upheld in whole or in part, the Executive Director for Operations will notify the person making such request of the denial, including the exemption relied upon, an explanation of how the exemption applies to the records withheld, and the reasons for asserting the exemption.

(2) If on appeal the denial of a request for waiver or reduction of fees for locating and reproducing records is upheld in whole or in part, the Executive Director for Operations will notify the person making such request of the denial, including a statement as to why the request does not meet the requirements of § 9.14a.

(3) The requester shall be informed that the denial is a final agency action and that judicial review is available in

a district court of the United States in the district in which the requester resides, or has his principal place of business, or in which the agency records are situated, or in the District of Columbia.

(d) Copies of all appeals and written determinations on appeal will be furnished by the Executive Director for Operations, or his designee, to the Director, Office of Administration, or his designee.

* * * * *

§ 9.14 Charges for production of records.

(a) Requests for the reproduction of records at the NRC Public Document Room, located in Washington, D.C. will be honored upon payment of the following charges:

(1) Sizes up to 8½ x 14 inches made on office copying machines—$0.08 per page copy. Larger sizes—$0.08 for each 8½ x 14 inch unit or fraction thereof per page copy. Microfiche—8½ x 11 inches—$0.15 per page copy.

(2) The charge for reproducing records other than those specified above will be computed on the basis of NRC's direct costs.

(3) The charges for requests made through the mails will be the same as paragraph (a) (1) and (2) of this section except that shipping or mailing costs shall be added. If the amount of any mailed in order is less than $2.00, excluding the shipping or mailing costs, the customer shall be charged a minimum of $2.00 plus costs of shipping or mailing.

(b) Requests for copies of records to be reproduced and furnished by the NRC at locations other than the NRC Public Document Room located in Washington, D.C., will be honored at the following charges:

(1) Sizes up to 8½ x 14 inches made on office copying machines—$0.10 per page copy. Larger sizes—$0.10 for each 8½ x 14 inch unit or fraction thereof per page copy.

(2) The charge for reproducing records other than those specified above will be computed on the basis of NRC's direct costs.

(3) If a request is for records at locations other than the NRC Public Document Room, a charge of $5.00 per hour will be made for searching for the requested records by clerical or administrative employees and a charge of $12.00 per hour for searching by professional or supervisory employees.

(4) When a computer search is necessary in order to fulfill a request, the computer search charge will be the actual direct cost of the computer search.

(5) Except as otherwise provided in § 9.14a, unless the request specifically states that whatever cost is involved will be acceptable, or acceptable up to a specified limit, the NRC will, for requests involving anticipated costs in excess of the minimum specified in § 9.14a(a), so advise the requester as provided in § 9.14(b), and the request will not be deemed to have been received until a deposit equal to the estimated costs is received, or the requester has agreed to bear the anticipated costs, or a determination has been made on a request for waiver or reduction of fees. Fees may be required to be paid in full prior to the issuance of the requested records.

(6) Refunds of unused deposits or additional billings will be made to adjust to the anticipated cost to the actual cost.

(c) In compliance with the Federal Advisory Committee Act, transcripts of testimony in NRC proceedings, which are transcribed by a reporting firm under contract with the NRC, may be purchased directly from the reporting firm at the cost of reproduction as provided for in the contract with the reporting firm, or may be purchased from the NRC at the cost of reproduction as provided in paragraphs (a) and (b) of this section.

(d) Copyrighted material will not be reproduced in violation of the copyright laws.

(e) The Director, Office of Administration, or his designee, or the Executive Director for Operations, on appeals, in accordance with the provisions of § 9.14a, will waive or reduce any fee required by this section upon a determination that waiver or reduction of the fee is in the public interest because furnishing the information can be considered as primarily benefiting the general public.

3. New sections 9.14a and 9.14b are added to read as follows:

§ 9.14a Waiver or reduction of fees.*

(a) Fees for searching and reproduction of records at locations other than the NRC Public Document Room shall be waived:

(1) for search fees when the time for the search does not exceed four hours, in the aggregate, for a request or series of related requests;

(2) where the records are requested by and made available to a Federal, State, or local government, to an intergovernmental agency, or to a foreign government or international agency, and furnishing the records without charge is an appropriate courtesy.

(b) Except as provided in paragraph (a) and (f) of this section, fees for searching and reproduction of records may be waived only upon request. A person requesting the NRC to waive or reduce search or reproduction fees under this subpart shall, as set forth in 9.14b(b) provide sufficient factual information to permit NRC to make the determination whether waiver or reduction of the fee is in the public interest because furnishing the information can be considered as primarily benefiting the general public.

(c) In making a request for waiver or reduction of fees, the requester shall provide a statement setting forth the following information to the extent possible:

(1) How the information obtained from the records, or how the conclusions or results from any review or analyses of the records, will be published or otherwise disseminated to the general public;

(2) The size of the public that will be benefited by the disclosure;

(3) The nature, significance and likelihood of any tangible benefit that the public may receive from dissemination of the information;

(4) The financial benefit, if any, the requester will receive from the use of the requested materials;

(5) The ability of the requester to pay for any of the anticipated costs;

(6) How the intended use of the various types of records requested is reasonably likely to:

(i) Result in actions to maintain or enhance the public's health, safety, or the quality of the environment;

(ii) Result in improved regulatory processes;

(iii) Reduce the cost of providing a government service;

(iv) Contribute substantially to public debate on an important policy issue; or

(v) Contribute substantially to matters of historical importance.

(d) Public benefit will not normally result:

(1) When the requested records will be used primarily for the personal benefit of an individual or group rather than the general public;

(2) When the requested records will be used primarily for a commercial purpose or financial benefit;

(3) When the requested records have already been made available, or are being made available in response to the request, for inspection and copying in the NRC Public Document Room or a Local Public Document Room;

(4) When the requested records will not add appreciably to the information already available to the public in the NRC Public Document Room or a Local Public Document Room;

(5) When the requested records consist primarily of technical data which will only be distributed or made available to the public by the requester without further analyses or comment;

* The application requirements contained in sections 9.14a(c) and 9.14b(d) have been approved by the U.S. General Accounting Office under number B-180225 (R0582).

(6) When the costs to the public outweigh any benefit which may accrue to the public.

(e) Based upon the information furnished by the requester in response to paragraph (c) and the criteria set forth in paragraph (d) of this section, and the NRC will determine if waiver or reduction of the fee is in the public interest because furnishing the information can be considered as primarily benefiting the general public. In determining whether to waive fees in whole or in part, the NRC will consider the total estimated search and reproduction costs necessary to comply with the request and the extent to which the requester has carried the burden of making the necessary public interest showing under paragraph (c) of this section.

(f) In the absence of a specific request for waiver or reduction of fees, if the information furnished by the requester is sufficient to meet the requirements of this section for waiver or reduction of fees, NRC may determine that production or disclosure of the requested records can be considered as primarily benefiting the general public.

(g) The NRC will not waive the reproduction costs for documents located or made available in the NRC Public Document Room or a local public document room in the absence of a compelling reason to do so.

§ 9.14b Processing of requests for a waiver or reduction of fees*

(a) Within 10 working days after receipt of a request for access to records which does not involve more than four hours of search time, or in which the NRC agrees to waive fees pursuant to § 9.14a(f), the NRC will respond to the request as provided in § 9.9. If the request is expected to require more than four hours of search time to locate the requested records and the NRC has not waived fees under § 9.14a(f), the NRC will notify the requester that fees will be assessed. The notification shall include the estimated cost of search fees and the nature of the search required. Requesters are encouraged to discuss with the NRC the possibility of narrowing the scope of the request while retaining the requester's original objective. The requester will be advised that he may agree to bear the estimated costs, submit a deposit equal to the estimated cost of complying with the request, or submit a request for waiver or reduction of fees pursuant to § 9.14a.

(b) Within 10 working days of the receipt of NRC's notice that fees will be assessed, the requester shall notify NRC in writing that he agrees to bear the estimated costs, submit a deposit equal to the estimated cost of responding to the request or submit a request for waiver or reduction of fees pursuant to § 9.14a. In making a request for waiver or reduction of fees, a requester must provide the information required by § 9.14a(c).

(c) Within 10 working days after receipt of a request for the waiver or reduction of fees made in accordance with § 9.14a, the NRC will waive or reduce the fees and notify the requester of the NRC's intent to promptly provide the records or will deny the request and provide a statement to the requester as to why the request does not meet the requirements of § 9.14a(e).

(d) In those cases where a waiver of fees was requested and denied and the requester has agreed to bear the estimated cost, the requester may within 30 days of receipt of the requested documents resubmit a request for a waiver or reduction of fees if the receipt of documents has materially changed the information originally furnished by the requester pursuant to 9.14a(c). This paragraph (d) will become ineffective after December 17, 1979 such that no requests for reconsideration submitted after this date will be reviewed unless the Commission takes action to extend or make permanent this provision.

(e) As provided in §§ 9.11 and 9.15, a denial of a request to waive or reduce fees may be appealed within 30 days to the Executive Director for Operations or to the Commission, as appropriate.

4. Section 9.15 is revised to read as follows:

§ 9.15 Committees, boards, panels, and offices reporting to the Commission.

(a) For boards, panels, and offices reporting directly to the Commission, and the Office of the Executive Legal Director, the initial determination on a request for records or request for waiver or reduction of fees for locating and reproducing such records, required by § 9.9 shall be made by the head of such board, panel, or office, or his designee, instead of the Director, Office of Administration, and an appeal of an adverse determination shall be made to the Commission instead of the Executive Director for Operations.

(b) The Advisory Committee Management Officer shall make the initial determination required by § 9.9 on requests for records of advisory committees established pursuant to Part 7 of this chapter, including the Advisory Committee on Reactor Safeguards, or requests for waiver or reduction of fees for locating and reproducing such records, and an appeal of an adverse determination shall be to the Commission.

(c) The head of boards, panels, and offices reporting directly to the Commission, and the Advisory Committee Management Officer for advisory committees established pursuant to Part 7 of this chapter, will make the initial determination required by paragraph (a) and (b) of this section only after consultation with the Office of the General Counsel.

Effective date. These amendments become effective on April 16, 1979.

(Sec. 161, Pub. L. 83-703, 68 Stat. 948 (42 U.S.C. 2201); sec. 201, Pub. L. 93-438, 88 Stat. 1242 (42 U.S.C. 5841); 5 U.S.C. 552).

Dated at Washington, D.C. this ninth day of March, 1979.

For the Nuclear Regulatory Commission.

SAMUEL J. CHILK,
Secretary of the Commission.

[FR Doc. 79-7913 Filed 3-15-79; 8:45 am]

[3510-24-M]

Title 13—Business Credit and Assistance

CHAPTER III—ECONOMIC DEVELOPMENT ADMINISTRATION, DEPARTMENT OF COMMERCE

PART 309—GENERAL RULES FOR FINANCIAL ASSISTANCE

Interim Regulation

AGENCY: Economic Development Administration (EDA), Department of Commerce.

ACTION: Interim rule.

SUMMARY: This amendment is intended to clarify regulations interpreting a statutory prohibition on the use of EDA assistance to relocate jobs from one labor area to another. As modified, EDA's nonrelocation regulations would allow, in certain limited situations, retail establishments to participate indirectly in EDA-assisted projects without regard to their relocation actions. The intended effect of this amendment is to bring EDA's nonrelocation regulations into closer conformance with their statutory authority.

DATES: Effective date: March 12, 1979. Comments by: May 15, 1979.

ADDRESSES: Send comments to: Assistant Secretary for Economic Development, U.S. Department of Commerce, Room 7800B, Washington, D.C. 20230.

FOR FURTHER INFORMATION ON THIS INTERIM RULE CONTACT:

James F. Marten, U.S. Department of Commerce, Room 7009, Washington, D.C. 20230, (202) 377-5441.

*The application requirements contained in sections 9.14a(c) and 9.14b(d) have been approved by the U.S. General Accounting Office under number B-180225 (R0582).

SUPPLEMENTARY INFORMATION:

The amendment to EDA's nonrelocation regulations adds an exception to the prohibition of 13 CFR 309.3(g). Subsection (g) presently denies financial assistance to any applicant or establishment which has relocated within 24 months of applying for EDA assistance or which is relocating or will relocate with EDA assistance. New paragraphs (g) (1) through (4) provide an exemption for retail stores which have multiple outlets, which are not directly aided by EDA financial assistance, which are not engaging in a pattern of operations to transfer operations from one region to another, and which will not experience a significant reduction in employment in its entire operations by participating indirectly in the EDA project. As drafted, the amendment affects only indirect beneficiaries of EDA assistance. It does not apply to applicants for or direct recipients of EDA assistance.

This amendment distinguishes between retail stores and manufacturing firms with respect to EDA's requirement of an assurance on past and future non-relocation. The reason for so distinguishing is the nature of retail stores and their essential difference from manufacturing firms in terms of relocation activities. The principal difference is that the area served by a retail store is governed by the market area for its goods. This market area is normally local and within a labor area. Such relocations would not normally involve a loss in the number of job opportunities in the area; therefore, they would not fall within the scope of activities prohibited for EDA assistance. On the other hand, industrial firms are most frequently regional, national or international in their operations. Such firms can, and do, relocate from one labor area to another for purposes such as reducing costs of production. These relocations reduce available job opportunities in a labor area and, thus, would act as a bar to EDA assistance.

Section 202(b)(1) of PWEDA, the statutory basis for the nonrelocation regulations, supports such a distinction. Following its prohibition of assistance which would aid establishments relocating from one area to another, section 202(b)(1) states:

Provided, however, That such limitations shall not be construed to prohibit assistance for the expansion of an existing business entity through the establishment of a new branch, affiliate, or subsidiary of such entity if the Secretary finds that the establishment of such branch, affiliate, or subsidiary will not result in an increase in unemployment of the area of original location or in any other area where such entity conducts business operations. * * * (42 USC 3142)

EDA feels that the amendment to 13 CFR 309.3 would further the expressed intent of Congress with respect to the relationship of EDA assistance and relocation of business establishments.

In accordance with the criteria of Department of Commerce Administrative Order 218-7, EDA has determined that this amendment does not constitute a significant regulation subject to the requirements of Executive Order 12044. In furtherance of the policies of that executive order and DAO 218-7 for all regulations, EDA will accept written comments on this amendment for 60 days after its publication in the FEDERAL REGISTER. After all comments are received, EDA will evaluate the suggestions and may revise the interim regulation, if appropriate, before publishing it as a final rule.

Accordingly, EDA amends 13 CFR 309.3(g) as follows:

§ 309.3 Nonrelocation.

* * * * *

(g) EDA financial assistance is not available to any establishment or applicant which has relocated within 24 months of applying for EDA assistance or which is relocating or will relocate in the future with EDA assistance. Retail stores are exempt from this requirement provided:

(1) The retail store has multiple outlets;

(2) The retail store is not a direct recipient of EDA financial assistance;

(3) The retail store is not engaged in a pattern of operations which would result in relocating a substantial portion of its operations from one region to another; and

(4) The indirect participation by the retail store will not result in a significant reduction of employment in the retail store's entire operation.

* * * * *

AUTHORITY: Sec. 701, Pub. L. 89-136, 79 Stat. 570 (42 U.S.C. 3211); Department of Commerce Organization Order 10-4, as amended (40 FR 56702, as amended).

Dated: March 12, 1979.

ROBERT HALL,
Assistant Secretary for Economic Development.

[FR Doc. 79-8016 Filed 3-15-79; 8:45 am]

[1505-01-M]

Title 16—Commercial Practices

CHAPTER I—FEDERAL TRADE COMMISSION

SUBCHAPTER B—GUIDES

PART 23—GUIDES FOR THE JEWELRY INDUSTRY

PART 24—GUIDES FOR THE LUGGAGE AND RELATED PRODUCTS INDUSTRY

Recodification of Parts and Removal of Obsolete Sections In Those parts

Correction

In FR Doc. 79-5798 appearing on page 11176 in the issue of Tuesday, February 27, 1979, make the following corrections:

(1) In the first column of page 11187, in the first line of the NOTE to § 23.5(c)(1), "When the 'Gold,'" should have read "When the term 'Gold,'".

(2) In the third column of page 11191, in the tenth line of paragraph (i) of § 24.2(b)(7), "G21" should have been a reference to the footnote "1".

[4110-03-M]

Title 21—Food and Drugs

CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

SUBCHAPTER A—GENERAL

[Docket No. 77C-0208]

PART 73—LISTING OF COLOR ADDITIVES EXEMPT FROM CERTIFICATION

PART 81—GENERAL SPECIFICATIONS AND GENERAL RESTRICTIONS FOR PROVISIONAL COLOR ADDITIVES FOR USE IN FOODS, DRUGS, AND COSMETICS

Ferric Ferrocyanide (Iron Blue); Confirmation of Effective Date

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This document confirms the effective date of the December 22, 1978, of a regulation which "permanently" lists ferric ferrocyanide (iron blue) as a color additive for use in externally applied drugs and cosmetics, including those intended for use in the

area of the eye, exempts the color from certification, and removes ferric ferrocyanide (iron blue) from the provisional listing.

DATE: Effective date confirmed: December 22, 1978.

FOR FURTHER INFORMATION CONTACT:

Gerad L. McCowin, Bureau of Foods (HFF-334), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C St. SW., Washington, DC 20204, 202-472-5740.

SUPPLEMENTARY INFORMATION: A regulation published in the FEDERAL REGISTER of November 21, 1978 (43 FR 54235) added new §§ 73.1299 and 73.2299 (21 CFR 73.1299 and 73.2299) to provide for the safe use of ferric ferrocyanide (iron blue) as a color additive for use in externally applied drugs and cosmetics, including those intended for use in the area of the eye. The regulation also amended § 81.1 *Provisional listing of color additives* (21 CFR 81.1) by deleting the entry in paragraph (g) for ferric ferrocyanide (iron blue) and amended § 81.27 *Conditions of provisional listing of additives* (21 CFR 81.27) by deleting from paragraph (c) the requirements for ferric ferrocyanide (iron blue).

Under the Federal Food, Drug, and Cosmetic Act (sec. 706 (b), (c), and (d), 74 Stat. 399-403 as amended (21 U.S.C. 376 (b), (c), and (d)) and under authority delegated to the Commissioner (21 CFR 5.1), notice is given that no objections or requests for hearing were filed in response to the regulation of November 21, 1978. Accordingly, the amendments promulgated thereby became effective on December 22, 1978.

Dated: March 8, 1979.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-7642 Filed 3-15-79; 8:45 am]

[4110-03-M]

[Docket No. 75N-0107]

FOODS FOR SPECIAL DIETARY USE

Vitamin and Mineral Products; Revocation of Regulations

AGENCY: Food and Drug Administration.

ACTION: Final Order.

SUMMARY: The Food and Drug Administration (FDA) revokes regulations that the United States Court of Appeals for the Second Circuit has ruled are invalid. The regulations had established definitions and a standard of identity and labeling requirements for dietary supplements of vitamins and minerals.

EFFECTIVE DATE: March 16, 1979.

FOR FURTHER INFORMATION CONTACT:

L. Robert Lake, Bureau of Foods (HFF-302), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C St. SW., Washington, DC 20204, 202-245-1254.

SUPPLEMENTARY INFORMATION: Regulations establishing definitions and a standard of identity and labeling requirements for dietary supplements of vitamins and minerals were first issued in 1973 after a lengthy administrative hearing. The regulations defined five types of preparations and prescribed maximum and minimum potencies for ingredients. These potencies were stated in terms of a new unit of measurement, the U.S. Recommended Daily Allowances (U.S. RDA) that were derived from the Recommended Dietary Allowances published by the Food and Nutrition Board of the National Academy of Sciences/National Research Council. In general, the minimum potency for a nutrient in a dietary supplement was established at 50 percent of the U.S. RDA for that nutrient; the maximum potency, at 150 percent of the U.S. RDA. The 1973 regulations were challenged by fifteen petitioners. In a lengthy opinion, the United States Court of Appeals for the Second Circuit "broadly sustain[ed] the regulations" but remanded them to the agency for further action. *National Nutritional Foods Ass'n* v. *FDA*, 504 F.2d 761 (2d Cir. 1974), *cert. denied*, 420 U.S. 946 (1975).

While FDA was in the process of implementing the Court's remand directions, Congress enacted new legislation (Pub. L. 94-278, Title V, sections 501-502, 90 Stat. 410-413; April 22, 1976) restricting FDA's authority to limit the maximum potency of vitamins and minerals and ingredient composition in dietary supplements offered for use by adults (other than pregnant or lactating women) and recognized as safe. Codified in part, these amendments became section 411 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350).

In the FEDERAL REGISTER of October 19, 1976 (41 FR 46156), FDA promulgated regulations (21 CFR 125.1, 125.2, 125.3, and 80.1 (recodified as 21 CFR 105.3, 105.60, 105.77, and 105.85, respectively, in the FEDERAL REGISTER of March 15, 1977 (42 FR 14302))) to comply with both the Court's remand directions and the 1976 vitamin and mineral amendments. In effect, the agency retained the standard of identity promulgated in 1973, amended it in accordance with the Court's instructions, and incorporated an exemption from the limitations on maximum potency and ingredient composition in dietary supplements offered for use by most adults to comply with the 1976 legislation.

Subsequently, a petition was submitted by National Nutritional Foods Association (NNFA) asking the agency to reconsider the procedural propriety of amending the regulations to comply with 1976 amendments without notice and comment. In the FEDERAL REGISTER of April 19, 1977 (42 FR 20292), FDA denied the petition, noting that the 1976 amendments contained a provision that the dietary supplement regulations be revised in accordance with 5 U.S.C. 553 to conform to the legislation; that 5 U.S.C. 553 contains a good cause exemption from notice and public procedures; and that the changes in the dietary supplement regulations to conform them to requirements of the 1976 amendments satisfied the good cause exemption.

On appeal, the Second Circuit held that the good cause exemption in 5 U.S.C. 553 is to be narrowly construed, and that the dietary supplement regulations do not qualify for the exemption and must be republished for comment. In addition, the court held, *inter alia*, that vitamins and minerals that are not generally recognized as safe are food additives under the act, and that the agency has authority to retain the minimum potency requirements for dietary supplements. *National Nutritional Foods Ass'n* v. *Kennedy*, 572 F. 2d 377 (2d Cir. 1978).

Copies of the judicial decisions cited above have been placed on file with the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, and are available for public inspection between 9 a.m. and 4 p.m., Monday through Friday.

Under the decision by the Court of Appeals, the Commissioner of Food and Drugs hereby orders that 21 CFR 105.3, 105.60, and 105.85 be revoked or revised. Those portions of the regulations which were to have been superseded by amendment of Part 105 are hereby reinstated. Accordingly, Parts 101, 105, and 201 are amended as follows:

PART 101—FOOD LABELING

1. In part 101:

a. By revising § 101.2(c)(1)(iii)(*a*), (2)(iii)(*a*), and (3)(ii)(*a*) to read as follows:

§ 101.2 Information panel of package form food.

* * * * *

(c) * * *
(1) * * *
(iii) * * *

(a) Nutrition labeling in accordance with § 101.9.

* * * * *

(2) * * *

(iii) * * *

(a) Nutrition labeling in accordance with § 101.9.

* * * * *

(3) * * *

(ii) * * *

(a) Nutrition labeling in accordance with § 101.9.

* * * * *

b. Section 101.9 is amended by revising paragraphs (a)(2) and (h)(1)(i) and (2) to read as follows:

§ 101.9 Nutrition labeling of food.

(a) * * *

(2) If any vitamin and/or mineral is added to a food so that a single serving provides 50 percent or more of the U.S. Recommended Daily Allowance (U.S. RDA) for adults and children 4 years or more of age, as specified in paragraph (c)(7)(iv) of this section, of any one of the added vitamins and/or minerals, unless such addition is permitted or required in other regulations, e.g., a standard of identity or nutritional quality guideline, or is otherwise exempted by the Commissioner, the food shall be considered a food for special dietary use within the meaning of § 105.3(a)(1)(iii) of this section.

* * * * *

(h) * * *

(1)(i) Except where expressly covered by § 105.65 of this chapter, infant, baby, and junior-type food promoted for infants and children under 4 years of age shall include nutrition information on the label and in labeling in compliance with this section.

* * * * *

(2) Dietary supplements are exempted, except that the labeling of a dietary supplement in food form, e.g., a breakfast cereal, shall conform to the labeling established in paragraph (c) of this section, including the order for listing vitamins and minerals established in paragraph (c)(7)(iv) of this section.

PARTS 105—FOODS FOR SPECIAL DIETARY USE

2. In Part 105:

a. Section 105.3 is amended by revising paragraph (a)(1), by deleting paragraphs (b) and (c), by revising paragraphs (d) and (e), and by deleting paragraphs (f) and (g) as follows:

§ 105.3 Definitions and interpretations.

* * * * *

(a)(1) The term "special dietary uses", as applied to food for man, means particular (as distinguished from general) uses of food, as follows:

(i) Uses for supplying particular dietary needs which exist by reason of a physical, physiological, pathological or other condition, including but not limited to the conditions of diseases, convalescence, pregnancy, lactation, allergic hypersensitivity to food, underweight, and overweight;

(ii) Uses for supplying particular dietary needs which exist by reason of age, including but not limited to the ages of infancy and childhood;

(iii) Uses for supplementing or fortifying the ordinary or usual diet with any vitamin, mineral, or other dietary property. Any such particular use of a food is a special dietary use, regardless of whether such food also purports to be or is represented for general use.

* * * * *

(b) and (c) [Reserved]

(d) If a food purports to be or is represented for special dietary use by man by reason of the presence of any constituent which is not utilized in normal metabolism, the label shall bear a statement of the percent by weight of such constituent, and, in juxtaposition with the name of such constituent, the word "nonnutritive". If such constituent is fibrous plant matter, it shall be considered to be crude fiber and its percent expressed as such. But if such constituent is saccharin or a saccharin salt, the label shall bear, in lieu of such statement and word, the statement "Contains saccharin (or saccharin salt, as the case may be), a nonnutritive, artifical sweetener which should be used only by persons who must restrict their intake of ordinary sweets," the blank to be filled in with the percent by weight of saccharin or saccharin salt in such food. The provisions of this section shall not be construed as authorizing the use of saccharin or its salts in any food other than one for use by persons who must restrict their intake of carbohydrates, or as relieving any food from compliance with any requirement of section 402(b) or (d), 403(g), or other provisions of the act.

(e) For the purposes of the regulations in this part, the terms "infant," "child," and "adult" mean persons not more than 12 months old, more than 12 months but less than 12 years old, and 12 years or more old, respectively.

§§ 105.60, 105.77, and 105.85 [Revoked]

b. By revoking § 105.60 *Restrictions, placement, false or misleading respresentations,* § 105.77 *Vitamins and minerals,* and § 105.85 *Dietary supplements of vitamins and minerals.*

PART 201—LABELING

§ 201.19 [Amended]

3. In Part 201, § 201.19 is amended by changing "§ 105.3(d)" to read "§ 105.3(e)."

Because this order is a ministerial act revoking regulations already ruled by the Court of Appeals to be invalid, and because it relieves a restriction and there is no useful purpose in postponing the effective date, the Commissioner concludes, under the Administrative Procedure Act (5 U.S.C. 553(b)(B) and (d)(1) and (3)), that notice and public procedure and delayed effective date are unnecessary.

Executive Order 12044 on improving government regulations requires the agency to consider economic impacts in the development of regulations. Because this action is being taken to revoke regulations which the Court of Appeals has already invalidated, no assessment of its economic impact is being made at this time. No economic impacts are expected to occur from the revocation since no new requirements are imposed at this time. The economic impact of vitamin and mineral supplement standards and labeling regulations will be evaluated in the course of reissuing these regulations through the normal rulemaking procedure.

Effective date. This order is effective March 15, 1979.

Dated: March 12, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-7982 Filed 3-15-79; 8:45 am]

[4110-03-M]

Subchapter D—Drugs for Human Use

[Docket No. 78N-0341]

PART 448—PEPTIDE ANTIBIOTIC DRUGS

Combination Otic Solutions and Suspensions; Postponement of Effective Date

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This document postpones the effective date of a final rule that revises provisions for certification or release of certain combination otic products. The effective date is postponed to allow time for completion of review of the requests for a hearing.

DATE: Postponement is effective March 12, 1979.

FOR FURTHER INFORMATION CONTACT:

Nathan J. Treinish, Bureau of Drugs (HFD-32), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3650.

SUPPLEMENTARY INFORMATION: In the FEDERAL REGISTER of January 30, 1979 (44 FR 5879), the Director of the Bureau of Drugs promulgated a final rule to be effective on March 12, 1979, amending Part 448 of the antibiotic regulations (21 CFR Part 448) by revising § 448.430 (21 CFR 448.430) which provides for certification of polymyxin-B sulfate otic solution.

Hearing requests were received from two firms. In response to the January 30, 1979 final rule, Lemmon Pharmacal Co. filed a hearing request concerning Otocort (NDA 60-730). Kleinfeld, Kaplan and Becker, as attorneys for Burroughs Wellcome Co., filed a hearing request concerning Aerosporin Otic Solution (NDA 60-756, DESI 8426) and Lidosporin Otic Solution (NDA 50-171, DESI 50171).

Any data, information, and analyses on which the firms rely to justify a hearing must be submitted by April 2, 1979. The hearing requests will be reviewed, and when the review is completed the Commissioner of Food and Drugs will announce in the FEDERAL REGISTER whether or not Lemmon or Burroughs Wellcome has demonstrated the existence of a genuine and substantial issue of fact requiring a hearing.

A certification regulation exists for Aerosporin but not for Lidosporin or Otocort. Lidosporin and Otocort have been released pending a final determination as to their effectiveness.

Therefore, the effective date of the January 30, 1979 regulation as it pertains to the revision of § 448.430 is hereby postponed to allow time for completion of review of the hearing request for the product covered by this monograph, Aerosporin Otic Solution. In regard to the other two products, which are released, the date for ceasing to release the products is hereby postponed to allow time for completion of review of the hearing requests. If the result at the completion of this proceeding so indicates, monographs will be prepared to cover these released products.

The January 30, 1979 notice also amended 21 CFR Parts 444, 449, and 455. Because no person filed objections or a request for hearing concerning those parts, they are not affected by this notice, and the March 12, 1979 effective date is hereby confirmed.

This action is taken under the Federal Food, Drug, and Cosmetic Act (secs. 502, 507, 52 Stat. 1050-1051 as amended, 59 Stat. 463 as amended (21 U.S.C. 352, 357)) and under authority delegated to the Commissioner (21 CFR 5.1) and redelegated to the Director, Bureau of Drugs (21 CFR 5.78).

Effective date. This postponement is effective March 12, 1979.

(Secs. 502, 507, 52 Stat. 1050-1051 as amended, 59 Stat. 463 as amended (21 U.S.C. 352, 357))

Dated: March 9, 1979.

J. RICHARD CROUT,
Director, Bureau of Drugs.

[FR Doc. 79-7970 Filed 3-15-79; 8:45 am]

[4110-03-M]

SUBCHAPTER E—ANIMAL DRUGS, FEEDS, AND RELATED PRODUCTS

[Docket No. 77N-0164]

PART 514—NEW ANIMAL DRUG APPLICATIONS

Criteria for Adequate and Well-Controlled Investigations

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This document updates the new animal drug regulations to provide for the use of untreated and individual controls as an alternate basis to establish the effectiveness of new animal drugs. As amended, the regulations more closely conform to those for human drugs.

EFFECTIVE DATE: April 16, 1979.

FOR FURTHER INFORMATION CONTACT:

Myron C. Rosenberg, Bureau of Veterinary Medicine (HFV-100), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-5247.

SUPPLEMENTARY INFORMATION: In the FEDERAL REGISTER of September 20, 1977 (42 FR 47218) the Food and Drug Administration proposed to update the new animal drug regulations to provide for the use of untreated controls as an alternate basis to establish the effectiveness of new animal drugs. The proposed amendment to the regulations would make § 514.111 (21 CFR 514.111) more equivalent to the corresponding § 314.111 (21 CFR 314.111) covering drugs for human use. Interested persons were given 60 days to comment.

Two responses to the proposal were received. Comments were received from the Animal Health Institute (a national association representing producers of animal health and nutrition products) and a manufacturer of drug products intended for veterinary use. Both responses concurred with the proposed amendment to § 514.111, and both suggested a further modification to § 514.111(a)(4) to add a fifth method for comparing the results of treatment or diagnosis with a control so as to permit quantitative evaluation. The suggested fifth method was individual control. The responses maintained that in some cases an animal may serve as its own control and the results obtained before or during treatment may be used for comparison with those obtained in the same animal at the completion of therapy or necropsy. Examples were given of the importance of individual control, e.g., evaluating anthelmintics.

The Commissioner of Food and Drugs has evaluated the comments received and available information regarding "individual control" and concludes that a change in the regulation suggested in the comments received should be adopted but does not agree that this is a fifth method of control. The Commissioner concludes, rather, that it is an established principle that with an appropriate design the same animal can be used for both the test drug and control using three of the four types of proposed controls. This clarification has been added to the statement of principles of adequate and well-controlled clinical (field) investigations and is being finalized as proposed with the revised statement.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 512, 701(a), 52 Stat. 1055, 82 Stat. 343-351 (21 U.S.C. 360b, 371(a))) and under authority delegated to the Commissioner (21 CFR 5.1), Part 514 is amended in § 514.111 by revising paragraph (a) (3), (4), and (5) to read as follows:

§ 514.111 Refusal to approve an application.

(a) * * *

(3) The methods used in and the facilities and controls used for the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality, and purity; or

(4) Upon the basis of the information submitted to the Food and Drug Administration as part of the application, or upon the basis of any other information before it with respect to such drug, it has insufficient information to determine whether such drug is safe for use under such conditions. In making this determination the Commissioner shall consider, among other relevant factors:

(i) The probable consumption of such drug and of any substance formed in or on food because of the use of such drug;

(ii) The cumulative effect on man or animal of such drug, taking into account any chemically or pharmacologically related substances;

(iii) Safety factors which, in the opinion of experts qualified by scientific training and experience to evaluate the safety of such drugs, are appropriate for the use of animal experimentation data; and

(iv) Whether the conditions of use prescribed, recommended, or suggested in the proposed labeling are reasonably certain to be followed in practice; or

(5) (i) Evaluated on the basis of information submitted as part of the application and any other information before the Food and Drug Administration with respect to such drug, there is lack of substantial evidence consisting of adquate and well-controlled investigations, including clinical (field) investigation, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and reasonably be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling.

(ii) The following principles have been developed over a period of years and are recognized by the scientific community as the essentials of adequate and well-controlled clinical (field) investigations. They provide the basis for the determination whether there is "substantial evidence" to support the claims of effectiveness for "new animal drugs."

(*a*) The plan or protocol for the study and the report of the results of the effectiveness study must include the following:

(*1*) A clear statement of the objectives of the study.

(*2*) A method of selection of the subjects that—

(*i*) Provides adequate assurance that they are suitable for the purposes of the study, diagnostic criteria of the condition to be treated or diagnosed, confirmatory laboratory tests where appropriate, and, in the case of prophylactic agents, evidence of susceptibility and exposure to the condition against which prophylaxis is desired;

(*ii*) Assigns the subjects to test groups in such a way as to minimize bias; and

(*iii*) Assures comparability in test and control groups of pertinent variables, such as species, age, sex, duration and severity of disease, management practices, and use of drugs other than those being studied. When the effect of such variables is accounted for by an appropriate design, and when, within the same animal, effects due to the test drug can be obtained free of the effects of such variables, the same animal may be used for both the test drug and the control using the controls set forth in paragraph (a)(5)(ii)(*a*)(*4*)(*i*), (*ii*), or (*iii*) of this section.

(*3*) An explanation of the methods of observation and recording of the animal response variable studied and the means of excluding bias or minimizing bias in the observations.

(*4*) A comparison of the results of treatment or diagnosis with a control in such a fashion as to permit quantitative evaluation. The precise nature of the control must be stated and an explanation given of the methods used to minimize bias on the part of the observers and the analysts of the data. Level and methods of "blinding," if used, are to be documented. Generally, four types of comparisons are recognized:

(*i*) No treatment: Where objective measurements of effectiveness are available and placebo effect is negligible, comparison of the objective results in comparable groups of treated and untreated animals.

(*ii*) Placebo control: Comparison of the results of use of the new animal drug entity with an inactive preparation designed to resemble the test drug as far as possible.

(*iii*) Active treatment control: An effective regimen of therapy may be used for comparison, e.g., where the condition treated is such that no treatment or administration of a placebo would be contrary to the well-being of the animals.

(*iv*) Historical control: In some circumstances involving diseases with high and predictable mortality (leukemia or tetanus) or with signs and symptoms of predictable duration or severity (some forms of parasitism, bovine hypocalcemia, canine eclampsia) or in the case of prohylaxis where morbidity is predictable, the results of use of a new animal drug entity may be compared quantitatively with prior experience historically derived from the adequately documented natural history of the disease or condition in comparable animals with no treatments or with a regimen (therapeutic, diagnostic, prophylactic) whose effectiveness is established.

(*5*) A summary of the methods of analysis and an evaluation of data derived from the study, including any appropriate statistical methods.

(*6*) Any of the criteria in this paragraph (a)(5)(ii) may be waived in whole or in part, either before the investigation or in the evaluation of a completed study, by the Director of the Bureau of Veterinary Medicine with respect to a specific clinical (field) investigation. A petition for such a waiver may be filed by any person who would be adversely affected by application of the criteria to a particular clinical investigation. The petition should show that some or all of the criteria are not reasonably applicable to the investigation and that alternative procedures can be or have been followed, the results of which will yield or have yielded data that can and should be accepted as substantial evidence of the drug's effectiveness. A petition for a waiver shall set forth clearly and concisely the specific provision or provisions in the criteria from which waiver is sought, why the criteria are not reasonably applicable to the particular clinical (field) investigation, what alternative procedures, if any, are to be or have been employed, what results have been obtained, and the basis on which it can be or has been concluded that the clinical (field) investigation will yield or has yielded substantial evidence of effectiveness, notwithstanding nonconformance with the criteria for which waiver is requested.

(*b*) Standardized test drug: For such an investigation to be considered adequate for consideration for approval of a new animal drug, the test drug must be standardized as to identity, strength, quality, purity, and dosage form to give significance to the results of the investigation.

(*c*) Uncontrolled studies or partially controlled studies are not acceptable as the sole basis for the approval of claims of effectiveness. Such studies, carefully conducted and documented, may provide corroborative support of well-controlled studies regarding efficacy and may yield valuable data regarding safety of the test drug. Such studies will be considered on their merits in the light of the principles listed here, with the exception of the requirement for the comparison of the treated subjects with controls. Isolated case reports, random experience, and reports lacking the details which permit scientific evaluation will not be considered.

* * * * *

Effective date. This regulation becomes effective on April 16, 1979.

(Secs. 512, 701(a), 52 Stat. 1055, 82 Stat. 343-351 (21 U.S.C. 360b, 371(a)))

Dated: March 6, 1979.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-7643 Filed 3-15-79; 8:45 am]

[4110-03-M]

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS NOT SUBJECT TO CERTIFICATION

Chlorphenesin Carbamate Tablets

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This document amends the animal drug regulations to codify a previously approved new animal drug application (NADA) providing for safe and effective use of a skeletal muscle relaxant. The NADA is held by the Upjohn Co.

EFFECTIVE DATE: March 16, 1979.

FOR FURTHER INFORMATION CONTACT:

Bob G. Griffith, Bureau of Veterinary Medicine (HFV-112), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3430.

SUPPLEMENTARY INFORMATION: The Upjohn Co., Kalamazoo, MI 49001, is sponsor of NADA 38-160V providing for use in dogs of chlorphenesin carbamate tablets to relieve the discomfort associated with skeletal muscle trauma and inflammation.

The firm's application was originally approved October 25, 1968. At that time, approvals were not routinely published in the FEDERAL REGISTER. The regulations are now amended to codify the application.

This action does not involve reevaluation of the original application and does not constitute reaffirmation of the drug's safety and effectiveness. Because this application was approved before July 1, 1975, a summary of safety and effectiveness data and information submitted in accordance with § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)) to support approval of this application is not required.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1) and redelegated to the Director of the Bureau of Veterinary Medicine (21 CFR 5.83), Part 520 is amended by adding new § 520.434 to read as follows:

§ 520.434 Chlorphenesin carbamate tablets.

(a) *Specifications.* Each tablet contains 400 milligrams of chlorphenesin carbamate.

(b) *Sponsor.* See No. 000009 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* 50 milligrams per pound of body weight on first day; 25 milligrams per pound of body weight each following day. Divide total daily dose into 2 or 3 equal doses—administer at 12- or 8-hour intervals.

(2) *Indications for use.* For use as an adjunct to therapy of acute inflammatory and traumatic conditions of skeletal muscles. The drugs provides relief of the signs of discomfort associated with myositis, muscle sprains, traumatic injuries, stifle injuries—especially when administered before or after surgery—and invertebral disc syndrome (can be used concurrently with adrenal corticosteroids).

(3) *Limitations.* Not recommended for pregnant animals or those with a known hepatic dysfunction. Periodic liver function studies are recommended for animals on prolonged treatment. If no response is evident within 5 days of the beginning of treatment, the diagnosis should be redetermined and appropriate therapy instituted. Not recommended for use with general anesthetics other than the barbiturates. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Effective date. This regulation is effective March 16, 1979.

(Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)))

Dated: March 6, 1979.

LESTER M. CRAWFORD,
Director, Bureau of Veterinary Medicine.

[FR Doc. 79-7644 Filed 3-15-79; 8:45 am]

[4110-03-M]

PART 510—NEW ANIMAL DRUGS

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS NOT SUBJECT TO CERTIFICATION

DIETHYLCARBAMAZINE CITRATE CHEWABLE TABLETS

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The animal drug regulations are amended to reflect approval of a new animal drug application (NADA) filed by VET-A-MIX Laboratories, Inc., providing for safe and effective use of an anthelmintic tablet for prevention of heartworm disease in dogs. The regulations are also amended to add the firm to the list of approved NADA sponsors.

EFFECTIVE DATE: March 16, 1979.

FOR FURTHER INFORMATION CONTACT:

Henry C. Hewitt, Bureau of Veterinary Medicine (HFV-112), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3430.

SUPPLEMENTARY INFORMATION: VET-A-MIX Laboratories, Inc., P.O. Box 86, Shenandoah, IA 51601, filed an NADA (92-836V) providing for use of a 45-milligram diethylcarbamazine citrate chewable tablet in dogs for prevention of heartworm disease (*Dirofilaria immitis*). The regulations are amended to reflect approval of this NADA and to add this firm to the list of approved sponsors.

In accordance with the freedom of information regulations and § 514.11(e)(2)(ii) of the animal drug regulations (21 CFR 514.11(e)(2)(ii)), a summary of safety and effectiveness data and information submitted to support approval of this application is released publicly. The summary is available for public examination at the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, from 9 a.m. to 4 p.m., Monday through Friday.

Therefore, under the Federal Food, Drug, and Cosmetic Act (Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1) and redelegated to the Director of the Bureau of Veterinary Medicine (21 CFR 5.83), Parts 510 and 520 are amended as follows:

1. In Part 510, § 510.600 is amended by adding a new sponsor alphabetically to paragraph (c)(1) and numerically to paragraph (c)(2), to read as follows:

§ 510.600 Names, addresses, and code numbers of sponsors of approved applications.

* * * * *

(c) * * *
(1) * * *

Firm name, address and Drug listing No.

* * * * *

VET-A-MIX Laboratories, Inc., P.O. Box 86, Shenandoah, IA 51601; 032998.

* * * * *

(2) * * *

Drug Listing No., Firm name and address

* * * * *

032998—VET-A-MIX Laboratories, Inc., P.O. Box 86, Shenandoah, IA 51601.

* * * * *

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2. In Part 520, § 520.622c is amended by adding new paragraphs (a)(3),

(b)(3), and (c)(2)(iii), to read as follows:

§ 520.622c Diethylcarbamazine citrate chewable tablets.

(a) * * *

(3) See No. 032998 in § 510.600(c) of this chapter for use as in paragraph (c)(2)(iii) of this section.

(b) * * *

(3) For 032998: 45 milligrams of the drug per tablet.

(c) * * *

(2) * * *

(iii) For prevention of heartworm disease (*Dirofilaria immitis*) in dogs.

* * * * *

Effective date. This regulation is effective March 16, 1979.

(Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)).)

Dated: March 6, 1979.

LESTER M. CRAWFORD,
Director, Bureau of Veterinary Medicine.

[FR Doc 79-7768 Filed 3-15-79; 8:45 am]

[4110-03-M]

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS NOT SUBJECT TO CERTIFICATION

Diethylcarbamazine Citrate Chewable Tablets

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The animal drug regulations are amended to reflect approval of a supplemental new animal drug application (NADA) providing for added use of the anthelmintic tablet as an aid in controlling ascarids in dogs. The application was filed by Philips Roxane, Inc.

EFFECTIVE DATE: March 16, 1979.

FOR FURTHER INFORMATION CONTACT:

Henry C. Hewitt, Bureau of Veterinary Medicine (HFV-112), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD. 20857, 301-443-3430.

SUPPLEMENTARY INFORMATION: Philips Roxane, Inc., St. Joseph, MO 64502, filed a supplemental NADA (108-863V) providing for use of diethylcarbamazine citrate chewable tablets as an aid in the control of ascarids (*T. canis*) in dogs, in addition to the currently approved use as an aid in treating ascarid infections in dogs and cats and prevention of heartworm disease in dogs. The regulations are amended to reflect approval of this supplement.

This approval did not involve reevaluation of the original application and does not constitute reaffirmation of the drug's safety and effectiveness.

In accordance with the freedom of information regulations and § 514.11(e)(2)(ii) of the animal drug regulations (21 CFR 514.11(e)(2)(ii)), a summary of the safety and effectiveness data and information submitted to support this approval is released publicly. The summary is available for public examination at the office of the Hearing Clerk (HFA-305), Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, from 9 a.m. to 4 p.m., Monday through Friday.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1) and redelegated to the Director of the Bureau of Veterinary Medicine (21 CFR 5.83), Part 520 is amended in § 520.622c by revising paragraphs (a), (b), and (c) (1) and (2), to read as follows:

§ 520.622c Diethylcarbamazine citrate chewable tablets.

(a) *Sponsors.* (1) See No. 000010 in § 510.600(c) of this chapter for use as in paragraph (c)(2)(i) of this section.

(2) See No. 011519 in § 510.600(c) of this chapter for use as in paragraph (c)(2)(ii) of this section.

(b) *Specifications.* (1) For 000010: 30 or 120 milligrams of diethylcarbamazine citrate per tablet.

(2) For 011519: 60 or 180 milligrams of the drug per tablet.

(c) *Conditions of use*—(1) *Amount.* 3 milligrams per pound of body weight per day for prevention of heartworm disease and control of ascarids; 25 to 50 milligrams per pound of body weight as an aid in treatment of ascarid infections.

(2) *Indications for use.* (i) For prevention of heartworm disease (*Dirofilaria immitis*) in dogs; as an aid in control of ascarids (*Toxocara canis*) in dogs; as an aid in treatment of ascarid (*Toxocara canis* and *Toxacaris leonina*) infections in dogs and cats.

(ii) For prevention of infection with *Dirofilaria immitis* (heartworm disease) in dogs; as an aid in treatment of ascarid (*Toxocara canis* and *Toxascaris leonina*) infections in dogs.

* * * * *

Effective date. This regulation is effective March 16, 1979.

(Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)).)

Dated: March 9, 1979.

LESTER M. CRAWFORD,
Director, Bureau of Veterinary Medicine.

[FR Doc. 79-7769 Filed 3-15-79; 8:45 am]

[4110-03-M]

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS NOT SUBJECT TO CERTIFICATION

Flumethasone Solution

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The animal drug regulations are amended to reflect approval of a supplemental new animal drug application (NADA) filed by Syntex Laboratories, Inc., providing for anti-inflammatory use of flumethasone solution in treating horses, dogs, and cats.

EFFECTIVE DATE: March 16, 1979.

FOR FURTHER INFORMATION CONTACT:

Donald A. Gable, Bureau of Veterinary Medicine (HFV-100), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4313.

SUPPLEMENTARY INFORMATION: Syntex Laboratories, Inc., 3401 Hillview Dr., Palo Alto, CA 94304 filed a supplemental NADA (30-414V) providing for the use of Flucort (flumethasone) Solution in treating dogs, cats, and horses for several diseases that respond to anti-inflammatory corticoids. The supplement deleted a prior approved use for cattle. The NADA was originally approved on October 21, 1965. Approval granted before enactment of the Animal Drug Amendments of 1968 (Pub. L. 90-399) did not require publication in the FEDERAL REGISTER or codification in the Code of Federal Regulations. The regulations are now amended and editorially revised to codify the current approval.

Approval of this supplement does not involve a reevaluation of the original application or a reaffirmation of the drug's safety and effectiveness. Because this application was originally approved before July, 1975, a summary of safety and effectiveness data and information submitted in accordance with § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)) to support this application is not required.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR

5.1) and redelegated to the Director of the Bureau of Veterinary Medicine (21 CFR 5.83), Part 522 is amended as follows:

[§ 522.960 Redesignated as § 522.960a]

1. By designating § 522.960 *Flumethasone suspension* as § 522.960a *Flumethasone suspension.*

2. By adding a new § 522.960 *Flumethasone implantation or injectable dosage forms.*

[§ 522.961 Redesignated as § 522.960b]

3. By designating § 522.961 *Flumethasone acetate injectable* as § 522.960b *Flumethasone acetate injectable.*

4. By adding new § 522.960c to read as follows:

§ 522.960c Flumethasone solution.

(a) *Specifications.* Each milliliter of sterile aqueous solution contains 0.5 milligram flumethasone.

(b) *Sponsor.* See No. 000033 in § 510.600(c) of this chapter.

(c) *Conditions of use.* It is used as follows:

(1) *Horses*—(i) *Amount.* 1.25 to 2.5 milligrams daily, intravenously, intramuscularly, or intra-articularly.

(ii) *Indications for use.* It is used for the treatment of musculoskeletal conditions due to inflammation, where permanent structural changes do not exist, e.g., bursitis, carpitis, osselets, and myositis; and allergic states, e.g., hives, urticaria, and insect bites.

(iii) *Limitations*—(*a*) Clinical and experimental data have demonstrated that corticosteroids administered orally or parenterally to animals may induce the first stage of parturition when administered during the last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis.

(*b*) When a long-term therapy is used, the dose should be individually adjusted to the minimum maintenance dose. A protein-rich diet is useful in dogs and cats on long-term therapy to counteract nitrogen loss if it should occur. A small amount of potassium chloride daily in the diet will counteract excessive potassium loss if this is present.

(*c*) It has been demonstrated that corticosteroids, especially at high dose levels, may result in delayed wound and fracture healing.

(*d*) Flumethasone may be administered to animals with bacterial diseases provided appropriate antibacterial therapy is administered simultaneously.

(*e*) The drug is not to be used in horses intended for slaughter for food purposes.

(*f*) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Dogs*—(i) *Amount.* 0.0625 to 0.25 milligram daily, intravenously, intramuscularly, or subcutaneously; 0.125 to 1.0 milligram daily, intralesionally, depending on the size and location of the lesion; 0.166 to 1.0 milligram daily, intra-articularly, depending on the severity of the condition and the size of the involved joint.

(ii) *Indications for use.* It is used for the treatment of musculoskeletal conditions due to inflamation of muscles or joints and accessory structures where permanent structural changes do not exist, e.g., arthritis, osteoarthritis, disc syndrome, and myositis (in septic arthritis, appropriate antibacterial therapy should be concurrently administered); certain acute and chronic dermatoses of varying etiology to help control associated pruritus, irritation, and inflammation; otitis externa in conjunction with topical medication; allergic states, e.g., hives, urticaria, and insect bites; and shock and shock-like states by intravenous administration.

(iii) *Limitations.* See paragraph (c)(1)(iii) of this section.

(3) *Cats*—(i) *Amount.* 0.03125 to 0.125 milligram daily intravenously, intramuscularly, or subcutaneously.

(ii) *Indications for use.* It is used for the treatment of certain acute and chronic dermatoses of varying etiology to help control associated pruritus, irritation, and inflammation.

(iii) *Limitations.* See paragraph (c)(1)(iii) of this section.

Effective date. This regulation is effective March 16, 1979.

(Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)).)

Dated: March 6, 1979.

LESTER M. CRAWFORD,
Director, Bureau of Veterinary Medicine.

[FR Doc. 79-7767 Filed 3-15-79; 8:45 am]

[4110-03-M]

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS NOT SUBJECT TO CERTIFICATION

Oxytetracycline Hydrochloride Injection

AGENCY: Food and Drug Administration.

ACTION: Final Rule.

SUMMARY: The animal drug regulations are amended to reflect approval of a supplemental new animal drug application (NADA) filed by Philips Roxane, Inc., providing for use of oxytetracycline hydrochloride injection in swine.

EFFECTIVE DATE: March 16, 1979.

FOR FURTHER INFORMATION CONTACT:

Richard A. Carnevale, Bureau of Veterinary Medicine (HFV-125), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1788.

SUPPLEMENTARY INFORMATION: Philips Roxane, Inc., 2621 North Belt Highway, P.O. Box 999, St. Joseph, MO 64502, filed a supplemental NADA (47-278V) providing for use of the injectable drug (50 milligrams of oxytetracycline per milliliter) in treating certain susceptible infections in swine in addition to its use in beef cattle, nonlactating dairy cattle, and sows. Approval of this supplement does not constitute reaffirmation of the safety of residues resulting from use of this drug.

In accordance with § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)) of the animal drug regulations, a summary of the safety and effectiveness data and information submitted to support the approval of this application is released publicly. The summary is available for public examination at the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, MD 20857, from 9 a.m. to 4 p.m., Monday through Friday.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i))), under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1) and redelegated to the Director of the Bureau of Veterinary Medicine (21 CFR 5.83), Part 522 is amended in § 522.1662a by revising paragraph (b)(1)(i), the introductory text of (b)(3), and (b)(3)(ii) to read as the follows:

§ 522.1662a Oxytetracycline hydrochloride injection.

* * * * *

(b)(1) *Specifications.* (i) 50 milligrams of oxytetracycline (as oxytetracycline hydrochloride) in each milliliter of sterile solution for use in beef and nonlactating dairy cattle and swine;

* * * * *

(3) *Conditions of use.* The drug is used for treatment of diseases due to oxytetracycline-susceptible organisms in beef cattle, nonlactating dairy cattle, and swine.

* * * * *

(ii) *Swine.* (*a*) It is used for the treatment of bacterial enteritis (scours, colibacillosis) caused by *Escherichia coli,* pneumonia caused by

Pasteurella multocida, and leptospirosis caused by *Leptospira pomona*. For sows, as an aid in the control of infectious enteritis (baby pig scours, colibacillosis) in suckling pigs caused by *Escherichia coli*.

(b) Administer by intramuscular injection at 3 to 5 milligrams of oxytetracycline per pound of body weight per day. For sows, administer intramuscularly at 3 milligrams of oxytetracycline per pound of body weight approximately 8 hours before farrowing or immediately after farrowing. Do not inject more than 5 milliliters per site intramuscularly.

(c) Do not use for more than 4 days. Discontinue use 26 days before slaughter.

* * * * *

Effective date. This regulation is effective March 16, 1979.

(Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)))

Dated: March 6, 1979.

LESTER M. CRAWFORD,
Director, Bureau of Veterinary Medicine.

[FR Doc. 79-7650 Filed 3-15-79; 8:45 am]

[4110-03-M]

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS NOT SUBJECT TO CERTIFICATION

Flumethasone, Neomycin Sulfate, and Polymyxin B Sulfate

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The animal drug regulations are amended to codify a previously approved new animal drug application (NADA) held by Syntex Laboratories, Inc., providing for safe and effective use of an antibacterial and anti-inflammatory ophthalmic solution in dogs and cats.

EFFECTIVE DATE: March 16, 1979.

FOR FURTHER INFORMATION CONTACT:

Donald A. Gable, Bureau of Veterinary Medicine (HFV-114), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4313.

SUPPLEMENTARY INFORMATION: Syntex Laboratories, Inc., 3401 Hillview Dr., Palo Alto, CA 94304, is sponsor of an NADA (38-801V) providing for use of an ophthalmic solution containing flumethasone, neomycin sulfate, and polymyxin B sulfate for treatment of dogs and cats. The firm currently holds approval (NADA 47-725V) for a formulation containing hydroxypropyl methylcellulose in addition to these three active ingredients. Its indications are the same as for NADA 38-801V, except that its use is limited to dogs.

The application (38-801V) was originally approved July 10, 1969. However, the approval was not published at that time. The regulations are amended to reflect approval of the application.

Codification of a previously approved NADA does not constitute reaffirmation of the drug's safety and effectiveness. Since this application was approved prior to July 1, 1975, a summary of safety and effectiveness data and information submitted in accordance with § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)) to support this application is not required.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1) and redelegated to the Director of the Bureau of Veterinary Medicine (21 CFR 5.83), § 524.960 is revised to read as follows:

§ 524.960 Flumethasone, neomycin sulfate, and polymyxin B sulfate ophthalmic solutions.

(a) *Specifications.* Each milliliter of ophthalmic preparation contains 0.10 milligram flumethasone, 5.0 milligrams neomycin sulfate (3.5 milligrams neomycin base), and 10,000 units of polymyxin B sulfate, with or without hydroxypropyl methylcellulose.

(b) *Sponsor.* See No. 000033 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*—(i) *Preparation containing hydroxypropyl methylcellulose.* Dogs: 1 to 2 drops per eye, every 6 hours.

(ii) *Preparation without hydroxyproply methylcellulose.* Dogs and cats: 2 to 3 drops per eye, every 4 hours.

(2) *Indications for use.* Treatment of the inflammation, edema, and secondary bacterial infections associated with topical ophthalmological conditions of the eye such as corneal injuries, incipient pannus, superficial keratitis, conjunctivitis, acute nongranulomatous anterior uveitis, kerato- conjunctivitis, and blepharitis.

(3) *Limitations.* (i) In treating ophthalmological conditions associated with bacterial infections, the drug is contraindicated in those cases in which microorganisms are not susceptible to the antibiotics incorporated in the drug.

(ii) The drug is contraindicated in infectious tuberculous lesions of the eye, early acute stages of viral diseases of the cornea and conjunctiva, herpes simplex lesions of the eye, and fungal infections of the conjunctiva and eyelids.

(iii) The usual precautions and contraindications for corticosteroids and adrenocorticoids are applicable with this drug. Corticosteroids may inhibit essential inflammatory responses intrinsic to the fundamental healing mechanism. Adrenocorticoid compounds have been reported to cause an increase in intraocular pressure. Intraocular pressure should be checked frequently. Ocular reexaminations should be made at frequent intervals during long-term therapy.

(iv) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Effective date. This regulation is effective March 16, 1979.

(Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)))

Dated: March 6, 1979.

LESTER M. CRAWFORD,
Director, Bureau of Veterinary Medicine.

[FR Doc. 79-7645 Filed 3-15-79; 8:45 am]

[4110-03-M]

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

Levamisole Hydrochloride

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This document amends the animal drug regulations to reflect the proper dosages of levamisole hydrochloride in animal feeds. The dosages were inadvertently amended during the 1975 recodification of the regulations.

EFFECTIVE DATE: March 16, 1979.

FOR FURTHER INFORMATION CONTACT:

Robert S. Brigham, Bureau of Veterinary Medicine (HFV-238), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-6243.

SUPPLEMENTARY INFORMATION: The regulation concerning use of levamisole hydrochloride in animal feeds (21 CFR 558.315) reflects the approval of new animal drug applications 44-015V and 45-455V. These approvals concern use of the drug in cattle and swine for treatment of certain helminth infections. The approved dosage is 0.36 to 3.6 grams of levamisole per pound of feed (0.08 to 0.8 percent) for cattle and 0.36 grams/pound (0.08 percent) for swine. With publication of the recodification of the animal drug regulations in the FEDERAL REGISTER of

March 27, 1975 (40 FR 13802), the dosage was inadvertently amended to read grams per ton. This document reestablishes the proper dosages.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1) and redelegated to the Director of the Bureau of Veterinary Medicine (21 CFR 5.83), § 558.315 *Levamisole hydrochloride (equivalent)* is amended by revising the headings of paragraphs (g)(1)(i) and (g)(2)(i) to read *"Amount per pound."*

Effective date. This regulation is effective March 16, 1979.

(Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)))

Dated: March 6, 1979.

LESTER M. CRAWFORD,
Director, Bureau of Veterinary Medicine.

[FR Doc. 79-7646 Filed 3-15-79; 8:45 am]

[4830-01-M]

Title 26—Internal Revenue

CHAPTER I—INTERNAL REVENUE SERVICE, DEPARTMENT OF THE TREASURY

SUBCHAPTER A—INCOME TAX

[T.D. 7601]

PART 1—INCOME TAX; TAXABLE YEARS BEGINNING AFTER DECEMBER 31, 1953

Interest Related to Exempt-Interest Dividends

AGENCY: Internal Revenue Service, Treasury.

ACTION: Final regulations.

SUMMARY: This document provides final regulations concerning interest related to exempt-interest dividends. Changes to the applicable law were made by the Tax Reform Act of 1976. The regulations provide the public with guidance needed for compliance with that Act and affect certain taxpayers who own shares of stock of certain regulated investment companies.

DATE: The regulations are effective for taxable years beginning after December 31, 1975.

FOR FURTHER INFORMATION CONTACT:

Benedetta A. Kissel of the Legislation and Regulations Division, Office of the Chief Counsel, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, D.C. 20224, Attention: CC:LR:T (202-566-4454, not a toll-free number).

SUPPLEMENTARY INFORMATION:

BACKGROUND

On July 28, 1978, the FEDERAL REGISTER published proposed regulations under section 265 of the Internal Revenue Code of 1954 (43 FR 32823). The regulations were proposed to conform the Income Tax Regulations (26 CFR Part 1) to section 2137(e) of the Tax Reform Act of 1976 (90 Stat. 1931). No public hearing was requested and none was held. After consideration of all comments regarding the proposed regulations, the regulations are adopted as revised by this Treasury decision.

DESCRIPTION OF REGULATIONS

The Tax Reform Act of 1976 added a new paragraph (4) to section 265. This new paragraph denies the taxpayer a deduction for interest on indebtedness incurred or continued to purchase or carry shares of stock of a regulated investment company that distributes exempt-interest dividends during the taxpayer's taxable year.

The proposed regulations disallow a deduction for all of the interest that relates to exempt-interest dividends. If the regulated investment company distributes both taxable and exempt-interest dividends to the shareholder during the shareholder's taxable year only a portion of the interest relates to exempt-interest dividends.

This Treasury decision makes minor changes and clarifies the provisions of the regulations as proposed.

DRAFTING INFORMATION

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

ADOPTION OF AMENDMENTS TO THE REGULATIONS

Accordingly, 26 CFR Part 1 is amended as follows:

The following new section is added immediately after § 1.265-2:

§ 1.265-3 Nondeductibility of interest relating to exempt-interest dividends.

(a) *In general.* No deduction is allowed to a shareholder of a regulated investment company for interest on indebtedness that relates to exempt-interest dividends distributed by the company to the shareholder during the shareholder's taxable year.

(b) *Interest relating to exempt-interest dividends.* (1) All or a portion of the interest on an indebtedness relates to exempt-interest dividends if the indebtedness is either incurred or continued to purchase or carry shares of stock of a regulated investment company that distributes exempt-interest dividends (as defined in section 852(b)(5) of the Code) to the holder of the shares during the shareholder's taxable year.

(2) To determine the amount of interest that relates to the exempt-interest dividends the total amount of interest paid or accrued on the indebtedness is multiplied by a fraction. The numerator of the fraction is the amount of exempt-interest dividends received by the shareholder. The denominator of the fraction is the sum of the exempt-interest dividends and taxable dividends received by the shareholder (excluding capital gain dividends received by the shareholder and capital gains required to be included in the shareholder's computation of long-term capital gains under section 852(b)(3)(D)).

(Sec. 7805, Internal Revenue Code of 1954 (68A Stat. 917; 26 U.S.C. 7805).)

JEROME KURTZ,
Commissioner of Internal Revenue.

Approved: March 1, 1979.

DONALD C. LUBICK,
Assistant Secretary of the Treasury.

[FR Doc. 79-8083 Filed 3-15-79; 8:45 am]

[3810-70-M]

Title 32—National Defense

CHAPTER I—OFFICE OF THE SECRETARY

[DOD Directive 5200.1]

PART 159—DOD INFORMATION SECURITY PROGRAM

Final Rule; Correction

AGENCY: Office of the Secretary of Defense.

ACTION: Correction of Final Rule.

SUMMARY: In FR Doc. 79-7096 appearing in the FEDERAL REGISTER on March 8, 1979 (44 FR 12669), an error was made in the 7th line under SUPPLEMENTARY INFORMATION. The cited DOD Directive 5000.1 should read: *5200.1.*

FOR FURTHER INFORMATION CONTACT:

Margaret Healy, Federal Register Liaison Officer, Washington Head-

quarters Services, Washington, D.C., (202) 697-4111.

H. E. LOFDAHL,
Deputy Director, Correspondence and Directives, Washington Headquarters Services, Department of Defense.

MARCH 12, 1979.

[FR Doc. 79-8018 Filed 3-15-79; 8:45 am]

[8320-01-M]

Title 38—Pensions, Bonuses, and Veterans' Relief

CHAPTER I—VETERANS ADMINISTRATION

PART 36—LOAN GUARANTY

Increase in the Maximum Allowable Setup Charges Which May Be Included in the Mobile Home Loan; Amendment to Release of Liability Provisions for Mobile Home Loans

AGENCY: Veterans' Administration.

ACTION: Final regulations.

SUMMARY: The VA (Veterans' Administration) is amending its regulations to increase the allowable setup charges payable by a veteran and which may be included in the loan amount for the purchase of a new mobile home. The increase in the setup fees is necessary because of the increased costs of both labor and materials used to place a mobile home on a lot. The increase in the allowable setup fees should generate greater participation in the VA mobile home program by veterans, lenders, and mobile home dealers.

The VA also is amending its regulations concerning release of liability. The amendment is necessary to make the release of liability provisions for mobile home loans uniform with the present release of liability provisions in effect for guaranteed and direct home loans.

EFFECTIVE DATE: March 9, 1979.

FOR FURTHER INFORMATION CONTACT:

Mr. George D. Moerman, Assistant Director for Loan Policy (264), Loan Guaranty Service, Veterans' Administration, Washington, D.C. 20420, 202-389-3042.

SUPPLEMENTARY INFORMATION: On September 7, 1978, the VA published for comment in the FEDERAL REGISTER (43 FR 39833) two proposed amendments to the mobile home regulations. The first amendment proposed an increase in the maximum allowable setup fees, and the second amendment proposed a change to the release of liability provisions. The VA received 37 comments concerning these proposals. All comments were favorable.

Section 36.4232(d)(2) is amended to increase the maximum allowable setup charges which may be included in the loan amount for a VA mobile home loan. The new VA maximums for allowable setup fees are $400 for a new single-wide mobile home and $800 for a new double-wide or larger mobile home. "Setup" is the cost of transporting a mobile home from the dealer's lot to the veteran's home site and the cost of labor and materials necessary to properly install a mobile home on a lot. If a dealer charges more than the VA maximum fee for setup, the amount above the VA maximum must be paid in cash by the veteran. In recent years the cost of both labor and materials to properly install a mobile home on a suitable lot have greatly increased. The increased costs of proper mobile home setup in many instances have exceeded the former maximum allowable setup fees ($200 for single-wide, $400 for double-wide), requiring the veteran to pay the extra cost of mobile home setup from his or her cash resources. The adoption of this regulatory amendment increasing the maximum setup fees which may be included in the VA loan amount will most likely assist veterans, particularly lower income veterans, to be able to afford mobile home housing.

The VA received 37 comments which strongly endorsed the increase in the allowable setup fees. Some of the commentators felt that the setup fees should be increased to between $500 to $800 for single-wide mobile homes and $1,000 to $1,200 for double-wide mobile homes. It is our belief that the new maximums will cover the expenses of the average setup of a single-wide or double-wide mobile home and that no further increase is warranted at this time. One commentator suggested that VA establish different maximum setup fees in each major region of the country. Another commentator suggested that VA automatically increase (or decrease) the maximum setup fees based upon a recognized cost-of-living index. Although both ideas have merit, the VA is opposed to establishing fees on a regional basis because it would unduly complicate the VA loan guaranty program. We also believe that tying setup fees or other allowable fees or charges to a cost-of-living index could be inflationary and might exceed the President's anti-inflation guidelines.

VA also is making language changes to § 36.4232(d)(1) for clarity and uniformity and to § 36.4232(b) and (d) to reflect the repeal of VA loan maximums by the Veterans' Housing Benefits Act of 1978 (Pub. L. 95-476, 92 Stat. 1497). Section 36.4221 is amended to reflect current titles of officials delegated authority to exercise certain powers of the Administrator.

VA is amending § 36.4285 by adding a new paragraph (f) concerning release of liability. The Veterans Compensation and Relief Act of 1972 (Pub. L. 92-328, 86 Stat. 393) enacted a new subsection (b) to section 1817 of title 38, United States Code. Section 1817(b) prescribes criteria for releasing an original veteran-borrower from personal liability to the Government when the default and resulting termination of a VA loan are caused by a person who assumes the original veteran-borrower's loan. Similar regulations have previously been in effect in the guaranteed home loan program (§ 36.4323 (g)) and the direct loan program (§ 36.4508(c)). This amendment places a uniform provision in the mobile home regulations. All comments received concerning this regulatory change were favorable with no comments received suggesting other alternatives.

These amendments, therefore, are adopted under authority granted to the Administrator by section 1819(g) of title 38, United States Code.

Accordingly, the proposed regulations are hereby adopted and are set forth below.

Approved: March 9, 1979.

MAX CLELAND,
Administrator.

1. In § 36.4221, paragraph (b) is revised to read as follows:

§ 36.4221 Delegation of authority.

* * * * *

(b) Designated positions:

Chief Benefits Director.
Director, Loan Guaranty Service.
Director, Regional Office.
Director, Medical and Regional Office Center.
Director, VA Center.
Loan Guaranty Officer.
Assistant Loan Guaranty Officer.

The authority hereby delegated to employees of the positions designated in this paragraph may, with the approval of the Chief Benefits Director, be redelegated.

* * * * *

2. In § 36.4232, paragraphs (b) and (d) are revised to read as follows:

§ 36.4232 Allowable fees and charges; mobile home unit.

* * * * *

(b) Any charge against the borrower properly made under paragraph (a) of this section may be included in the

loan and paid out of the proceeds of the loan. (38 U.S.C. 1819(g))

* * * * *

(d) Subject to the limitations set forth in this section, the following may be included in the loan made for the purchase of a new (not used) mobile home unit and paid out of the proceeds of the loan:

(1) The actual cost of transportation or freight not to exceed $400 for a single-wide mobile home or $600 for a double-wide mobile home;

(2) Setup charges for installing the mobile home on site not to exceed $400 for a single-wide mobile home or $800 for a double-wide mobile home. (38 U.S.C. 1819(g))

If the actual costs exceed the limitations in this section, the veteran must certify that any excess cost has been paid in cash from the veteran's own resources without borrowing.

3. Section 36.4285 is amended as follows:

By deleting the word "his" and inserting the word "the" in the first sentence in paragraph (a), by deleting the word "him" and inserting the word "the holder" in paragraph (b), and by revising paragraph (e) and adding paragraph (f) as set forth below:

§ 36.4285 Subrogation and indemnity.

* * * * *

(e) Whenever any veteran disposes of residential property securing a guaranteed loan obtained under 38 U.S.C. 1819, the Administrator, upon application made by such veteran, shall issue to the veteran a release relieving him or her of all further liability to the Administrator on account of such loan (including liability for any loss resulting from any default of the transferee or any subsequent purchaser of such property) if the Administrator has determined, after such investigation as the Administrator may deem appropriate, that there has been compliance with the conditions prescribed in 38 U.S.C. 1817(a). The assumption of full liability for repayment of the loan by the transferee of the property must be evidenced by an agreement in writing in such form as the Administrator may require. Release of the veteran from liability to the Administrator will not impair or otherwise affect the Administrator's guaranty on the loan, or the liability of the veteran to the holder. Any release of liability granted to a veteran by the Administrator shall inure to the spouse of such veteran. The release of the veteran from liability to the Administrator will constitute the Administrator's prior approval to a release of the veteran from liability on the loan by the holder thereof. This release will not result in the veteran being entitled to further loan benefits unless the requirements of § 36.4203 are met.

(f) If, on or after July 1, 1972, any veteran disposes of residential property securing a guaranteed loan obtained by him or her under 38 U.S.C. 1819, without securing a release from liability with respect to such loan under 38 U.S.C. 1817(a) and a default subsequently occurs which results in liability of the veteran to the Administrator on account of the loan, the Administrator may relieve the veteran of such liability if the Administrator determines that:

(1) A transferee either immediate or remote is legally liable to the Administrator for the debt of the original veteran-borrower established after the termination of the loan, and

(2) The original loan was current at the time such transferee acquired the property, and

(3) The transferee who is liable to the Administrator is found to have been a satisfactory credit risk at the time he or she acquired the property. (38 U.S.C. 1817(b).)

[FR Doc. 79-8025 Filed 3-15-79; 8:45 am]

[1505-01-M]

Title 39—Postal Service

CHAPTER I—UNITED STATES POSTAL SERVICE

PART 955—RULES OF PRACTICE BEFORE THE BOARD OF CONTRACT APPEALS

Adoption of Rules Providing for Optional Small Claims Expedited and Accelerated Procedures and Rules for Subpoenas

Correction

In FR Doc. 79-7153 appearing at page 13013 in the issue for Friday, March 9, 1979, on page 13014, first column, eleventh line of § 955.35(b)(1), "appeals" should read "appear".

[6712-01-M]

Title 47—Telecommunication

CHAPTER I—FEDERAL COMMUNICATIONS COMMISSION

[FCC 79-135]

PART 97—AMATEUR RADIO SERVICE

Extending Grace Period for Renewal of an Expired Amateur Radio Service Operator License

AGENCY: Federal Communications Commission.

ACTION: Order (Rulemaking).

SUMMARY: The Amateur Radio Services rules are being amended to extend the grace period for renewal of an expired amateur radio license from one year to five years. At present, persons who do not renew within one year of the expiration of their license must be retested in telegraphy and radio theory. Extension of the grace period will reduce the number of re-examinations and/or requests for waiver of the re-examination requirement.

EFFECTIVE DATE: March 16, 1979.

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

FOR FURTHER INFORMATION CONTACT:

Mr. Stephen J. Francis, Private Radio Bureau, (202-632-7175).

SUPPLEMENTARY INFORMATION:

Adopted: February 28, 1979.

Released: March 5, 1979.

Order. In the Matter of Amendment of Part 97 to extend grace period for renewal of an expired Amateur Radio Service operator license.

1. The purpose of this Order is to amend Part 97 of the Commission's rules to lengthen the "grace" period for renewal of an expired amateur radio operator license. Section 97.13(d) of the Commission's rules now states that, "If a license is allowed to expire, application for renewal may be made during a period of grace of one year after the expiration date. During this one year period of grace, an expired license is not valid."

2. Applicants who allow the one year period of grace to expire must normally be reexamined to demonstrate again their qualifications to be amateur radio operators. The Commission, however, receives many requests for waivers of § 97.13(d) from applicants, who, for various reasons, have unknowingly permitted their licenses to lapse beyond the one year period of grace.

3. In considering whether or not to grant waivers of § 97.13(d), the Commission evaluates the circumstances surrounding the non-renewal of these licenses. The rule is waived in cases

when (1) circumstances beyond the licensee's control, such as a physical disability or a death of a close family member prevent the licensee from filing a timely application and (2) the period since expiration of the "grace period" has been of brief duration. When a waiver is granted, the Commission presumes the applicant is still fully qualified to operate an amateur station.

4. It is evident from experience gained in processing several hundred requests for waivers in recent years that the overwhelming majority of requests result in waivers. For this reason, the Commission is amending § 97.13(d) to change the period of grace from one to five years. The Commission concludes that the five-year period is one in which it is reasonable to presume that the licensee will remain fully qualified. While there is no clear demarcation, we believe that an extension of this period beyond the equivalent of one additional license term is unwarranted.

5. The rule amendment will reduce Commission workload in two ways: (1) The Commission will receive fewer requests for waivers, each of which now require individual attention and handling; and (2) the Commission will administer fewer second examinations to ex-licensees who failed to renew their licenses within the "grace period".

6. Authority for these amendments is contained in Sections 4(i) and 303 of the Communications Act of 1934, as amended. The Commission finds, that for good cause the prior notice and public procedure provisions of the Administrative Procedure Act (5 U.S.C. 553) are unnecessary because the Commission believes that there would be no objection to the relief from previously imposed restrictions. Early adoption would simplify application filing requirements, accelerate the speed for processing applications, and reduce delay in eliminating restrictions.

7. *It is ordered,* That effective March 16, 1979, Part 97 of the Commission's rules and regulations is amended as set forth below.

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

FEDERAL COMMUNICATIONS COMMISSION,
WILLIAM TRICARICO,
Secretary.

Part 97 of Chapter I of Title 47 of the Code of Federal Regulations is amended as follows:

1. In § 97.13 paragraph (d) is revised to read as follows:

§ 97.13 Renewal or modification of operator license.

* * * * *

(d) If a license is allowed to expire, application for renewal may be made during a period of grace of five years after the expiration date. During this five year period of grace, an expired license is not valid. A license renewed during the grace period will be dated currently and will not be backdated to the date of its expiration. Application for renewal shall be submitted on FCC Form 610 and shall be accompanied by the applicant's expired license.

* * * * *

[FR Doc. 79-8017 Filed 3-15-79; 8:45 am]

[7035-01-M]

Title 49—Transportation

CHAPTER X—INTERSTATE COMMERCE COMMISSION

SUBCHAPTER B—PRACTICE AND PROCEDURE

PART 1125—STANDARDS FOR DETERMINING RAIL SERVICE CONTINUATION SUBSIDIES

Northeast-Midwest Region of the United States; Interpretation of Standards

AGENCY: Rail Services Planning Office, Interstate Commerce Commission.

ACTION: Publication of Interpretation Number 4.

SUMMARY: Conrail requested an interpretation of § 1125.1(d), of the Regional Subsidy Standards, regarding cost overruns that exceed the 15 percent overrun provision when they occur in the final subsidy year. This interpretation is being issued pursuant to § 1125.4(c) of these regulations.

FOR FURTHER INFORMATION CONTACT:

James Wells, Chief, Cost Evaluation Branch, Rail Services Planning Office, 202-254-7552.

INTERPRETATION NO. 4

MARCH 14, 1979

On February 5, 1979, the Consolidated Rail Corporation (Conrail) requested the Rail Services Planning Office (Office) to interpret § 1125.1(d) of the regulations. This interpretation is issued in response to the request.

The Commonwealth of Virginia and the Accomack-Northhampton Transportation District filed replys to Conrail's request. A subsequent letter was then sent to the Office, dated February 28, 1979, by Conrail which further clarified its position on issues was there tangent to the primary concern of their request. The main issue concerning Conrail is the resolution of cost overruns that exceed the 15 percent provisions of the regulations in the final subsidy period. When the subsidized service was operated, between April 1, 1976 and March 31, 1977, § 1125.1(d) governed the issue.

Conrail states that § 1125.1(d) of the regulations does not cover the situation when a cost overrun in excess of 15 percent occurs in the final subsidy year. It is Conrail's position that whether or not notice is given within the 10-month period specified in the regulations, the operator should be able to recover all costs incurred in the provision of service. Conrail states that allowing all costs in excess of 15 percent to be added to the subsequent year's subsidy does not apply when an overrun occurs in the final subsidy period.

The issue of cost overruns was first included in the regulations on January 8, 1975 (40 FR 1631) when § 1125.1 was amended by adding subsection (c). The reasoning behind this amendment was stated by the Office (40 FR 1625) as follows:

> The amended standards will place a 15 percent upward ceiling to the end-of-year adjustment, which will tend to act as an incentive to the railroad to keep costs within the estimated level. It will also provide a maximum level of payment for a given subsidy year, thus eliminating the open-end aspects of the agreement. Treating the remainder of the adjustment as a subsequent year cost will allow the railroad to recoup its legitimate reimbursement if the agreement is continued and allow the subsidizer a chance to reconsider his subsidy decision in the light of a new estimated level of payment. If the agreement is not continued, the railroad would lose the amount of the carryover but would be relieved of the duty to continue service.

Section 1125.1(c) was amended on March 28, 1975 (40 FR 14189) to include the 10 month notification provision that would insure payment to the operator if a cost overrun occurred that exceeded 15 percent.

The basis for this change was explained by the Office in the notice (40 FR 14187) as follows:

> While the Office continues to see advantages in establishing a ceiling to the subsidy payment for a given year, the arguments to the contrary have some merit. The fact that the New England Regional Commission, representing six New England States, favors modifying the rule indicates that the necessity for a fixed ceiling is not as important as the Office originally believed it to be. Accordingly, the standards will be modified to require a carryover only if the operator fails to notify the subsidizer of the fact in one of the first three quarterly Financial Status Reports required under § 1125.8(f) or if the increase results from an expense preapproved by the subsidizer. This modification will assure that the subsidizer is kept informed of the financial status of the line and will provide timely information either

to secure the additional funds or to minimize the losses. It will also provide a means to cover expenses that were not anticipated but which both parties agree are necessary to the continued operation of the line.

This provision of the Standards was included in § 1125.1(d) on March 26, 1976 (41 FR 12838) and subsequently changed to § 1125.5(b) (43 FR 1695) on January 11, 1978, when the Standards were reissued to correspond to the ICC's revised accounting system.

The Office feels that the bases for the inclusion of this provision in its original form and the subsequent amendment allowing payment if notice is given to the subsidizer are still valid. Although the regulations are silent on the point raised by Conrail, the Office's discussions in prior proceedings regarding this issue plainly point out that the operator will bear any cost overrun that exceeds 15 percent if there is no notification given the subsidizer. The fairness of this provision is that the ten month notification period should be sufficient time for the operator to recognize and notify the subsidizer of a potential overrun. This is especially true when one considers that the subsidizer only needs to be notified of the fact that an overrun will occur and no specific cost information or details are required.

H. G. HOMME, Jr.,
Secretary.

[FR Doc. 79-8092 Filed 3-15-79; 8:45 am]

[3510-22-M]

Title 50—Wildlife and Fisheries

CHAPTER VI—FISHERY CONSERVATION AND MANAGEMENT NATIONAL OCEANIC AND ATMOSPHERIC ADMINISTRATION DEPARTMENT OF COMMERCE

PART 651—ATLANTIC GROUNDFISH FISHERIES

Notice of Fishery Opening; Adjustment of Catch Limitations; Correction of Regulations

AGENCY: National Oceanic and Atmospheric Administration/Commerce.

ACTION: Notice of fishery opening and subsequent annual closure, Establishment of catch limitations, Correction of Regulation.

SUMMARY: This notice modifies the notice of February 2, 1979 (44 FR 6732) which closed several Atlantic groundfish fisheries. These fisheries are reopened with new catch limitations. These include cod and haddock in the Gulf of Maine for the 61-125 GRT vessel class and the haddock fishery in the Gulf of Maine for the 0-60 GRT vessel class. The yellowtail flounder fishery west of 69° W. longitude is reopened with reduced catch limitations until April 28, 1979, when the annual optimum yield, less expected incidental catch, is expected to be caught. This notice also corrects an error in the regulations implementing the fishery management plan for Atlantic groundfish which provided that these closures were required by the plan.

DATES: Except for the annual closure of the yellowtail flounder fishery west of 69° W. longitude which will occur to 0001 hours EST, April 28, 1979, all other actions described in this notice are effective at 0001 hours EST, March 13, 1979.

FOR FURTHER INFORMATION CONTACT:

Dr. Robert H. Hanks, Acting Regional Director, Northeast Region, National Marine Fisheries Service, Federal Building, 14 Elm Street, Gloucester, Massachusetts 01930. Telephone: (617) 281-3600.

SUPPLEMENTARY INFORMATION: On February 2, 1979, the Assistant Administrator for Fisheries (Assistant Administrator) took several actions under regulations implementing the fishery management plan (FMP) for Atlantic groundfish developed by the New England Fishery Management Council (Council) (44 FR 885). The salient principle of that FMP was to spread fishing effort and the resulting harvest of groundfish over a 12-month period. The mechanism for controlling the harvest was a system of quarterly incremental allocations which appeared in the regulations. Adjustments in the harvest levels were made in accordance with the previous quarterly harvests. If the previous quarterly allocation was exceeded, the regulations imposed additional restrictions in the next succeeding quarter. In some cases, the regulations required a temporary closure of the fishery.

The Council has explained that the quarterly allocations were merely intended to serve as guideposts. There was no intention that quarterly overrun automatically required temporary closures. Section 651.24(c) of the regulations implementing the plan, however, presently reads in relevant part, "The Assistant Administrator *shall*, by publication * * *" impose closures when quarterly quotas are reached. This notice corrects this error by changing the term "shall" to "may" to reflect the original intent of the Council.

At its February meeting, the Council asked the Assistant Administrator to rescind the closures which had just taken effect. The Council pointed out that the trip limitations should be adjusted to keep cumulative catches in line with the quarterly allocations. The Council also pointed out that while quarterly allocations may be exceeded, annual optimum yields must not be exceeded.

The Council, at a special meeting on February 16, again considered the impact of the recent extended closures in the New England groundfish fishery. At that time, as on its previous meeting, it heard considerable public testimony concerning the social and economic problems created by the closures.

It became obvious to the Council during the testimony that the yellowtail closure has a serious impact upon the small class of vessels which have no alternative species of fish at this time of year. This impact, of course, will carry over into processing and support services within the industry. It was the consensus of public testimony at two Council meetings that the yellowtail fishery should remain open at this time of year under restrictive trip limitations, and that closures should be imposed as necessary later in the year when weather and other species present viable economic alternatives to the industry.

The case for rescinding the closures in the Gulf of Maine cod and haddock fisheries is also compelling, particularly in view of the large numbers of fishermen and coastal communities involved. The Council has asked that all the fisheries which were closed on February 4 be reopened while the Council considers an appropriate amendment to the groundfish plan, which may possibly reduce the necessity for repeated closures of the fishery.

In order to rescind the closures and to increase catch limitations, Appendix B is revised to reflect the new trip limits. Cod and haddock in the Gulf of Maine for the 61-125 GRT vessel class is reopened. Haddock in the Gulf of Maine for the 0-60 GRT vessel class is also reopened. Both vessel classes will have weekly limitations of 2,500 pounds each of cod and haddock. Yellowtail flounder vessels fishing west of 69° W. longitude are restricted to 2,000 pounds per trip or per week, whichever is longer. No yellowtail flounder vessel may land more than 5,000 pounds of yellowtail flounder regardless of the location of the catch. There are no overruns allowed in any groundfish fishery. Appendix B, revised to show the catch limitations in effect as of March 13 is set out below.

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

Signed at Washington, D.C., this the 12th day of March, 1979.

TERRY L. LEITZELL,
Assistant Administrator for Fisheries, National Marine Fisheries Service.

The first sentence of § 651.24(c) is amended in part to read as follows:

§ 651.24 [Amended]

* * * * *

(c) Notice of Closure. The Assistant Administrator may, by publication of

* * *

Appendix B to Part 651 is revised to read as set forth below:

APPENDIX B—CATCH LIMITATIONS (REVISED)

[Effective March 13, 1979]

	Gulf of Maine		Georges Bank and South vessel class	
	Limits	Overruns	Limits	Overruns
Cod (pounds/week)				
0-60 GRT	2,500	0	4,900	0
61-125 GRT	2,500	0	9,800	0
Over 125 GRT	Closed Jan. 1		14,000	0
Fixed gear	5,000	0	13,000	0
Haddock (pounds/week)				
0-60 GRT	2,500	0	3,500	0
61-125 GRT	2,500	0	7,000	0
Over 125 GRT	Closed Jan. 1		10,000	0
Fixed gear	8,000	0	8,000	0

Yellowtail Flounder [1]	West of 69°	East of 69° West
0-60 GRT	2,000	5,000
61-125 GRT	2,000	5,000
Over 125 GRT	2,000	5,000

[1] Pounds per week or trip, whichever time period is longer. A vessel may land no more than 5,000 pounds, even if it fished on both sides of the 69° W. line. No overruns are allowed.

[FR Doc. 79-7924 Filed 3-13-79; 10:12 am]

[3510-22-M]

PART 653—ATLANTIC HERRING

Closing Fishery for Atlantic Herring in the Gulf of Maine

AGENCY: National Oceanic and Atmospheric Administration/Commerce.

ACTION: Notice closing the fishery for Atlantic herring in the Gulf of Maine.

SUMMARY: This notice closes the fishery for Atlantic herring in the Gulf of Maine, effective March 15, 1979. The fishery is being closed because it has been determined that the winter/spring quota has already been caught. Allowable incidental catches of Atlantic herring for fishermen fishing for mackerel are set forth in the supplementary information.

EFFECTIVE DATE: This action is effective as of 12:01 a.m. March 15, 1979.

FOR FURTHER INFORMATION CONTACT:

Dr. Robert T. Hanks, Acting Regional Director, Northeast Region, National Marine Fisheries Service, Federal Building, 14 Elm Street, Gloucester, Massachusetts 01930; Telephone (617) 281-3600.

SUPPLEMENTARY INFORMATION: Emergency regulations governing fishing for Atlantic herring were published on December 28, 1978 (43 FR 60474), and subsequently extended. These regulations implement the fishery management plan for Atlantic herring prepared by the New England Fishery Management Council pursuant to the Fishery Conservation and Management Act of 1976, 16 U.S.C. 1801 *et seq.* The regulations establish seasonal catch quotas by area. When it is projected that a quota, less an anticipated amount taken incidentally, will be caught, the Assistant Administrator issues a notice closing that area to fishing for Atlantic herring.

Statistics show that 3,594 metric tons (mt) of three-year-old and older herring were taken from the Gulf of Maine by February 15, 1979. The winter/spring quota (December 1, 1978–June 30, 1979 for this area is 4,000 mt. The Assistant Administrator has estimated that the quota was taken by March 7, 1979.

Pursuant to 50 CFR 653.22(a), the Assistant Administrator prohibits fishing for Atlantic herring in the Gulf of Maine, effective March 15, 1979. Under the provision of 50 CFR 653.22(c)(2) vessels fishing for mackerel in the Gulf of Maine may have an incidental catch of herring which does not exceed 20 percent of the total catch on board. 50 CFR 653.22(c)(1) allows vessels fishing in the Gulf of Maine for other species to have an incidental catch of herring which is not greater than 5 percent of the total fish on board. The catch on board for vessels fishing for mackerel must contain not less than 75 percent by weight of mackerel of all fish on board.

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

Signed at Washington, D.C. this 12th day of March, 1979.

TERRY L. LEITZELL,
Assistant Administrator for Fisheries, National Marine Fisheries Service.

[FR Doc. 79-7925 Filed 3-13-79; 10:12 am]

proposed rules

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.

[3410-02-M]

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[7 CFR Part 1068]

MILK IN THE UPPER MIDWEST MARKETING AREA

Proposed Suspension of Certain Provisions of the Order

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed suspension of rule.

SUMMARY: This notice invites written comments on a proposal to suspend a requirement under the Upper Midwest marketing order that handlers make a partial payment for milk received from producers by the 25th day of the month. The operator of a pool distributing plant indicated that producers supplying the plant want such payment to be made about 8 days later so that their partial payments and final payments for milk will be spaced about 15 days apart. The proposed suspension would be for May 1979 through April 1980.

DATE: Comments are due April 2, 1979.

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

FOR FURTHER INFORMATION CONTACT:

Martin J. Dunn, Marketing Specialist, Dairy Division, Agricultural Marketing Service, U.S. Department of Agriculture, Washington, D.C. 20250, 202-447-7311.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, pursuant to the provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C 601 *et seq.*), the suspension of paragraph (a)(4) of § 1068.73 of the order regulating the handling of milk in the Upper Midwest marketing area is being considered for the period May 1979 through April 1980.

All persons who want to send written comments about the proposed suspension should send four copies to the Hearing Clerk, United States Department of Agriculture, Washington, D.C. 20250, on or before April 2, 1979.

The documents that are sent will be made available for public inspection at the Office of the Hearing Clerk during regular business hours (7 CFR 1.27(b)).

Paragraph (a) of § 1068.73 requires handlers to make a partial payment to cooperative associations and nonmember producers on or before the 25th day of the month for milk delivered during the first 15 days of the month. Suspension of paragraph (a)(4) would remove this requirement only with respect to producers for whom a cooperative is not collecting payments; the requirement would remain in effect for milk bought from a cooperative association.

Paragraph (a)(4) of § 1068.73 has been suspended since November 1976 (41 FR 51389, 42 FR 22360, 42 FR 59747, 43 FR 14025 and 43 FR 19341). A handler requested that the suspension be extended for an additional period of twelve months pending a hearing to consider an order amendment requiring a partial payment on or before the 3rd day of the month, 15 days prior to the final payment date, which is the 18th day of the month. This would enable handlers to accommodate their producers who request that their payments be spaced 15 days apart.

Signed at Washington, D.C., on March 9, 1979.

WILLIAM T. MANLEY,
Deputy Administrator,
Marketing Program Operations.

[FR Doc. 79-8082 Filed 3-15-79; 8:45 am]

[3410-02-M]

[7 CFR Part 1133]

MILK IN THE INLAND EMPIRE MARKETING AREA

Termination of Rulemaking Proceeding

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Termination of rulemaking proceeding.

SUMMARY: This action terminates a rulemaking proceeding on a proposal by a dairy farmer cooperative to relax the limit on the amount of milk that handlers and cooperative associations may "divert" off the fluid market to manufacturing outlets. A public hearing on the proposal was held July 28, 1978. Recently, the proponent cooperative association informed the Department that since the hearing it has been making certain changes in the marketing of its members' milk. Because of these changes, the cooperative believes that there is no longer a need for relaxing the diversion limits as proposed and supported at the hearing. In view of this situation, there is no basis for continuing the proceeding.

FOR FURTHER INFORMATION CONTACT:

Maurice M. Martin, Marketing Specialist, Dairy Division, Agricultural Marketing Service, U.S. Department of Agriculture, Washington, D.C. 20250, (202) 447-7183.

SUPPLEMENTARY INFORMATION: Prior documents in this proceeding:

Notice of hearing—issued July 10, 1978, published July 13, 1978 (43 FR 30066).

Order suspending certain provisions—issued September 1, 1978, published September 8, 1978 (43 FR 39955).

Order suspending certain provisions—issued December 7, 1978, published December 12, 1978 (43 FR 58079).

Notice of proposed termination—issued February 5, 1979, published February 12, 1979 (44 FR 8897).

This order, which is issued pursuant to the provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601 *et seq.*), terminates the proceeding as set forth in a notice of hearing on a proposal to amend certain provisions of the order regulating the handling of milk in the Inland Empire marketing area. The aforesaid notice of hearing was issued July 10, 1978 (43 FR 30066) and the hearing was held on July 28, 1978.

A notice proposing termination of the proceeding was issued February 5, 1979, and published in the FEDERAL REGISTER February 12, 1979 (44 FR 8897). Interested persons were asked to comment on the proposed action.

STATEMENT OF CONSIDERATION

This action terminates a rulemaking proceeding, which began July 10, 1978, on a proposal that would have increased the limit on the amount of producer milk that a cooperative association or other handlers may divert from pool plants to nonpool plants during each month. The hearing, which was held on July 28, 1978, was requested by a cooperative association that supplies the market with a sub-

stantial part of its fluid needs and handles much of the market's reserve milk production.

The proponent cooperative, Northwest Dairymen's Association, through its agent, Consolidated Dairy Products Company, recently notified the Department of certain changes it is making in the marketing of its members' milk under the order. Because of these changes, the cooperative believes that there is no longer a need for relaxing the diversion limits as proposed and supported at the hearing.

On the basis of available information, it is clear that marketing conditions have changed significantly since the hearing, thereby making the record evidence out of date. Hence, there is no basis for continuing the proceeding. Moreover, interested parties were asked to comment on the proposed termination. No views were received.

Accordingly, the proceeding initiated by the notice of hearing issued July 10, 1978, is hereby terminated.

Signed at Washington, D.C., on March 9, 1979.

WILLIAM T. MANLEY,
Deputy Administrator,
Marketing Program Operations.

[FR Doc. 79-8081 Filed 3-15-79; 8:45 am]

[7510-01-M]

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[14 CFR Part 1214]

SPACE TRANSPORTATION SYSTEM PERSONNEL RELIABILITY PROGRAM

Proposed Criteria and Procedures

AGENCY: National Aeronautics and Space Administration.

ACTION: Proposed regulation.

SUMMARY: The National Aeronautics and Space Administration (NASA) is proposing a program to establish criteria and procedures for assuring the highest standards of reliability in personnel assigned to mission-critical positions in connection with the Space Transportation System. This proposed regulation is part of an overall program to assure the protection of the Space Transportation System by providing special physical security measures, safety precautions, and operational standards for mission-critical positions.

DATE: Comments must be received not later than April 16, 1979.

ADDRESS: Comments and requests for additional information should be sent to: Haggai Cohen, Mail Code MR-4, NASA Headquarters, Washington, D.C. 20546.

FOR FURTHER INFORMATION CONTACT:

Haggai Cohen, 202-755-3155.

SUPPLEMENTARY INFORMATION: The Space Transportation System is a national resource providing a capability to support a wide range of scientific, applications, commercial, and international uses.

14 CFR Part 1214 is amended by adding a new Subpart 1214.5 reading as follows:

Subpart 1214.5—Space Transportation System Personnel Reliability Program

Sec.
1214.500 Scope.
1214.501 Applicability.
1214.502 Definitions.
1214.503 Policy.
1214.504 Screening requirements.
1214.505 Program Implementation.
1214.506 Identification of positions.

AUTHORITY: The National Aeronautics and Space Act of 1958, as amended, 72 Stat. 426, 42 U.S.C. 2451 *et seq.*

Subpart 1214.5—Space Transportation System Personnel Reliability Program

§ 1214.500 Scope.

This Subpart 1214.5 establishes a program designed to ensure that personnel assigned to mission-critical positions in connection with the Space Transportation System meet established screening requirements. This program supplements the DOD and NASA program requirements for security clearances.

§ 1214.501 Applicability.

(a) This regulation applies to NASA Headquarters and field installations whose personnel are engaged in activities that are critical to the success of Space Transportation missions.

(b) The provisions of the regulation apply to all personnel assigned to mission-critical positions in connection with the Space Transportation System.

(c) This regulation does *not* include flight crew or payload specialists when covered by other NASA Management Instructions which have equivalent screening requirements.

§ 1214.502 Definitions.

(a) *Mission-Critical Position.* Any position requiring physical access to the vehicle, or command capability through the Launch Processing System or the Mission Control Center as well as any other positions wherein the concerned NASA installation determines that faulty, negligent or malicious actions could result in a program contingency.

(b) *Two-Person Concept.* The practice of requiring the presence of two authorized persons, each capable of detecting incorrect or unauthorized procedures, during the performance of tasks or operations vital to the Space Shuttle.

(c) *Medical Authority.* A NASA civil service or contract physician responsible for reviewing medical records, providing results of medical evaluations and interpreting evaluations as they relate to reliable performance of mission-critical duties.

(d) *Program Contingency.* Any program-related failure, accident or incident that significantly delays or jeopardize the program or a mission, prevents accomplishment of a major mission objective or terminates a mission prematurely.

§ 1214.503 Policy.

(a) The Space Transportation System is a national resource providing a capability to support a wide range of scientific, applications, commercial, defense and international uses. Since it will contribute significantly to ensuring a scientifically, technologically and economically strong and secure nation, the interest of the national security, as well as program reliability, operational and safety considerations require that extraordinary measures be taken to provide for the protection of the system.

(b) Measures to ensure this protection are:

(1) Special physical security provisions,

(2) Two-person concept of operations in connection with selected, most vital pre-launch and post-launch tasks, and

(3) Procedures to ensure that personnel assigned to perform mission-critical duties meet specified screening requirements.

§ 1214.504 Screening Requirements.

(a) Only those persons shall be assigned to, employed in, or retained in mission-critical positions who have been determined to be competent and reliable in the performance of their assigned duties pursuant to the screening requirements of this section, and whose assignment, employment or retention is clearly consistent with optimum Space Transportation System safety and security.

(b) Determinations of acceptability for assignments to mission-critical positions shall be made on the basis of the following criteria:

(1) Ability to perform mission-critical duties as evidenced by performance during training, simulations and on the job.

(2) An initial medical evaluation of the individual and as necessary thereafter, but not less than every two years, to ensure health is adequate for reliable performance of mission-critical duties. The medical evaluation by competent medical authority may be made by: (i) Medical history and rec-

ords which are sufficiently comprehensive and current for the purpose; or (ii) an appropriate medical examination.

(3) Verification of the existence of a current personnel security clearance at the level commensurate with the classification of the information required in the position.

(4) A review of the results of a National Agency Check (including a name check of the FBI fingerprint records) completed within the past five years. When the National Agency Check indicates that a more extensive investigation has been completed, the results of that investigation will also be reviewed.

(5) Local agency checks as appropriate.

§ 1214.505 Program Implementation.

(a) Each NASA installation to which this regulation is applicable will identify positions occupied by personnel assigned to mission-critical duties. The number of positions so identified must be the absolute minimum necessary to meet operational requirements. The unnecessary designation of such positions not only increases the costs required to administer the program, but also reduces its total effectiveness.

(b) Each NASA installation to which this regulation is applicable will establish:

(1) A *certification system* acceptable to the Associate Administrator for Space Transportation Systems to ensure that the screening requirements of this instruction are met for designated mission-critical positions. The certification system is to provide for the issuance of a NASA identification for each authorized individual who passes the prescribed requirements; and

(2) A *management review process* to validate the objectivity of individual certification determinations and ensure that reassignments or other personnel actions taken pursuant to this regulation are duly processed under the appropriate personnel policies and procedures applicable to each individual; and

(3) Appropriate procedures for review of certification determinations which shall be provided to affected individuals.

(c) The launch centers, in conjunction with other involved NASA centers, contractors or agencies, will identify the vital pre-launch and post-launch tasks where the two-person concept of operations should be used.

(d) The full intent of the provisions of this regulation will be incorporated in any contract under which contractor employees will be assigned to mission-critical positions. An appropriate procurement provision is being separately prepared for this area.

(e) NASA Headquarters (OSTS) will periodically review the program to assure reasonable uniformity in implementation procedures and the identification of mission-critical positions.

ROBERT A. FROSCH,
Administrator.

[FR Doc. 79-8024 Filed 3-15-79; 8:45 am]

[1505-01-M]

FEDERAL TRADE COMMISSION

[16 CFR Part 13]

[Docket C-2523]

GAC CORP., ET AL.

Show Cause Order With Analysis To Aid Public Comment

Correction

In FR Doc. 79-6096 appearing on page 11560 in the issue for Thursday, March 1, 1979, make the following corrections:

(1) In the first column of page 11563, third line from the top, change ". . . remedial work exceed . . ." to "remedial work will exceed . . .".

(2) In the middle column of page 11565, change the last line to read, ". . . modify the 1974 Commission Order, and it is not intended to constitute an official interpretation of the . . .".

[4310-70-M]

DEPARTMENT OF THE INTERIOR

National Park Service

[36 CFR Part 7]

FIRE ISLAND NATIONAL SEASHORE

Operation of Motor Vehicles

AGENCY: National Park Service, Interior.

ACTION: Proposed rule.

SUMMARY: This amendment corrects a deficiency in the language contained in the special regulations adopted on January 1, 1978 (42 FR 62482) pertaining to off-road operation of motor vehicles at Fire Island National Seashore. The proposal designates two check points for vehicles entering the Seashore at Kismet and Smith Point. It eliminates a trip to the mainland as a requirement for completing a round trip over seashore beaches.

DATES: Written comments, suggestions or objections will be accepted until April 16, 1979.

ADDRESS: Written comments should be directed to: Superintendent, Fire Island National Seashore, 120 Laurel Street, Patchogue, New York 11772.

FOR FURTHER INFORMATION CONTACT:

Richard W. Marks, Superintendent, Fire Island National Seashore, Telephone: (516) 289-4810.

SUPPLEMENTARY INFORMATION: On January 1, 1978, the National Park Service adopted final rules pertaining to the control of off-road vehicle use at Fire Island National Seashore. The regulations were adopted to provide a greater degree of control over an activity which had increased greatly in recent years. The intent of this particular section was to limit the use of off-road vehicles within the boundaries of Fire Island National Seashore, yet provide access for those residents and users of the seashore on days when no ferry or alternative transportation was available. It was unenforceable because it required Service personnel to assume that ORV travel to and from the Seashore included a trip to the mainland.

On February 19, 1978, a resident of Ocean Beach, New York, within the boundaries of Fire Island National Seashore was charged with violation of Title 36, CFR 7.20 (a)(10)(ii) which states:

> On any day on which travel by motor vehicle is authorized due to a lack of alternative transportation, travel shall be limited to not more than one round trip per vehicle per day between the mainland and the island, and may be performed at any time except the following periods: * * *.

In subsequent proceedings, on April 14, 1978, in the U.S. Magistrate Court at Patchogue, New York, the charges against the defendant were dismissed. The court's decision included the following passage:

> The facts (of the case) are not in dispute. The defendant was observed operating a vehicle to which a valid permit was issued, entering Seashore lands at the westerly boundary thereof on Fire Island at a point known as the Kismet checkpoint. The park ranger on duty at the post testified that records at the Kismet checkpoint indicated the vehicle driven by the defendant had left Fire Island Seashore lands headed westbound through the checkpoint on three occasions during the same day and that it was returning for the third time to Seashore lands. In other words, it was completing a third trip that day out of and was returning to Seashore lands at the Kismet checkpoint when the violation was charged. The park ranger stated that he did not observe whether or not the defendant's vehicle had crossed the bridges and the Robert Moses Causeway to the mainland of Long Island at any time during that day. The defendant testified, and the court finds, that neither he nor the vehicle in question had made any round trip from Fire Island to the mainland of Long Island on the day in question; defendant stated that he had driven the vehicle only to parking lot number 3 at Robert

Moses State Park, which is on Fire Island but not within lands of the Fire Island National Seashore.

The court also observed:

that Judge Dooling, in a memorandum decision and order in *George Biderman et al.*, v. *Secretary of Interior et al.*, 72 C. 1060, dated July 19, 1974, recognized that as a practical matter the authorities charged with the duty of managing and protecting the Fire Island National Seashore can control the entry of vehicles to or from Seashore lands only at two checkpoints located at the easterly and westerly boundaries of the park. He stated "Motor Vehicle access can be controlled only at the points at which the motor vehicles pass from State Park land to Federal land after crossing the bridges from Long Island.

The U.S. Magistrate further stated:

There may also be severe practical problems involved in enforcing the one round trip per vehicle per day regulation where the checkpoint at the place of entry to and exit from Seashore lands is a considerable distance from the bridges leading to the mainland of Long Island so that it is not possible to observe from the checkpoint whether or not a vehicle in fact travels to the mainland, but assumptions cannot be used in the place of evidence in a criminal proceeding.

Since it is not practical to observe a vehicle's destination once it has left the boundaries of Fire Island National Seashore, or correct to assume that by leaving the Seashore one continues to the mainland, the National Park Service proposes to correct the error contained in the existing regulation. The proposed amendment designates two checkpoints to serve as control stations for ORV activity. These are known as Kismet (west) and Smith Point (east) and are the current vehicular access points to Fire Island.

(Sec. 3 of the Act of August 25, 1916 (39 Stat. 535, as amended, (16 U.S.C. 3); 245 DM 1 (42 FR 12931); and National Park Service Order 77 (38 FR 7478, as amended))

DRAFTING INFORMATION

The following persons participated in the writing of this regulation: William Schenk, Fire Island National Seashore; and James W. Carrico, National Park Service, Washington, D.C.

IMPACT ANALYSIS

The National Park Service has determined that this document does not contain a major proposal requiring preparation of a regulatory analysis under Executive Order 12044; nor is it a major Federal Action significantly affecting the quality of the human environment, which would require preparation of an Environmental Impact Statement.

Dated: March 8, 1979.

DANIEL J. TOBIN, Jr.,
Associate Director, Management and Operations, National Park Service.

§ 7.20 [Amended]

In consideration of the foregoing, it is proposed to amend Part 7 of Title 36 of the Code of Federal Regulations by the revision of § 7.20(a)(10)(ii) to read as follows:

(a) * * *

(10) * * *

(ii) On any day on which travel by motor vehicle is authorized due to a lack of alternative transportation, travel shall be limited to not more than one round trip per calendar day through or observed at either the Smith Point of the Kismet checkpoint to or from any other location within the authorized boundaries of the Seashore and may be performed at any time except the following periods:

* * * * *

[FR Doc. 79-8086 Filed 3-15-79; 8:45 am]

[3510-16-M]

DEPARTMENT OF COMMERCE

Patent and Trademark Office

[37 CFR Part 2]

COMPULSORY COUNTERCLAIMS IN TRADEMARK OPPOSITION AND CANCELLATION PROCEEDINGS

Proposed Rulemaking

AGENCY: Patent and Trademark Office, Commerce.

ACTION: Proposed rulemaking.

SUMMARY: The Patent and Trademark Office proposes to amend the rules of practice to make it compulsory to file a counterclaim for the cancellation of the registration pleaded by an opposer in an opposition proceeding or a petitioner in a cancellation proceeding when the grounds for such counterclaim exist at the time the answer is filed. Under present rules, a counterclaim for cancellation is not a compulsory counterclaim. By making counterclaim compulsory all potential claims between the parties involving the marks actually or potentially in issue are settled in one proceeding.

DATES: Comments must be received on or before May 15, 1979.

ADDRESSES: Comments may be addressed to the Commissioner of Patents and Trademarks, Washington, D.C. 20231. All comments received will be available for public inspection in Room 11 E 10, Crystal Plaza, Building 3, 2021 Jefferson Davis Highway, Arlington, Virginia.

FOR FURTHER INFORMATION CONTACT:

David J. Kera, Patent and Trademark Office (703-557-3551).

SUPPLEMENTARY INFORMATION: These amendments provide that if, in a trademark opposition or cancellation proceeding, the defendant (applicant in an opposition proceeding or respondent in a cancellation proceeding) has grounds for petitioning to cancel any of the registration of which ownership is pleaded by the plaintiff (opposer in an opposition proceeding or petitioner in a cancellation proceeding), the petition to cancel the plaintiff's registration or registrations shall be a compulsory counterclaim. The effect of the amendment of the rules will be that, if the counterclaim is not filed as provided by the rules, the defendant will thereafter be barred from petitioning to cancel the registration or registrations pleaded by the plaintiff in the prior proceeding on any ground that existed at the time when the answer was filed.

Since the decision in *Outdoor Sports Industries, Inc.* v. *Joseph & Feiss Company*, 177 USPQ 535 (TTAB, 1973), petition denied, 177 USPQ 533 (Comr., 1973), the Trademark Trial and Appeal Board consistently held that an attack upon the validity of a plaintiff's registration was a compulsory counterclaim. See: *Textron, Inc.* v. *The Gillette Company*, 180 USPQ 152 (TTAB, 1973); *Kajita* v. *Walter Kidde & Company*, 185 USPQ 436 (TTAB, 1975); *Delta Tire Corporation* v. *Sports Car Club of America, Incorporated*, 185 USPQ 443 (TTAB, 1975); *Scovill Manufacturing Company* v. *Stocko Metallwarenfabriken Henkels und Sohn KG*, 188 USPQ 24 (TTAB, 1975); *Endo Laboratories, Inc.* v. *Fredericks*, 197 USPQ 560 (TTAB, 1977). Such counterclaim must be a petition for cancellation of the plaintiff's registration. See §§ 2.106(b), 2.114(b).

However, the Court of Customs and Patent Appeals, in *Thuron Industries, Inc.* v. *The Conard-Pyle Company*, 198 USPQ 403 (1978), held that, under the present rules in 37 CFR Part 2 and Rule 13, FRCP, a counterclaim for cancellation of a plaintiff's registration is not a compulsory counterclaim. The court reasoned that the present rule, 37 CFR 2.106(b), uses the permissive word "may" but not a mandatory word, such as "shall" or "must," so that the present rule makes a counterclaim permissive but not compulsory. The court also indicated that Rule 13(a), FRCP, does not support the position that a counterclaim for cancellation of a registration pleaded by a plaintiff is compulsory because the grounds for cancellation do not arise out of the transaction or occurrence

that is the subject matter of the opposing party's claim.

Finally, the court expressed concern that a practice of making counterclaims compulsory might preclude a party, in certain circumstances, from filing a concurrent use application.

It was the Board's experience in the five years after *Outdoor Sports Industries, Inc.* v. *Joseph & Feiss Company, supra,* that the compulsory counterclaim practice in opposition and cancellation proceedings had a salutary effect in avoiding piecemeal litigation of a multiplicity of actions and counteractions. The question of the registrability of the defendant's mark is intimately related to the question whether the plaintiff's mark should remain on the register or should be cancelled. Whether considered as a matter of damage to the plaintiff or the proscription of section 2 (d) of the act, a registration pleaded by the plaintiff is a premise upon which the complaint is based and the continued validity of a pleaded registration, when it is or may be challenged, must be decided as a prerequisite to a final determination of the registrability of the defendant's mark. All potential claims between the parties involving the marks actually or potentially in issue are settled in one proceeding. Discovery and trial on all of the issues are expedited and duplication of effort is avoided. Briefs and arguments on the issues are presented once and not several times. The parties are saved time and expense and the Board conserves its resources of personnel and time. The determination whether the plaintiff is entitled to retain its registration can be made before the issue of the registrability of the defendant's mark is decided. See: *King Candy Company* v. *Eunice King's Kitchen, Inc.*, 182 USPQ 108 (CCPA, 1974) [registered mark of even a subsequent-user opposer must be considered in an opposition]; cf. *Morehouse Manufacturing Corporation* v. *J. Strickland and Company,* 160 USPQ 715 (CCPA, 1969).

It has never been, and is not now, the Board's position that a concurrent use application is a compulsory counterclaim or even, properly speaking, a counterclaim of any kind to an opposition or petition for cancellation. This proposed amendment, if adopted, will not affect in any manner the practice of permitting the parties to an opposition proceeding, if they so agree, to have their respective rights adjudicated, when the statutory requirements can be fulfilled, in a concurrent use proceeding. See: Tips From the TTAB, The Concurrent User as Opposer, Vol. 67 Trademark Reporter, No. 6, page 654 (November-December, 1977).

In accordance with § 2.116(a), this proposed amendment, if adopted, will govern compulsory counterclaims in opposition and cancellation proceedings in lieu of Rule 13, FRCP.

In the usual situation contemplated by Rule 13, FRCP, both parties are presumably aware, when the complaint is filed, of the basic facts and circumstances surrounding the complaint. The defendant, as a result of this knowledge, is able to plead a counterclaim in the answer. However, in an opposition or cancellation proceeding before the Board, the applicant or respondent may know little or nothing about the registration upon which the opposer or petitioner is basing a claim of damage. The facts which may be the basis for a counterclaim to cancel the registration pleaded by an opposer or petitioner may not emerge until after the answer is due. To accommodate the special conditions of a proceeding before the Board as compared to litigation in a court, a rule on counterclaims is being proposed.

Notice is hereby given that pursuant to the authority contained in Section 41 of the Act of July 5, 1946, as amended (60 Stat. 427, 88 Stat. 1949, 15 U.S.C. 1123, as amended) and section 6 of the Act of July 19, 1952, as amended (85 Stat. 364, 88 Stat. 1949, 35 U.S.C. 6, as amended), the Patent and Trademark Office proposes to amend Title 37 of the Code of Federal Regulations by amending §§ 2.106 and 2.114.

It is proposed to revise the sections as follows (additions are indicated by arrows; deletions are bracketed):

1. By revising § 2.106(b) to read as follows:

§ 2.106 Answer.

* * * * *

(b) (1) An answer may contain any defense, [and it may also contain a request for affirmative relief by way of cancellation of a registration pleaded in the opposition; but no defense attacking the validity of such registration may be otherwise raised in the proceeding. Such request for affirmative relief must be verified or include a declaration in accordance with § 2.20 and must be accompanied by the fee as required by section 14 of the act. A reply to such request for affirmative relief is required within twenty days after service thereof; but no other reply to the answer need be filed.] including the affirmative defenses of unclean hands, laches, estoppel, acquiescence, fraud, mistake, or prior judgement. When pleading special matters, the Federal Rules of Civil Procedure shall be followed. A reply to an affirmative defense need not be filed. When a defense attacks the validity of a registration pleaded in the opposition, paragraph (b)(2) of this section shall govern.

(b)(2)(i) A defense attacking the validity of any one or more of the registrations pleaded in the opposition shall be a compulsory counterclaim if grounds for such counterclaim exist at the time when the answer is filed. If grounds for a counterclaim are known to the applicant when the answer to the opposition is filed, the counterclaim shall be pleaded with or as part of the answer. If grounds for a counterclaim are learned during the course of the opposition proceeding,the counterclaim shall be pleaded promptly after the grounds therefor are learned. A counterclaim need not be filed if it is the subject of another proceeding.

(ii) An attack on the validity of a registration pleaded by an opposer will not be heard unless a counterclaim or separate proceeding is filed to seek the cancellation of such registration.

(iii) The provisions of §§ 2.111 through 2.115, inclusive, shall be applicable to counterclaims. A time, not less than thirty days, will be designated within which an answer to the counterclaim must be filed.

(iv) The times for pleading, discovery, testimony, briefs or oral argument will be reset or extended when necessary, upon motion by a party, to enable a party fully to present or meet a counterclaim or separate petition for cancellation of a registration.

* * * * *

2. By revising § 2.114(b) to read as follows:

§ 2.114 Answer

* * * * *

(b) (1) An answer may contain any defense, [and it may also contain a request for affirmative relief by way of cancellation of a registration pleaded in the petition; but no defense attacking the validity of such registration may be otherwise raised in the proceeding. Such request for affirmative relief must be verified, or include a declaration in accordance with § 2.20, and must be accompanied by the fee as required by section 14 of the act. A reply to such request for affirmative relief is required within twenty days after service thereof but no other reply to the answer need be filed.] including the affirmative defenses of unclean hands, laches, estoppel, acquiescence, fraud, mistake, or prior judgment. When pleading special matters, the Federal Rules of Civil Procedure shall be followed. A reply to an affirmative defense need not be filed. When a defense attacks the validity of a registration pleaded in the petition, paragraph (b)(2) of this section shall govern.

(b)(2)(i) A defense attacking the validity of any one or more of the regis-

trations pleaded in the petition shall be a compulsory counterclaim if grounds for such counterclaim exist at the time when the answer is filed. If grounds for a counterclaim are known to respondent when the answer to the petition is filed, the counterclaim shall be pleaded with or as part of the answer. If grounds for a counterclaim are learned during the course of the cancellation proceeding, the counterclaim shall be pleaded promptly after the grounds therefor are learned. A counterclaim need not be filed if it is the subject of another proceeding.

(ii) An attack on the validity of a registration pleaded by a petitioner for cancellation will not be heard unless a counterclaim or separate proceeding is filed to seek the cancellation of such registration.

(iii) The provisions of §§ 2.111 through 2.115, inclusive, shall be applicable to counterclaims. A time, not less than thirty days, will be designated within which an answer to the counterclaim must be filed.

(iv) The times for pleading, discovery, testimony, briefs, or oral argument will be reset or extended when necessary, upon motion by a party, to enable a party fully to present or meet a counterclaim or separate petition for cancellation of a registration.

* * * * *

Dated: February 28, 1979.

DONALD W. BANNER,
Commissioner of Patents and Trademarks.

[FR Doc. 79-8026 Filed 3-15-79; 8:45 am]

[6560-01-M]

ENVIRONMENTAL PROTECTION AGENCY

[40 CFR PART 52]

[FRL 1077-6]

STATE IMPLEMENTATION PLANS

Receipt—Wyoming

AGENCY: Environmental Protection Agency.

ACTION: Notice of Receipt of Wyoming SIP.

SUMMARY: The purpose of this notice is to announce the receipt of a State Implementation Plan (SIP) revision for Wyoming and to invite public comment. On January 26, 1979, pursuant to the requirements of Part D of the Clean Air Act as amended in 1977, the State of Wyoming submitted to EPA a revision to its SIP for the trona plant area of southwest Wyoming, which was designated as nonattainment for total suspended particulates (TSP). As required by the Act, the purpose of this revision is to implement new measures for controlling the emissions of particulates in the nonattainment area and to demonstrate that these measures will provide for attainment of the national ambient air quality standards for TSP as expeditiously as practicable, but no later than December 31, 1982. Failure to have an approved SIP which demonstrates attainment could result in certain growth and economic limitations.

ADDRESSES: Copies of the SIP revision are available at the following addresses for inspection:

Environmental Protection Agency, Region VIII, Regional Library, 1860 Lincoln Street, Denver, Colorado 80295.

Environmental Protection Agency, Public Information Reference Unit, 401 M Street, S.W., Washington, D.C. 20460.

Wyoming Department of Environmental Quality, Hathaway Office Building, Cheyenne, Wyoming 82001.

Written comments should be sent to:

Mr. Robert R. DeSpain, Chief, Air Programs Branch, Region VIII, Environmental Protection Agency, 1860 Lincoln Street, Denver, Colorado 80295.

FOR FURTHER INFORMATION CONTACT:

Mr. Robert R. DeSpain, Chief, Air Programs Branch, Region VIII, Environmental Protection Agency, 1860 Lincoln Street, Denver, Colorado 80295.

SUPPLEMENTARY INFORMATION: On March 3, 1978 (43 FR 8962), and on September 11, 1978 (43 FR 40412), pursuant to the requirements of Section 107 of the Clean Air Act, as amended in 1977, EPA designated areas in each state as nonattainment with respect to the criteria air pollutants. In Wyoming, a 24 square mile area referred to as the trona plant area was designated nonattainment with respect to total suspended particulates.

Additionally, the Part D of the Amendments required each state to revise its SIP to meet specific requirements in the areas designated as nonattainment. These SIP revisions were due on January 1, 1979, and must demonstrate attainment of the national ambient air quality standards, as expeditiously as practicable, but no later than December 31, 1982, or in limited instances for carbon monoxide and photochemical oxidants, no later than December 31, 1987.

On January 26, 1979, EPA received the revised SIP for the State of Wyoming and is currently reviewing that SIP with respect to the requirements of the Clean Air Act. At the completion of that review, a notice will be published in the FEDERAL REGISTER proposing approval or disapproval of the revised SIP.

Interested persons are invited to review the revised SIP at one of the locations listed above and comment on its approvability. The proposed notice referred to above will announce the last date which comments can be received. This public comment period may end less than sixty days after EPA's proposal of approval or disapproval.

Dated: February 28, 1979.

ALAN MERSON,
Regional Administrator.

[FR Doc. 79-8088 Filed 3-15-79; 8:45 am]

[3125-01-M]

COUNCIL ON ENVIRONMENTAL QUALITY

[40 CFR Part 1517]

PUBLIC MEETING PROCEDURES

Proposed Rule

AGENCY: Council on Environmental Quality.

ACTION: Proposed Amendments to Procedures.

SUMMARY: These proposed amendments clarify and supplement the procedures followed by the Council in complying with the Government in Sunshine Act. The amendments reflect the Council's intention ot conduct, open to public observation, biweekly meetings involving Council discussions of agency business including, where appropriate, matters outside the scope of these procedures. The amendments reflect the intent of the Council to conduct its official collegial business in accordance with the requirements of the Act. They also clarify that actions by the Council Chairman, acting as Director of the Office of the Environmental Quality, and Council actions involving advice to the President are outside the scope of the procedures.

DATES: All comments received by April 16, 1979 will be considered by the Council before final action is taken on the proposed amendments.

ADDRESS: Written comments concerning these proposed amendments are invited. Comments should be submitted to: Nicholas C. Yost, General Counsel, Council on Environmental Quality, 722 Jackson Place, N.W., Washington, D.C. 20006.

FOR FURTHER INFORMATION CONTACT:

Foster Knight, Counsel, Council on Environmental Quality, 722 Jackson Place, N.W., Washington, D.C. 2006, telephone (202)395-4616.

SUPPLEMENTARY INFORMATION: On April 22, 1977 the Council pub-

lished its final procedures implementing the Government in Sunshine Act. These procedures track the statutory language of the Government in Sunshine Act without explaining how the general statutory provisions apply to the Council's almost unique situation and role as a collegial agency within the Executive Office of the President. Since the adoption of its implementing procedures, the Council has received inquiries concerning its compliance with the Act, indicating that there exists uncertainty about public access to Council activities. In addition, the Council's operations have been modified by Reorganization Plan No. 1 (July 15, 1977), in which the Council's role as adviser to the President has been strengthened and certain operational functions transferred to the Environmental Protection Agency. Accordingly, to clarify and supplement the application of the Act to the Council's activities, to eliminate present ambiquities, and to provide greater guidance to the public, the Council has determined that its existing Sunshine Act procedures should be revised.

The principal revisions are contained in a proposed amendment to § 1517.1 (Policy and Scope) and the addition of a new subsection (b) in § 1517.3 (Open Meeting Requirements). These proposed amendments provide that the Council will hold a noticed meeting open to public observation every two weeks to discuss Council business. The agendas for such bi-weekly meetings would include official collegial Council business subject to the Act and when appropriate non-collegial actions and other matters outside the scope of this part. These bi-weekly meetings will be noticed in accordance with the notice provisions in § 1517.6.

The proposed amendments clarify that the Sunshine Act procedures apply to the Council's collegial actions, which are defined to mean Council actions which by statute, regulation, Executive Order or internal Council procedure, require an affirmative vote of at least two Council members in order for the action to be taken on behalf of the Council. The proposed amendments clarify that the adoption of regulations shall constitute collegial business for the purpose of these procedures.

Certain actions are taken by the Chairman in his capacity as Director of the Office of Environmental Quality pursuant to the Environmental Quality Improvement Act of 1970. In taking these actions (including personnel matters, contracts with outside consultants and budget) the Director acts non-collegially as head of the agency. Since these actions by statutory authority are non-collegial, they are excluded from the scope of the procedures. In addition, Council actions involving advice to the President are outside the scope of the procedures.

CHARLES H. WARREN,
Chairman, Council on Environmental Quality.

MARCH 14, 1979.

Sections 1517.1, 1517.2 and 1517.3 are revised to read as follows:

§ 1517.1 Policy and scope.

Consistent with the policy that the public is entitled to the fullest information regarding the decisionmaking processes of the Federal Government, it is the purpose of this part to open the *collegial* meetings of the Council on Environmental Quality to public observation while protecting the rights of individuals and the ability of the Council to carry out its primary responsibility of providing advice to the President. Actions taken by the Chairman acting as Director of the Office of Environmental Quality and Council actions involving advice to the President are outside the scope of this part. In addition to conducting the meetings required by this part, it is the Council's policy to conduct, open to public observation, bi-weekly meetings involving Council discussions of Council business, including where appropriate, matters outside the scope of this part. This part does not affect the procedures set forth in Part 1515 pursuant to which records of the Council are made available to the public for inspection and copying, except that the exemptions set forth in § 1517.4(a) shall govern in the case of any request made to copy or inspect the transcripts, recording or minutes described in § 1517.7.

§ 1517.2 Definitions.

For the purpose of this part—

(a) The term "Council" shall mean the Council on Environmental Quality established under Title II of the National Environmental Policy Act of 1969 (42 U.S.C. 4321-4347).

(b) The term "meeting" means the deliberations of at least two Council members where such deliberations determine or result in the joint conduct or disposition of official collegial Council business, but does not include deliberations to take actions to open or close a meeting under §§ 1517.4 and 1517.5 or to release or withhold information under §§ 1517.4 and 1517.7. "Meeting" shall not be construed to prevent Council members from considering individually Council business that is circulated to them sequentially in writing.

(c) The term "official collegial Council business" means any Council action which by statute, regulation, Executive Order, or internal Council procedures requires an affirmative vote of at least two Council members in order to be taken on behalf of the Council. It shall include the adoption of regulations and shall not include advice to the President, nor actions taken by the Chairman acting as Director of the Office of Environmental Quality under the Environmental Quality Improvement Act of 1970.

(d) "Director" means the Chairman of the Council on Environmental Quality acting as the head of the Office of Environmental Quality pursuant to the Environmental Quality Improvement Act of 1970, Pub. L. 91-224, 42 U.S.C. 4371-4374.

§ 1517.3 Open meeting requirement.

(a) Every portion of every meeting of the Council is open to public observation subject to the exemptions provided in § 1517.4. Members of the Council may not jointly conduct or dispose of the business of the Council other than in accordance with this part.

(b) The Council will conduct open to public observation a bi-weekly meeting involving Council discussions of Council business including where appropriate matters outside the scope of this part. Such meetings will be noticed pursuant to § 1517.6.

(c) Members of the public may attend open meetings of the Council for the sole purpose of observation and may not participate in or photograph any meeting without prior permission of the Council. Members of the public who desire to participate in or photograph an open meeting of the Council may request permission to do so from the General Counsel of the Council before such meeting. Members of the public may record open meetings of the Council by means of any mechanical or electronic device unless the Council determines such recording would disrupt the orderly conduct of such meeting.

(Pub. L. 94-409; (5 U.S.C. 552b (g)))

[FR Doc. 79-8154 Filed 3-15-79; 8:45 am]

[3510-22-M]

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[50 CFR Part 260]

STANDARDIZATION OF FISHERY PRODUCTS

Request for Information and Comments

AGENCY: National Marine Fisheries Service, National Oceanic and Atmospheric Administration, U.S. Department of Commerce.

ACTION: Extension of comments period of advanced notice of proposed rulemaking.

SUMMARY: On November 15, 1978 (43 FR 53047), an advance notice of proposed rulemaking, was published describing guidelines, standards, and procedures the National Marine Fisheries Service (NMFS) is considering for fishery products inspected by its programs. Since these guidelines, standards, and procedures will have an impact on voluntary fishery products inspection and certification, the comments of all concerned parties are invited. Requests were received asking for an extension of the comment period. In view of such requests, and extension is hereby granted.

DATE: Comments by June 1, 1979.

ADDRESS: Written comments should be directed to: Mr. Thomas J. Billy, National Oceanic and Atmospheric Administration, National Marine Fisheries Service, Washington, D.C. 20235.

FOR FURTHER INFORMATION CONTACT:

Mr. James R. Brooker, Seafood Quality and Inspection Division, U.S. Department of Commerce, NOAA, National Marine Fisheries Service, Washington, D.C. 20235, 202-634-7458.

Dated: March 13, 1979.

WINFRED H. MEIBOHM,
Executive Director, National Marine Fisheries Service.

[FR Doc. 79-8089 Filed 3-15-79; 8:45 am]

notices

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.

[3410-05-M]

DEPARTMENT OF AGRICULTURE

Agricultural Stabilization and Conservation Service

FEED GRAIN DONATIONS FOR THE ZUNI INDIAN TRIBE IN NEW MEXICO

Pursuant to the authority set forth in Section 407 of the Agricultural Act of 1949, as amended (7 U.S.C. 1427) and Executive Order 11336, I have determined that:

1. The chronic economic distress of the needy members of the Zuni Indian Tribe in New Mexico has been materially increased and become acute because of severe and prolonged drought creating a serious shortage of range forage requiring abnormal feeding of livestock. This reservation is designated for Indian use and is utilized by members of the Indian tribe for grazing purposes.
2. The use of feed grain or products thereof made available by the Commodity Credit Corporation for livestock feed for such needy members of the tribe will not displace or interfere with normal marketing of agricultural commodities.
3. Based on the above determinations, I hereby declare the reservation and grazing lands of this tribe to be acute distress areas and authorize the donation of feed grain owned by the Commodity Credit Corporation to livestock owners who are determined by the Bureau of Indian Affairs, Department of the Interior, to be needy members of the tribe utilizing such lands. These donations by the Commodity Credit Corporation may commence upon signature of this notice and shall be made available through May 31, 1979, or to such other time as may be stated in a notice issued by the Department of Agriculture.

Signed at Washington, D.C. on March 8, 1979.

STEWART N. SMITH,
Acting Administrator.

[FR Doc. 79-7912 Filed 3-15-79; 8:45 am]

[3410-11-M]

Forest Service

FREMONT NATIONAL FOREST GRAZING ADVISORY BOARD

Meeting

The Fremont National Forest Grazing Advisory Board will meet at 10:00 A.M. on Friday, April 27, 1979 at the Forest Supervisor's Office, 34 North D, Lakeview, Oregon 97630. The purpose of this meeting is:

1. Organize the Advisory Board.
2. Development of rules for public participation in meetings.
3. Discuss use of range betterment funds.
4. Review range allotment management planning.

The meeting will be open to the public. Persons who wish to attend should notify Ralph B. Roberts, 34 North D, Lakeview, Ore., 97630, phone 947-2151. Written statements may be filed with the Board before or after the meeting.

The committee has established the following rules for public participation: none.

Dated: March 6, 1979.

JOHN W. CHAMBERS,
Forest Supervisor.

[FR Doc. 79-7993 Filed 3-15-79; 8:45 am]

[3410-11-M]

GUADALUPE ESCARPMENT WILDERNESS PROPOSAL; LINCOLN NATIONAL FOREST, EDDY COUNTY, NEW MEXICO

Intent Not To Prepare a Final Environmental Impact Statement

Pursuant to section 102(2)(c) of the National Environmental Policy Act of 1969, the Forest Service, Department of Agriculture prepared a draft environmental statement for the Guadalupe Escarpment Wilderness Proposal on the Lincoln National Forest, USDA-FS-DES-03-08-79-01.

This draft environmental statement was transmitted to EPA on October 18, 1978, and a notice appeared in the FEDERAL REGISTER on October 26, 1978. Public hearings were conducted in Albuquerque, New Mexico, on December 7, 1978, in Carlsbad, New Mexico, on December 9, 1978, and in El Paso, Texas, on December 11, 1978.

The final environmental statement on the Roadless Area Review and Evaluation (RARE II) was transmitted to EPA on January 4, 1979, and recommends area 03077, Southern Guadalupe Mountains, for wilderness designation. Area 03077 is identical to the Guadalupe Escarpment Wilderness Proposal except that it does not include the land managed by the Bureau of Land Management.

Since the RARE II recommendation is identical to the Guadalupe Escarpment Wilderness Proposal, except as noted above, a final environmental statement on the Guadalupe Escarpment Wilderness Proposal will not be prepared.

The public hearing transcripts and written comments concerning the draft environmental statement and proposal are available for public review at the office of the Forest Supervisor, Lincoln National Forest, Federal Building, 11th and New York, Alamagordo, New Mexico.

Dated: March 8, 1979.

M. J. HASSELL,
Regional Forester.

[FR Doc. 79-7994 Filed 3-15-79; 8:45 am]

[3410-30-M]

Food and Nutrition Service

NUTRITION EDUCATION DEMONSTRATION AND DEVELOPMENT PROJECTS

Plans for Use of Funds

Notice is hereby given that the Food and Nutrition Service (FNS), U.S. Department of Agriculture, plans to provide funds pursuant to Section 18 of the Child Nutrition Act of 1966 (CNA) as amended, Public Law 94-105, 89 Stat. 528 (42 U.S.C. 1787).

Section 18 of the CNA authorizes the Secretary to make cash grants to State educational agencies for conducting experimental or demonstration projects to teach children the nutritional value of foods and the relationship of nutrition to human health, and to withhold a portion (not less than 1 percent) of funds appropriated under this section for research and development projects relevant to nutrition education for children. Section 18 is to be implemented by making cash grants to State educational agencies, or by making contractual agreements with States, nonprofit organizations, universities, private firms or citizen groups. A total of $1,000,000 is included in the Department's appropriation for nutrition education demonstration and development projects for the fiscal year 1979 beginning October 1, 1978. Of this amount $420,000 has been set aside for cash grants to State educational agencies for experimental or demonstration projects as set forth in Part A of this notice. Priority in awarding these funds will be given to projects which are anticipated to have

results with national or regional implications and application. Funds in the amount of approximately $580,000 are set aside and reserved for cooperative agreements or other contractual arrangements to carry out research and development projects as set forth in Part B of this notice.

A. GRANTS TO STATE EDUCATIONAL AGENCIES

Grants will be awarded only to State educational agencies responsible for administering the child nutrition programs which include any or all of the following: national school lunch program, school breakfast program, and child care food program. The purpose of the grants will be to support experimental or demonstration nutrition education projects which realistically address the nutritional needs of specific populations. Such populations may include but are not limited to handicapped children, pre-school children, adolescents and ethnic groups. Nutrition education activities and information should be compatible with the individuals, or groups served, and with community characteristics, and cultural or ethnic food patterns. These projects should prepare children to make nutritionally sound food choices and to establish healthful dietary habits.

All State education agencies interested in applying for these funds are required to submit the following information not later than June 15, 1979.

1. An application signed by the appropriate State official must be submitted by a State educational agency that administers an FNS child nutrition program.

2. Project plans shall include but need not be limited to the identification of:

a. Model and innovative approaches to nutrition education activities which inform children about the nutritional value of food, the relationship of nutrition to growth, development and health, and factors which influence eating habits.

b. Model and innovative approaches for integrating nutrition education activities into child nutrition programs.

c. Plans for nutrition education activities involving food service personnel.

d. Measurable objectives and instructional content, methods and materials.

e. Project evaluation plans for determining the effectiveness of the subject content, methods and materials in achieving cognitive, behavioral and attitudinal changes in children.

f. Local school districts or institutions participating in the Child Care Food Program who will participate in the conduct of the projects.

g. Number of children to be reached and their ages together with an explanation of why the number and ages of the children were selected.

h. The amount of funds that will be made available to local school districts or to institutions participating in the Child Care Food Program for implementation of the projects.

i. Plans to implement any successful models on a statewide basis.

3. The application shall be submitted on a form entitled "Application for Federal Assistance (Non-Construction Programs)" SF-424. Request for this form should be addressed or telephone request made to:

Contracting Officer, Administrative Service Division, Food and Nutrition Service, Room 790, U.S. Department of Agriculture, Washington, D.C. 20250, phone 202/447-8179.

4. All parts of the application must be completed in accordance with the instructions contained in SF-424. Part IV-Program Narrative shall include all requirements under paragraphs 1 through 4 and under paragraphs 5a and 5b. The applicant will be required to certify compliance with applicable provisions of the law and administrative regulations described in part V of SF-424.

5. The term of the project shall not exceed 24 months. State clearinghouse approval is not required. However, a copy of the application should be forwarded for review to the State clearinghouse in accordance with part I of OMB Circular A-95 (41 FR 2052) attachments A, part I, paragraph 8, entitled "Exceptions." Grants will be administered under the provisions of OMB Circular A-102. Particular attention should be given to the following areas in the circular:

(1) Attachment "A"—cash depositories.

(2) Attachment "C"—standards for grantee financial management systems.

(3) Attachment "O"—procurement standards.

The subject grant program is listed in the Appendix I of the Catalog of Federal Domestic Assistance, 10.563.

Applications received will be reviewed on a competitive basis according to the criteria defined in paragraph 2 and the requirements of the program narrative part IV of SF-424 as defined in paragraph 5. Announcements of grant awards will be made on or about August 31, 1979.

B. CONTRACTS OR COOPERATIVE AGREEMENTS WITH STATES, NONPROFIT ORGANIZATIONS, UNIVERSITIES, AND COMMERCIAL FIRMS

Funds will not be awarded under this notice. Rather, this Part is only a statement of intent that funds will be made available for research and development projects carried out through cooperative agreements or other contractual arrangements with State agencies, nonprofit organizations, universities, and commercial firms for: (1) evaluation of nutrition education and training programs and development of nutrition education evaluation methodologies, (2) outreach activities to expand the benefits of the school breakfast program to additional children including the development of various techniques and methods of teaching the nutritional value of breakfast and the importance of the principles of good nutrition to health, and (3) programs designed to encourage parents, teachers, and students to work with the food service manager to improve the quality of food served in both the breakfast and lunch programs and where applicable to encourage local school officials to start a breakfast program.

Bids and technical proposals to perform projects under Part B of this notice in accord with specifications established by FNS will be solicited through Requests for Proposals. Announcement of these contractual actions will be published in the Commerce Business Daily from time to time. Prospective bidders wishing to submit proposals may request to be put on the bidders list by contacting the Contracting Officer in Part I, paragraph 3.

Dated: March 13, 1979.

CAROL TUCKER FOREMAN,
Assistant Secretary for Food and Consumer Services.

[FR Doc. 79-8084 Filed 3-15-79; 8:45 am]

[3410-11-M]

Office of the Secretary

OZARK NATIONAL FOREST

Transfer of Certain Lands; Addition

In FR Document 78-550 appearing at page 1520 in the FEDERAL REGISTER of January 10, 1978, the following addition should be made in the land description for Marion County, Arkansas:

1. On page 1521, Column 2, following subheading "T. 17N., R.14W., Sec. 26" and "That part of the NE¼NE¼ lying North and East of the Buffalo River containing 0.56 of an acre, more or less."

Effective Date: March 16, 1979.

BOB BERGLAND,
Secretary.

MARCH 13, 1979.

[FR Doc. 79-8085 Filed 3-15-79; 8:45 am]

[3510-22-M]

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

MARINE MAMMALS

Issuance of Permit

On January 24, 1979, notice was published in the FEDERAL REGISTER (43 FR 4995), that an application had been filed with the National Marine Fisheries Service by Kolmardens Djurpark, S-610 23 Kolmarden, Sweden, for a permit to take three (3) Atlantic bottlenose dolphins (*Tursiops truncatus*) for the purpose of public display.

Notice is hereby given that on March 8, 1979, and as authorized by the provisions of the Marine Mammal Protection Act of 1972 (16 U.S.C. 1361-1407), the National Marine Fisheries Service issued a Public Display Permit for the above taking to Kolmardens Djurpark, subject to certain conditions set forth therein.

The Permit is available for review in the following offices:

Assistant Administrator for Fisheries, National Marine Fisheries Service, 3300 Whitehaven Street, N.W., Washington, D.C.; and

Regional Director, National Marine Fisheries Service, Southeast Region, 9450 Koger Boulevard, Duval Building, St. Petersburg, Florida 33702.

Dated: March 8, 1979.

JACK GEHRINGER,
Deputy Assistant Administrator for Fisheries, National Marine Fisheries Service.

[FR Doc. 79-8021 Filed 3-15-79; 8:45 am]

[3510-22-M]

MARINE MAMMALS

Receipt of Application for General Permit

Notice is hereby given that the following application has been received to take marine mammals incidental to the course of commercial fishing operations as authorized by the Marine Mammal Protection Act of 1972 (16 U.S.C. 1361-1407) and the regulations thereunder.

The United Fishermen's Organization of Southern California, P.O. Box 3538, Terminal Island, California 90731, has applied for general permits in: Category 3, "Encircling Gear, Purse Seining Not Involving the Intentional Taking of Marine Mammals"; and Category 5, "Other Gear".

The applications are available for review in the office of the Assistant Administrator for Fisheries, National Marine Fisheries Service, Washington, D.C. 20235.

Interested parties may submit written views on this application within 20 days of the date of this notice to the Assistant Administrator for Fisheries, National Marine Fisheries Service, Department of Commerce, Washington, D.C. 20235.

Dated: March 12, 1979.

WILLIAM ARON,
Director, Office of Marine Mammals and Endangered Species.

[FR Doc. 79-8022 Filed 3-15-79; 8:45 am]

[3510-25-M]

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

CERTAIN MAN-MADE FIBER APPAREL FROM HAITI

Additional Import Controls

MARCH 13, 1979.

AGENCY: Committee for the Implementation of Textile Agreements.

ACTION: Controlling certain man-made fiber apparel products in Category 659 during the fifteen-month period which began on January 1, 1978.

(A detailed description of the categories in terms of T.S.U.S.A. numbers was published in the FEDERAL REGISTER on January 4, 1978 (43 FR 884), as amended on January 25, 1978 (43 FR 342), March 3, 1978 (43 FR 8828), June 22, 1978 (43 FR 26773), September 5, 1978 (43 FR 39408), and January 2, 1979 (44 FR 94)).

SUMMARY: Under the terms of paragraph 17 of the Bilateral Cotton, Wool and Man-Made Fiber Textile Agreement of March 22 and 23, 1976, as amended, between the Governments of the United States and Haiti, the Government of the United States has decided to control imports of certain man-made fiber apparel products in Category 659, produced or manufactured in Haiti and exported to the United States during the fifteen-month period which began on January 1, 1978, in addition to those categories previously designated (See 44 FR 6491). The designated consultation level is being increased to 440,000 pounds at the request of the Government of Haiti and will be controlled at that level for the agreement period that began on January 1, 1978.

EFFECTIVE DATE: March 19, 1979.

FOR FURTHER INFORMATION CONTACT:

M. Shirley Hargrove, Trade and Industry Assistant, Office of Textiles, U.S. Department of Commerce, Washington, D.C. 20230 (202/377-5423).

SUPPLEMENTARY INFORMATION: On February 1, 1979, there was published in the FEDERAL REGISTER (44 FR 6491) a letter dated January 29, 1979 from the Chairman of the Committee for the Implementation of Textile Agreements to the Commissioner of Customs which established levels of restraint for certain specified categories of cotton and man-made fiber textile products, produced or manufactured in Haiti, which may be entered into the United States for consumption, or withdrawn from warehouse for consumption, during the fifteen-month period which began on January 1, 1978 and extends through March 31, 1979. In accordance with the terms of the bilateral agreement, the United States Government has decided also to control imports in Category 659 for the agreement period which began on January 1, 1978. Accordingly, there is published below a letter from the Chairman of the Committee for the Implementation of Textile Agreements to the Commissioner of Customs directing that imports in this Category be limited to the designated level of restraint. The level has not been adjusted to reflect any imports during the period which began on January 1, 1978. Adjustments will be made to account for imports during the period beginning on January 1, 1978 and extending through the effective date of this action.

ARTHUR GAREL,
Acting Chairman, Committee for the Implementation of Textile Agreements.

MARCH 13, 1979.

COMMISSION OF CUSTOMS,
Department of the Treasury, Washington, D.C. 20229.

DEAR MR. COMMISSIONER: This directive amends, but does not cancel, the directive issued to you on January 29, 1979 by the Chairman, Committee for the Implementation of Textile Agreements, concerning imports into the United States of certain cotton and man-made fiber textile products, produced or manufactured in Haiti.

Under the terms of the Arrangement Regarding International Trade in Textiles done at Geneva on December 20, 1973, as extended on December 15, 1977; Pursuant to the Bilateral Cotton, Wool and Man-Made Fiber Textile Agreement of March 22 and 23, 1976, as amended, between the Governments of the United States and Haiti; and in accordance with the provisions of Executive Order 11651 of March 3, 1972, as amended by Executive Order 11951 of January 6, 1977, you are directed to prohibit, effective on March 19, 1979, and for the fifteen month period beginning on January 1, 1978 and extending through March 31, 1979, entry into the United States for consumption, and withdrawal from warehouse for consumption, of man-made fiber textile products in Category 659, produced or manufactured in Haiti, in excess of 440,000 pounds.[1]

Man-made fiber textile products in the foregoing category which have been released from the custody of the U.S. Customs Service under the provisions of 19 U.S.C.

[1]The level of restraint has not been adjusted to reflect any imports after December 31, 1977.

1448(b) and 1484(a)(1)(A) prior to the effective date of this directive shall not be denied entry under this directive.

A detailed description of the categories in terms of T.S.U.S.A. numbers was published in the FEDERAL REGISTER on January 4, 1978 (43 FR 884), as amended on January 25, 1978 (43 FR 3421), March 3, 1978 (43 FR 8828), June 22, 1978 (43 FR 26773), September 5, 1978 (43 FR 39408), and January 2, 1979 (43 FR 94)).

In carrying out the above directions, entry into the United States for consumption shall be construed to include entry for consumption into the Commonwealth of Puerto Rico.

The actions taken with respect to the Government of Haiti and with respect to imports of man-made fiber textile products from Haiti have been determined by the Committee for the Implementation of Textile Agreements to involve foreign affairs functions to the United States. Therefore, the directions to the Commissioner of Customs, being necessary to the implementation of such actions, fall within the foreign affairs exception to the rule-making provisions of 5 U.S.C. 553. This letter will be published in the FEDERAL REGISTER.

Sincerely,

ARTHUR GAREL,
Acting Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 79-8040 Filed 3-15-79; 8:45 am]

[6820-33-M]

COMMITTEE FOR PURCHASE FROM THE BLIND AND OTHER SEVERELY HANDICAPPED

PROCUREMENT LIST 1979

Correction of Proposed Addition

The document published in the FEDERAL REGISTER on March 9, 1979 (44 FR 13061) proposing the addition to Procurement List 1979 is amended to correct the proposal for mattress, innerspring as follows:

CLASS 7210

Mattress, Innerspring (Felted Cotton Padding) with Vinyl/Nylon Laminated Ticking (Veterans Administration only)

The above for all requirements which are not furnished by Federal Prison Industries.

Comments on the proposed addition to the Procurement List of the above mattress must be received on or before April 18, 1979.

E. R. ALLEY, Jr.,
Acting Executive Director.

[FR Doc. 79-8019 Filed 3-15-79; 8:45 am]

[6820-33-M]

PROCUREMENT LIST 1979

Proposed Additions

AGENCY: Committee for Purchase from the Blind and Other Severely Handicapped.

ACTION: Proposed Additions to Procurement List.

SUMMARY: The Committee has received proposals to add to Procurement List 1979 commodities to be produced by workshops for the blind and other severely handicapped.

COMMENTS MUST BE RECEIVED ON OR BEFORE: April 18, 1979.

ADDRESS: Committee for Purchase from the Blind and Other Severely Handicapped, 2009 14th Street North, Suite 610, Arlington, Virginia 22201.

FOR FURTHER INFORMATION CONTACT:

C. W. Fletcher, (703) 557-1145

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 47(a)(2), 85 Stat. 77.

If the Committee approves the proposed additions, all entities of the Federal Government will be required to procure the commodities listed below from workshops for the blind or other severely handicapped.

It is proposed to add the following commodities to Procurement List 1979, November 15, 1978 (43 FR 53151):

CLASS 1005

Swab, Small Arms, Cleaning, 1005-00-912-4248, 1005-00-288-3565.

CLASS 3990

Pallets, Wood, 24" x 40", 3990-00-X77-1721 (Requirements for the New Cumberland, Pennsylvania Army Depot only).

CLASS 8970

Life Raft, Individual, 8970-01-028-9406.

E. R. ALLEY, Jr.,
Acting Executive Director.

[FR Doc. 79-8020 Filed 3-15-79; 8:45 am]

DEPARTMENT OF DEFENSE

Department of the Navy

CHIEF OF NAVAL OPERATIONS EXECUTIVE PANEL ADVISORY COMMITTEE, COMMAND, CONTROL AND COMMUNICATIONS SUB-PANEL

Meeting

Pursuant to the provisions of the Federal Advisory Committee Act (5 U.S.C. App. I), notice is hereby given that the Command, Control and Communications Sub-Panel of the Chief of Naval Operations (CNO) Executive Panel Advisory Committee will meet on April 3-4, 1979, at San Diego, California. The first session will be held at the Naval Oceans System Center, San Diego, on April 3, 1979, from 9:00 a.m. to 4:00 pm. The second session will be held at the Fleet ASW Training Center, San Diego, on April 4, 1979, from 9:00 a.m. to 12:00 noon. The third session will be held at the Fleet Combat Training Center, San Diego, on April 4, 1979, from 1:00 pm. until 4:00 p.m. All sessions of the meeting will be closed to the public.

The entire agenda for the meeting will consist of discussions of new developments in command, control and communications, and long range planning and programming. The agenda will consist of classified information that is specifically authorized by Executive order to be kept secret in the interest of national defense and is, in fact, properly classified pursuant to such Executive order. Accordingly, the Secretary of the Navy has determined in writing that the public interest requires that all sessions of the meeting be closed to the public because they will be concerned with matters listed in section 552b (c)(1) of title 5, United States Code.

For further information concerning this meeting, contact Commander Robert B. Vosilus, USN, Executive Secretary of the CNO Executive Panel Advisory Committee, 1401 Wilson Boulevard, Room 405, Arlington, VA 22209, telephone number (202) 694-3191.

Dated: March 13, 1979.

P. B. WALKER,
Captain, JAGC, U.S. Navy, Deputy Assistant Judge Advocate General (Administrative Law).

[FR Doc. 79-8046 Filed 3-15-79; 8:45 am]

[6450-01-M]

DEPARTMENT OF ENERGY

AUTOMOTIVE PROPULSION RESEARCH AND DEVELOPMENT

Contractor Coordination Meeting

AGENCY: Department of Energy.

ACTION: Notice of meeting.

SUMMARY: The Department of Energy will hold a contractor coordination meeting on automotive propulsion research and development, and members of the public are hereby invited to attend as observers. Contractors and staff of the Department of Energy and the National Aeronautics and Space Administration will present papers on the current state of research and development on advanced automotive propulsion systems and on alternative fuels.

DATES: April 24-26, 1979, 9 a.m., to 5 p.m.

ADDRESS: Hyatt Regency Dearborn Hotel, Dearborn, Michigan.

FOR FURTHER INFORMATION CONTACT:

Mrs. Alma Anderson, U.S. Department of Energy, Mail Station 2221C, 20 Massachusetts Avenue, N.W., Washington, D.C. 20545, Telephone (202) 376-4675.

SUPPLEMENTARY INFORMATION: Today's notice follows through on a statement in the notice of proposed regulations (43 FR 31929, 31932 (July 24, 1978)) under section 304(f) of the Department of Energy Act of 1978—Civilian Applications (Act), 15 U.S.C. 2703(f) (1970), in which the Department of Energy (DOE) announced its intention to open contractor coordination meetings to public attendance. Section 304(f) requires the DOE to issue administrative regulations prescribing procedures, standards, and criteria for review and certification of automotive propulsion research and development to be funded by new grants, cooperative agreements, or contracts, or as new DOE or agency projects under the Act. The purpose of the review and certification process is to insure that research and development newly funded under the Act will supplement rather than supplant, duplicate, displace, or lessen the same activities in the private sector.

The final regulations (43 FR 55228, November 24, 1978) provide for notice to the public of proposed research and development and an opportunity to file written objections. To enable the public to avail itself of the opportunity to participate in the review and certification process, the DOE stated in the notice of the proposed regulations that it would give notice of meetings, such as the one announced today, since relevant information is to be presented.

Below is a preliminary agenda:

Date	Topic	Session
April 24..	Program Overview.....	Morning.
	Gas turbine systems panel discussion.	Afternoon.
April 25..	Stirling engine panel discussion.	Morning.
	Technology applications and supporting research and technology *and* Alternative fuels (concurrent sessions).	Afternoon.
April 26..	Vehicle systems *and* Alternative fuels (concurrent sessions).	Morning.
	Diesel panel discussion *and* Alternative fuels (concurrent sessions).	Afternoon.

Registrants at the meeting pay a $25 registration fee for which they receive refreshments, copies of papers presented at the meeting, and subsequently a copy of the report of the proceedings. Members of the public may register and pay the fee if they wish to avail themselves of these services and materials. However, if they do not, they are free simply to attend meeting sessions and listen to the proceedings. Members of the public intending to respond to this notice are requested to so advise the information contact named above in advance so that appropriate seating arrangements can be made.

Issued in Washington, D.C. on March 12, 1979.

OMI WALDEN,
Assistant Secretary, Conservation and Solar Applications.

[FR Doc. 79-7963 Filed 3-15-79; 8:45 am]

[6450-01-M]

Economic Regulatory Administration

ANALYSIS OF REFINERS NO. 2 DISTILLATE COSTS AND REVENUES: JULY 1976-DECEMBER 1978

Public Hearing

AGENCY: Economic Regulatory Administration, Department of Energy.

ACTION: Notice of public hearing.

SUMMARY: The Economic Regulatory Administration (ERA) of the Department of Energy (DOE) conducted a study entitled *Analysis of Refiners' No. 2 Distillate Costs and Revenues: July 1976-December 1978.* No. 2 distillates include No. 2 home heating oil. The ERA is announcing a hearing to consider the relation of refiner cost increases and revenue increases for No. 2 distillates in the period from deregulation (July 1976) through December 1978.

Participants in the hearing will include the Office of Fuels Regulation (OFR), which prepared the cost-revenue study, the nine refiners whose data OFR analyzed in the cost-revenue study, and other interested persons as determined by the ERA.

DATES: Requests to participate by Thursday, March 22, 1979.

PRE-HEARING CONFERENCE: 9 a.m., Friday, March 23, 1979.

HEARING: Date to be announced at pre-hearing conference.

ADDRESSES: Send "request to participate in No. 2 distillates hearing" to Mrs. Deborah Kidwell, Box XA, Room 2313, 2000 M Street, N.W., Washington, D.C. 20461.

PRE-HEARING CONFERENCE: 9 a.m., Friday, March 23, 1979, 2000 M Street, N.W., Room 2104, Washington, D.C. 20461.

FOR FURTHER INFORMATION CONTACT:

William Webb, Office of Public Information, Economic Regulatory Administration, 2000 M Street, N.W., Room B-110, Washington, D.C. 20461, (202) 634-2170.

Mrs. Deborah Kidwell, 2000 M Street, N.W., Room 2313, Washington, D.C. 20461, (202) 254-5201.

William C. Gillespie (Economic Regulatory Administration), 2000 M Street, N.W., Room 2109, Washington, D.C. 20461, (202) 254-5140.

SUPPLEMENTARY INFORMATION:

I. Background.
II. The OFR Cost-Revenue Study.
III. Further Actions.

NOTICE OF PUBLIC HEARING TO CONSIDER ANALYSIS OF REFINERS NO. 2 DISTILLATE COSTS AND REVENUES: JULY 1976-DECEMBER 1978

I. BACKGROUND

Middle distillates, including No. 2 oils, were exempted from price and allocation regulation under the Emergency Petroleum Allocation Act (EPAA) on July 1, 1976. Section 12(f) of the EPAA authorizes the reimposition of price or allocation regulation on an exempted product when such regulation is necessary to attain and is consistent with the specified objectives of the EPAA. In light of its continuing authority under Section 12(f), and in response to congressional and public concern about middle distillate prices, the Federal Energy Administration (FEA) and, subsequently, the Department of Energy (DOE) undertook to monitor certain No. 2 oil prices during the winters of 1976/1977 and 1977/1978. As part of its 1978 program, DOE announced that the Office of Administrative Review (now the Office of Hearings and Appeals) (OHA) would conduct a public evidentiary hearing for the purpose of examining the performance of all levels of distribution of the No. 2 heating oil industry and the need for any further regulatory action. OHA conducted such a hearing, and, on November 20, 1978, that office issued a *Decision and Recommendations—No. 2 (Home) Heating Oil.*

At the refining level, the OHA found that the evidence through the 1977/1978 heating season "would apper to indicate a trend of stabilizing prices and declining price increases. . . . " (p. 83). The OHA found, nevertheless, on the basis of the evidence before it, that "the price for No. 2 heating oil at the refining level subsequent to decontrol has increased at a greater rate than the cost increases refiners have been incurring." (p. 131). The OHA recognized that "price increases above the level of increased costs do not necessarily connote unreasonable or inequitable prices." (p. 88). It was the OHA's view, however, that its findings raised "serious questions as to the adequacy of competitive forces at the refiner level as a means of restraining inequitable prices." (*Id.*)

II. THE OFR COST-REVENUE STUDY

Once a product is deregulated, it is not possible to determine the actual extent to which refiners' prices are different from what they would have been under continuing regulation. It is possible to compute hypothetical maximum prices for each refiner by applying the regulations retroactively to the revenues and costs that were realized under deregulation. Those hypothetical maxima, however, are not necessarily what the maxima would have been under continuing regulation. Had regulations actually been in effect, refiners would have had available a number of strategies which might have made it possible legally to charge substantially the same prices under regulation as were actually charged under deregulation.

Nevertheless, an analysis which retroactively applies the regulatory standards to test actual cost and revenue increases since deregulaion is useful in assessing refiner price behavior in the deregulated market. Such a study can approximate the extent to which prices under deregulation were significantly higher or lower than they could have been under regulation and, more broadly, can help clarify the relationship and patterns of cost increases and price increases.

OHA's findings concerning the relationship of cost increases to price increases rested upon imputed rather than actual data, and aggregated rather than individual company data, in the application of certain elements of the refiner price rule. Moreover, OHA compared cost and revenue increases since June, 1976, which could have affected the results if costs and revenues had not increased at the same rate between May 15, 1973 (the actual base date under the refiner price rule) and June, 1976.

Accordingly, the Economic Regulatory Administration (ERA), in December, 1978, directed the nine principal refiners of No. 2 oils to provide actual monthly cost and revenue increases as against May, 1973, for the period July, 1976, through December, 1978.[1] Such data made it possible to achieve a better approximation than OHA was able to achieve on the basis of the data available to it of what the effects of continued regulation might have been on prices charged for No. 2 oils. The OFR conducted an extensive analysis of this data, which is presented in a report that will be available from the Office of Public Information, Room B-110, 2000 M Street, N.W., Washington, D.C. The report is entitled, *Analysis of Refiners' No. 2 Distillate Costs and Revenues: July 1976–December 1978.*

[1]The OHA report covered the period July 1976 through April 1978.

III. FURTHER ACTIONS

The Department has determined to convene a hearing to consider the relation of costs and revenues for No. 2 oils in the period from deregulation through December, 1978. The hearing will be conducted by ERA. Matters which may be addressed by participants in the hearing include:

(1) The methodology of the cost-revenue study.
(2) The findings of the cost-revenue study.
(3) Economic implications of the findings of the cost-revenue study, including implications as to competition at the refiner level.

The cost/revenue study extends through December 1978. Heating oil prices continued to rise in January and February 1979. Rather than address these most recent price increases in the hearing without benefit of analysis of actual, company-specific refiner cost and revenue data, DOE will update the cost-revenue study this summer.

Participants in the hearing will include the OFR, the nine refiners whose data OFR analyzed in the cost-revenue study[2] and other interested persons as determined by ERA. Except insofar as answers by a non-participant may be required by the presiding official, only participants will be allowed to present statements and otherwise participate in the hearing. Interested persons wishing to participate should file a request with ERA Office of Public Hearings Management, Attn.: D. Kidwell, Box XA, 2000 M Street, NW., Room 2313, Washington, D.C. 20461. Such requests should be received not later than March 22, 1979. Requests should describe the nature of the person's interest and why the person believes that participation will contribute to an understanding of the issues in the hearing.

In order to provide interested persons an opportunity to be heard on the procedures that are appropriate for the hearing, a pre-hearing conference will be held on Friday, March 23, at 9:00 a.m., in Room 2105 at 2000 M Street, NW., Washington, D.C.

Only persons who have filed a request to participate will be allowed to speak at the pre-hearing conference. The pre-hearing conference will aid in identifying the nature of the interests of persons wishing to participate in the hearing. The pre-hearing conference will discuss whether participants should be provided opportunity directly to question other participants, or whether all questions should be submitted to the presiding officer as is the practice in Departmental rulemaking proceedings. Participants are invited to consider whether direct questioning by participants subject to an agreed time limit (for example, one hour for each questioner) would be practical and appropriate, and whether there are suitable groupings of participants with common interests so that questioning can be conducted by a single representative of that interest. Participants are also invited to address the procedural matters discussed below. The time and place of the hearing will be announced at the pre-hearing conference, and thereafter can be ascertained by telephoning the Office of Public Hearings Management (202) 254–5401, and inquiring as to the "No. 2 distillates hearing."

The DOE has tentatively concluded that it will use its compulsory process to compel answers by any person, whether or not the person presents a statement in the hearing, to questions which, in the judgment of the presiding official, are of relevance and importance to the subjects under consideration, could not reasonably be answered by some other means, are not repetitive, and would not be unduly burdensome to answer. The presiding official will determine in the circumstances whether, if the need to utilize process for such purposes arises, the answers should be oral or in writing.

The DOE will present the cost-revenue study, and otherwise guide the conduct of the hearing, so as to maintain the confidential status of information which it deems proprietary. The conduct of a hearing concerning actual recent costs necessitates considerable care in avoiding disclosures with a potential to reduce competition. During the course of the hearing, questions may arise, the answers to which would involve examination of proprietary data. The DOE has tentatively concluded that where such questions are otherwise appropriate, the OFR staff will re-analyze proprietary data in its possession in an effort to develop an answer to the question which does not reveal the underlying proprietary data. The availability of the OFR staff for this purpose must lie within the discretion of the presiding official, involving as it does a serious potential for disruption of OFR workload.

Unless the DOE decides to reimpose regulation under Section 12(f) of the EPAA, the DOE does not contemplate preparing another report on No. 2 oils on the basis of the hearing announced today. The cost-revenue study, the record in the hearing, and the planned update of the cost-revenue study in early summer, are all part of the DOE's continuing processes of information acquisition and policy formulation. These ongoing activities are not limited to the materials that will be

[2]Amerada Hess Corporation; Atlantic Richfield Company; Exxon Corporation; Gulf Oil Corporation; Marathon Oil Corporation; Phillips Petroleum Company; Standard Oil of Indiana; Sun Oil Company; Texaco, Inc.

the subject of the hearing and will not end with the completion of the hearing.

Issued in Washington, D.C., March 13, 1979.

DAVID J. BARDIN,
Administrator, Economic Regulatory Administration.

[FR Doc. 79-8104 Filed 3-15-79; 8:45 am]

[6560-01-M]

ENVIRONMENTAL PROTECTION AGENCY

Office of Enforcement

[FRL 1077-8]

FUELS AND FUEL ADDITIVES

Proposed Interpretive Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of Proposed Interpretive Rule.

SUMMARY: This notice announces EPA's proposed interpretation of the term "substantially similar" as it is used in section 211(f)(1) of the Clean Air Act (Act). This interpretation will enable fuel and fuel additive manufacturers to determine whether their fuels or fuel additives are covered by or excluded from the prohibitions of section 211(f)(1) and (3) of the Act. The proposed interpretation expands an earlier interpretation issued by EPA. 43 FR 11258 (1978), 43 FR 24131 (1978).

DATE: Comments received on or before April 16, 1979, will be considered in formulating a final interpretation.

ADDRESS: Comments should be submitted to: Docket EN-79-5, Central Docket Section (A-130), Environmental Protection Agency, Washington, D.C. 20460. The docket, located in room 2903B, is open from 8:00 a.m. to 4:00 p.m. for public inspection of record material.

FOR FURTHER INFORMATION CONTACT:

Margaret Pêna, Attorney-Advisor, Mobile Source Enforcement Division (EN-340), Environmental Protection Agency, Washington, D.C. 20460, (202) 426-4147.

SUPPLEMENTARY INFORMATION: Section 211(f)(1) of the Clean Air Act prohibits, after March 31, 1977, any fuel or fuel additive manufacturer from first introducing into commerce, or increasing the concentration in use of, any fuel or fuel additive for general use in light duty motor vehicles manufactured after model year 1974 which is not *substantially similar* to any fuel or fuel additive utilized in the certification of any model year 1975, or subsequent model year, vehicle or engine under section 206 of the Act.

Under section 211(f)(3), any manufacturer of any fuel or fuel additive which prior to March 31, 1977, and after January 1, 1974, first introduced in commerce or increased the concentration in use of a fuel or fuel additive that would otherwise have been prohibited under section 211(f)(1) of the Act if introduced on or after March 31, 1977, shall, not later than September 15, 1978, cease to distribute such fuel or fuel additive in commerce.

EPA proposes to treat a fuel or fuel additive for general use in light duty motor vehicles manufactured after model year 1974 as *substantially similar* to any fuel or fuel additive utilized in the certification of any 1975 or subsequent model year vehicle or engine under section 206 of the Act if any fuel satisfies the following first criterion, or any fuel additive satisfies any one of the following three criteria:

(1) The fuel or fuel additive [1] Contains either carbon and hydrogen exclusively, or carbon, hydrogen and oxygen exclusively and will be sold to consumers as or in an unleaded fuel with the resulting fuel possessing the range of physical and chemical characteristics [2] of the unleaded fuel that was used or could have been used in certification for model year 1975, and subsequent model year vehicles, or;

(2) The fuel additive contains carbon, hydrogen and nitrogen; or carbon, hydrogen, oxygen and nitrogen, and the additive's total concentration in the fuel does not exceed 0.25% by weight of the fuel,[3] or;

(3) The fuel additive has a molecular structure and chemical composition identical to a fuel additive which was used in the certification of any 1975 or subsequent model year, vehicle or engine, and has a concentration in unleaded gasoline that has not been increased by more than 50% by weight.

[1] For purposes of this interpretive rule, the term "fuel additive" refers only to the active portion of the additive package excluding that component consisting of carrier oils and solvents whose primary function is to insure the additive's compatibility with the fuel. Carrier oils and solvents are not a focal point of this interpretation since they are primarily composed of carbon and hydrogen.

[2] "Possessing physical and chemical characteristics" means that the volatility, density, stoichiometry, viscosity, and chemical composition (including inherent impurities) of the candidate fuel do not vary by more than the usual commercial variation of unleaded fuel, as reported in the Department of Energy and Motor Vehicle Manufacturers Association surveys.

[3] For the purposes of this interpretive rule, impurities which produce gaseous combustion products (e.g., products which exist as a gas at standard temperature and pressure) may be present in the additive at trace levels. An impurity is that substance which is present through contamination or remains naturally, after processing of the additive is completed.

The first section of this interpretation is based on the type of fuels required by regulation to be used in certification testing. Regulations at 40 CFR 86.113-79(a)(1) and (2) prescribe those fuels used in testing 1975 and subsequent model year vehicles or engines. Motor vehicles or motor vehicle engines should have been designed so that they are capable of complying with emissions standards using any unleaded fuel which complies with these specifications and requirements for certification test fuels.

Fuels are typically composed of carbon and hydrogen only. With regard to the addition of oxygenated compounds, as long as the resulting fuel possesses the physical and chemical characteristics of unleaded fuel,[4] the presence of oxygen in the fuel is not expected to result in significantly different emissions performance than fuels without oxygen containing compounds.

With regard to the second portion of the interpretation, EPA believes, based on information obtained from industry and certification fuel specification submittals, that additives used in certification: (1) are used at concentrations not greater than 0.25% by weight; (2) are composed of only the elements carbon, hydrogen, oxygen or nitrogen; and (3) produce combustion products which exist as a gas at standard temperature and pressure.[5]

Most of the additives used in certification, which have been used for years in small concentrations (up to 0.25% by weight), have had no known detrimental effects on emissions. Our belief that an incremental increase of up to 50% of these additives will not significantly alter emissions performance serves as the basis for the final portion of our interpretation.

Dated: March 14, 1979.

BARBARA BLUM,
Acting Administrator.

[FR Doc. 79-8105 Filed 3-15-79; 8:45 am]

[6712-01-M]

FEDERAL COMMUNICATIONS COMMISSION

NORTH ATLANTIC FACILITIES

Acceptance of Plan Which Includes TAT-7 Cable in 1983

FEBRUARY 26, 1979.

The Commission has found substantially acceptable a comprehensive

[4] *See* note 2 *supra.*

[5] Combustion products which exist as a gas at standard temperature and pressure normally pass through the system without leaving deposits on the catalyst which could deactivate or plug the emission control device.

facilities construction and use plan for the North Atlantic region. The plan considered was negotiated by the United States International Service Carriers (USISC) with their foreign correspondents in CEPT* and Teleglobe/Canada**. That plan provides for the construction and use of cable and satellite facilities between the U.S. and 20 countries in Europe and includes implementation of a seventh transatlantic submarine cable (TAT-7) in mid-1983. While finding the bulk of the negotiated plan acceptable the Commission did express reservations as to some aspects of it.

The Commission action was in accordance with the procedures it established in October 25, 1978, in Docket No. 18875. At that time, the Commission instituted procedures concerning adoption of policies governing the licensing of transatlantic communications facilities through 1985. The procedures instituted consisted of five phases. In the first phase, the staff, with the assistance of the USISC and Comsat, was to update two plans previously considered by the Commission. In the second phase, these plans were to be used as bounds within which the USISC would negotiate a comprehensive cable and satellite plan with their correspondents in CEPT and Teleglobe/Canada. In the third phase, the negotiated plan was to be submitted to the Commission and issued for public comment. Thereafter, the Commission was to review the negotiated plan to determine whether it was in compliance with the guidelines established in the initial phase.

On Thursday, February 22, 1979, the Commission, acting in Phase 3, found the negotiated plan acceptable with respect to 18 of the 20 CEPT countries. However, with respect to the provisions covering Belgium and the United Kingdom, the Commission required further discussions in an attempt to resolve certain aspects of the negotiated plan which it found were outside the guidelines it had previously established. These aspects concern additional capital expenditures, over and above those involved with the TAT-7 cable that AT&T would incur under the negotiated plan.

The Commission noted that with regard to France, the plan does not provide for use of a third satellite path. While accepting the plan as it pertains to France, the Commission did urge the USISC to reexamine this matter with their French correspondent.

In addition, the Commission concluded that further information should be requested from the USISC regarding the appropriate distribution to be made of circuits should forecasted levels of traffic not be realized. In particular, the Commission sought assurance that the principles underlying the distribution of traffic shortfalls would be consistent with those underlying the distribution of forecasted traffic.

In taking this action, the Commission noted that it had no serious reservations with most of the negotiated plan. It concluded that the plan represents a significant step toward its objective of developing, for the first time, a comprehensive plan for cable and satellite use on which European, Canadian, and U.S. entities agree. In view of this, the Commission stated that while it could not now adopt the negotiated plan *in toto*, Phases 4 and 5 of this procedure can proceed concurrently with the further discussion to be held. In this manner, work can begin on these two final phases while the few remaining issues are being resolved thereby providing the best opportunity to meet the Commission's previously established schedule. Thus, the Commission indicated that it was now prepared to accept and begin processing the application necessary to authorize the construction of a TAT-7 cable to become operational in mid-1983.

The Commission stated that the negotiated plan represents an important step in achievement of mutual agreement on a comprehensive construction and use plan for both cable and satellite facilities in the North Atlantic. It further noted that the substantial degree of progress achieved represents a great deal of effort and cooperation by the many entities involved. The Commission further stated that it believes the remaining issues can be resolved quickly so that complete agreement on the comprehensive plan can be reached.

Action by the Commission February 26, 1979. Commissioners Ferris (Chairman), Lee, Quello, Washburn, Fogarty, White and Brown, with Chairman Ferris and Commissioners Washburn and Fogarty issuing separate statements.

FEDERAL COMMUNICATIONS COMMISSION,
WILLIAM J. TRICARICO,
Secretary.

SEPARATE STATEMENT OF CHARLES D. FERRIS

In Re Transatlantic Communication Facilities Construction and Use Plan.

Today's action by the Commission on the Transatlantic Communication Facilities Construction and Use Plan agreed to by our European correspondent and submitted by the United States International Service Carriers is a major step toward mutual agreement on a comprehensive facilities implementation and utilization plan for the North Atlantic region through 1985. Such an agreement has eluded the Commission for a number of years, yet its accomplishment is one of the Commission's highest priorities.

Such an agreement, if achieved, would allow a more orderly review of facilities proposals previously handled in an *ad hoc* manner. It would reduce regulatory delay. It would decrease the risk of facilities being built that would burden U.S. ratepayers with unnecessary costs. It would help us develop common methodologies for traffic forecasting and circuit utilization. And it would demonstrate conclusively that the shared communications needs of the countries in the North Atlantic region are more important than their differences in regulatory organization or facilities ownership.

The plan proposed by the International Service Carriers is in compliance, in many important ways, with the parameters established by the Commission last year. I believe that it is significant that so much agreement has been achieved in so short a time among countries with substantially divergent interests. Because of this progress, I am confident that agreement can be reached quickly on questions which remain to be resolved or issues which require clarification.

Several features of the proposed plan, however, do depart significantly from the parameters of plans 3 (revised) and 4-M and, if implemented, would cost U.S. consumers millions of dollars above the cost of the cable itself. There is no adequate justification now before the Commission for the use of the 300 additional circuits between the U.S. and Great Britain on TAT-6 and CANTAT-2 or for the 20 additional circuits between the U.S. and Belgium on CANTAT-2.

The parameters for negotiation adopted by the Commission were not viewed by us as immutable—particularly given our concern for the interests of other nations—and the Commission has today found satisfactory utilization plans which differ from those proposed by the Commission. But the Commission cannot remain indifferent to the effects of other new proposals which would place a significant burden on U.S. ratepayers.

I look forward to the results of further discussions on the need for the additional circuits, particularly since there is less expensive technology which would obtain the same result. I am confident that the results of these discussions will allow us to proceed with the schedule originally set forth in our October order.

SEPARATE STATEMENT OF COMMISSIONER ABBOTT WASHBURN

Re: Docket 18875.

FEBRUARY 26, 1976.

It is not clear if the accommodation of shortfall or increased demand will be in keeping with the concept of balanced loading as described in Section B-1 Attachment III of the USISC's April 29, 1977 filing in this docket. Per our Commission discussion, this is an important point and should the USISC need to confer with their European correspondents to provide clarification, nothing in today's announcement should inhibit such discussions.

*An organization of the postal and telecommunications entities of twenty-six European countries.

** The Canadian overseas telecommunications entity.

SEPARATE STATEMENT OF COMMISSIONER JOSEPH R. FOGARTY

In Re: Adoption of International Facilities Plan 3, Revised, for Atlantic Basin.

I join in the Commission's decision to accept Plan 3 (Munich)[1] for communications facility planning between the United States and Canada, on one side of the Atlantic, and Western Europe on the other, during the period through 1985. Since I dissented in 1977 to adoption of any facilities plan,[2] and since I continue to have many reservations about the need for additional cable capacity during the planning period, I am taking this opportunity to explain my vote and outline what I hope the Commission will accomplish by this outcome.

The decisions in this proceeding have been among the most difficult thus far in my tenure at the Commission. After hearing oral argument, studying the record, and meeting with our foreign correspondents on several occasions, I remain unconvinced that an additional cable is needed to meet projected demand within the planning period. Troublesome as this is, several other factors have led me to decide that the long-run public interest will be served by authorization of TAT-7 in 1983. These factors are:

Increased revenue requirements to be charged to the U.S. ratepayer are so minimal, on a per-circuit or per-call basis, that the additional costs more than likely will not be reflected in higher rates.

Additional competition from cable, coupled with Commission pressure or directives, should prompt Comsat to pass through future cost savings resulting from lower lease rates from INTELSAT, thus lowering overall rates to the public.

Compromise with the Europeans and Canadians should facilitate a more meaningful planning process in the future and promote a recognition of our policies favoring open entry and competition in the provision of common carrier services.

I wish to discuss each of these in turn.

The Commission's estimate of revenue requirements associated with construction of TAT-7 during the planning period, when allocated over projected years of service, should increase overall revenue requirements by far less than one percent, as National Telecommunications and Information Administration pointed out in oral argument.[3] Since cable and satellite costs are averaged in determining the international carriers' rates to the public, the overall revenue requirement impact will be even less. As international carrier rates of return are essentially unregulated, and will remain so unless and until the Commission is able to complete its International Audit in Docket No. 20778, I am confident that this insignificant increase in revenue requirements will not cause the carriers to increase rates and thereby possibly precipitate an immediate rate proceeding.

Second, the Commission has based its comparative cost analysis of cable and satellite on the total investment, allocated by circuit over each medium's service life. The applicants and others, however, have advocated use of per-circuit lease costs for satellites and investment costs for the proposed cable. The issue, as I see it, is the extent to which satellite investment will be reflected in INTELSAT's lease costs and in Comsat's charges to the carriers. While I recognize that INTELSAT's charges have generally reflected its costs in the long run, and have declined over time, Comsat has not passed through these cost savings in its tariff rates. Now, however, with our adoption of the Comsat rate case settlement,[4] I expect that the Commission will require Comsat to flow through future INTELSAT reductions on a dollar-for-dollar basis. If it does not, or if future Commission orders are required to force Comsat to flow through its savings, the Commission should reject future Comsat cost comparison arguments. Thus, if Comsat refuses to put its rates where its mouth is, then we would, I trust, be much more sympathetic to a comparison of Comsat's present lease rates with projected cable investment in determining relative costs of the media.

I would also hope that as the Commission extends its competitive policies further into the international arena, Comsat will find itself in direct competition with undersea cables to a greater extent than is now the case. Since Comsat rates are now higher than the projected costs of new cable investment to Europe, competitive pressures should have their impact on Comsat's charges, and the result may help demonstrate the validity of the Commission's methods of cost comparison.

My third point goes to the reason for my dissent in 1977. I believed then and I believe now, that we have had no meaningful overall planning process with the Europeans and Canadians looking toward an efficient system of international communications facilities spanning the Atlantic. Meetings among representatives of our countries have not succeeded in developing any agreement as to those facilities and circuits required over the coming years. Proposal, and now acceptance, of a form of Plan 3 is in large part an effort on the Commission's part to break this deadlock, propose a reasonable compromise, and thus re-vitalize the languishing consultative process. As I said in 1977, "we have no planning process; there is no 'master plan' of any meaning." It is my hope, and the expressed hope of the Commission, that the investment our ratepayers are making in TAT-7 during the planning period will result in a more efficient trans-Atlantic transmision network in the years to come.

We are shortly to meet with the foreign correspondents in Montreal to begin a new round of consultation and planning. I expect that this meeting will give us some idea of the validity of these hopes. Certainly, authorizing the cable will not guarantee a meaningful planning process for the future. But I am convinced that, if we had affirmed our adoption of Plan 4-M, without proposing Plan 3 as well, there would be no possibility of developing such a process. I believe that only by compromising with the Europeans and Canadians in this way can we hope to hold discussions that can reasonably lead to development of a master plan. As part of these discussions, we must determine common methodologies for estimating *circuit* needs for the planning period, and only then negotiate the *facilities* to meet these needs. If INTELSAT planning were to be completed before we begin such discussions, as has been the case in the past, such a process is not possible.

Coupled with the need for circuit planning is the necessity for the foreign correspondents to recognize our competitive policies. Many other foreign correspondents have balked at dealing with more than a small number of United States carriers. The specialized carriers which we have authorized to offer international services have met with almost universal opposition when seeking operating arrangements abroad. Now that the Commission has considered and, to some degree, deferred to the policies and expressed needs of the foreign governments, we should expect "tit for TAT" from the Europeans in terms of *their* recognition of *our* competitive policies and *their* agreement to deal with *our* multiplicity of carriers. Without such reciprocity, I cannot see how we can give any weight or consideration to the Europeans' internal needs and policies in our future dealings. In the final analysis, receprocity must be a two-way street, a dialogue rather than a monologue.

These considerations have convinced me that the public interest is best served by substantially accepting Plan 3 (Munich) and by authorizing a seventh Transatlantic cable to be activated in 1983.

[FR Doc. 79-8028 Filed 3-15-79; 8:45 am]

[1] With the limited exceptions noted in the Public Notice.

[2] See Report, Order and Third Statement of Policy and Guidelines, 67 FCC 2d 358, 421 (1977).

[3] Tr., P. 473.

[4] See Memorandum Opinion and Order, 68 FCC 2d 941 (1978).

[6730-01-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 obtain a copy of each of the agreements and the justifications offered therefor at the Washington Office of the Federal Maritime Commission, 1100 L Street, NW., Room 10423 or may inspect the agreements at the Field Offices located at New York, N.Y.; New Orleans, Louisiana; San Francisco, California; Chicago, Illinois; and San Juan, Puerto Rico. Interested parties may submit comments on each agreement, including requests for hearing, to the Secretary, Federal Maritime Commission, Washington, D.C., 20573, on or before March 26, 1979. Comments should include facts and arguments concerning the approval, modification, or disapproval of the proposed agreement. Comments shall discuss with particularity allegations that the agreement is unjustly discriminatory or unfair as between carriers, shippers, exporters, importers, or ports, or between exporters from the United States and their foreign competitors, or operates to the detriment of the commerce of the United States, or is contrary to the public interest, or is in violation of the Act.

A copy of any comments should also be forwarded to the party filing the agreements and the statement should indicate that this has been done.

Agreement No. 9929-3 (Sub. No. 1).
Filing party: Mr. Edward Schmeltzer, Esquire, Schmeltzer, Aptaker & Sheppard, P.C., 1800 Massachusetts Avenue, NW., Washington, D.C. 20036.
Summary: Agreement No. 9929-3 (Sub-No. 1), between Hapag-Lloyd A.G., Intercontinental Transport (ICT) B.V. and Compagnie Generale Maritime, modifies the parties' basic joint service agreement under the name of Combi Line, by amending Article 4.3 thereof to provide that the non-LASH services of the parties shall remain effective "*pendente lite* FMC Docket No. 77-7." This service is to expire April 8, 1979.

By order of the Federal Maritime Commission.

Dated: March 13, 1979.

FRANCIS C. HURNEY,
Secretary.

[FR Doc. 79-8047 Filed 3-15-79; 8:45 am]

[1610-01-M]

GENERAL ACCOUNTING OFFICE

REGULATORY REPORTS REVIEW

Denial of Interstate Commerce Commission Reporting Requirement

On December 27, 1978, we received ICC's request—pursuant to section 409 of Pub. L. 93-153—to extend for 1 year the Quarterly Report of Freight Loss and Damage Claims—Motor Carriers, Form QL&D-M.

The Federal Reports Act, 44 U.S.C. 3512 (a) and (c), requires GAO to determine, among other things that the "information required—is obtained with a minimum burden" on respondents before an independent regulatory agency uses the reporting requirement to collect information. During our review of ICC's QL&D-M form, we found that ICC and the Department of Transportation, the form's primary user, do not currently use or plan to use the information required on this form's Schedule B. As a result of this finding, we concluded that the reporting burden imposed by Schedule B has not been minimized and the schedule does not comply with the Federal Reports Act. Accordingly, by letter dated March 12, 1979, to ICC, we approved Schedules A and C of ICC's QL&D-M form through September 30, 1979, and we denied clearance for Schedule B. We hereby advise respondents that any request by ICC for Schedule B information in the Quarterly Report of Freight Loss and Damage Claims—Motor Carriers will violate the Federal Reports Act.

NORMAN F. HEYL,
Regulatory Reports Review Staff.

[FR Doc. 79-7973 Filed 3-15-79; 8:45 am]

[1610-01-M]

REGULATORY REPORTS REVIEW

Receipt of Report Proposal

The following request for clearance of a report intended for use in collecting information from the public was received by the Regulatory Reports Review Staff, GAO, on March 8, 1979. See 44 U.S.C. 3512(c) and (d). The purpose of publishing this notice in the FEDERAL REGISTER is to inform the public of such receipt.

The notice includes the title of the request received; the name of the agency sponsoring the proposed collection of information; the agency form number, if applicable; and the frequency with which the information is proposed to be collected.

Written comments on the proposed FTC request are invited from all interested persons, organizations, public interest groups, and affected businesses. Because of the limited amount of time GAO has to review the proposed request, comments (in triplicate) must be received on or before April 2, 1979, and should be addressed to Mr. John M. Lovelady, Assistant Director, Regulatory Reports Review, United States General Accounting Office, Room 5106, 441 G Street, NW, Washington, DC 20548.

Further information may be obtained from Patsy J. Stuart of the Regulatory Reports Review Staff, 202-275-3532.

FEDERAL TRADE COMMISSION

The FTC is requesting clearance of a new, voluntary, Rulemaking Conference Impact Evaluation Questionnaire. The FTC pursuant to the authority granted under the Magnuson-Moss/FTC Improvement Act has established a compensation program for public participation in its rulemaking proceedings. Funds are available to compensate groups and individuals who represent an interest that would not be adequately represented otherwise, and where consideration of such interest is necessary for a fair determination of the issues. Applicants must also demonstrate that they would be unable to participate effectively without public compensation because of an inability to meet the costs which such participation would entail. In an effort to broaden the access to this program and participation in its proceedings the FTC has sponsored a model seminar to train likely candidates for reimbursement in the basics of the application process, on the role of public participants and on how to tailor and manage an effective participation effort. Over fifty community and consumer group leaders attended the model seminar held September 27, 1978. In an attempt to assess the effectiveness of the training seminar format and materials used, the FTC will survey the attendees and the information obtained through the use of the questionnaire will be used to determine whether the program should be extended and offered to similar individuals across the country. The FTC estimates that respondent burden for the questionnaire will average one hour for each of the 53 attendees to the first seminar and that if the other six seminars are held there will be approximately 300 additional respondents who will be asked to complete the questionnaire.

NORMAN F. HEYL,
Regulatory Reports Review Officer.

[FR Doc 79—7972 Filed 3-15-79; 8:45 am]

[6820-61-M]

GENERAL SERVICES ADMINISTRATION

[Intervention Notice 84; Docket No. U-5979]

MICHIGAN PUBLIC SERVICE COMMISSION AND CONSUMERS POWER CO.

Proposed Intervention in Electric Rate Increase Proceeding

The Administrator of General Services seeks to intervene in a proceeding before the Michigan Public Service Commission involving an application of the Consumers Power Company for an increase in its interim electric rate relief. The Administrator of General Services represents the interests of the executive agencies of the United States Government as users of utility services.

Persons desiring to make inquiries of GSA concerning this case should submit them, in writing, to Mr. Spence W. Perry, Assistant General Counsel, Regulatory Law Division, General Services Administration, 18th & F Streets, NW., Washington, DC 20405, telephone (202) 566-0726, on or before April 16, 1979, and refer to this notice number.

Persons making inquiries are put on notice that the making of an inquiry shall not serve to make any persons parties of record in the proceeding.

(Sec. 201(a)(4), Federal Property and Administrative Services Act, 40 U.S.C. 481(a)(4).)

Dated: February 22, 1979.

JAY SOLOMON,
Administrator of General Services.

[FR Doc. 79-7996 Filed 3-15-79; 8:45 am]

[6820-24-M]

[Intervention Notice 83; Case No. U-6006]

MICHIGAN PUBLIC SERVICE COMMISSION AND DETROIT EDISON CO.

Proposed Intervention in Rate Increase Proceeding

The Administrator of General Services seeks to intervene in a proceeding before the Michigan Public Service Commission involving an application of the Detroit Edison Company for an increase in its annual electric revenues. The Administrator of General Services represents the interests of the executive agencies of the United States Government as users of utility services.

Persons desiring to make inquiries of GSA concerning this case should submit them, in writing, to Mr. Spence W. Perry, Assistant General Counsel, Regulatory Law Division, General Services Administration, 18th & F Streets, NW., Washington, DC 20405, telephone (202) 566-0726, on or before April 16, 1979, and refer to this notice number.

Persons making inquiries are put on notice that the making of an inquiry shall not serve to make any persons parties of record in the proceeding.

(Sec. 201(a)(4), Federal Property and Administrative Services Act, 40 U.S.C. 481(a)(4).)

Dated: February 8, 1979.

JAY SOLOMON,
Administrator of General Services.

[FR Doc. 79-7995 Filed 3-15-79; 8:45 am]

[6820-24-M]

[Federal Property Management Regulations; Temporary Regulation E-61]

SECRETARY OF DEFENSE

Delegation of Authority

Subject: Delegation of authority.

1. *Purpose.* This regulation delegates authority to the Secretary of Defense to represent the interests of the executive agencies of the Federal Government in an electric and gas rate proceeding.

2. *Effective date.* This regulation is effective immediately.

3. *Delegation.*

a. Pursuant to the authority vested in me by the Federal Property and Administrative Services Act of 1949, 63 Stat. 377, as amended, particularly sections 201(a)(4) and 205(d) (40 U.S.C. 481(a)(4) and 486(d)), authority is delegated to the Secretary of Defense to represent the consumer interests of the executive agencies of the Federal Government before the Kentucky Public Service Commission involving the application of the Louisville Gas and Electric Company for an increase in rates.

b. The Secretary of Defense may redelegate this authority to any officer, official, or employee of the Department of Defense.

c. This authority shall be exercised in accordance with the policies, procedures, and controls prescribed by the General Services Administration, and shall be exercised in cooperation with the responsible officers, officials, and employees thereof.

Dated: February 14, 1979.

JAY SOLOMON,
Administrator of General Services.

[FR Doc. 79-7997 Filed 3-15-79; 8:45 am]

[4110-03-M]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

ADVISORY COMMITTEES

Meetings

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: This notice announces forthcoming meetings of public advisory committees of the Food and Drug Administration (FDA). This notice also sets forth a summary of the procedures governing committee meetings and methods by which interested persons may participate in open public hearings conducted by the committees and is issued under section 10(a) (1) and (2) of the Federal Advisory Committee Act (Pub. L. 92-463, 86 Stat. 770-776 (5 U.S.C. App. I)), and FDA regulations 921 CFR Part 14) relating to advisory committees. The following advisory committee meetings are announced:

Committee name	Date, time, and place	Type of meeting and contact person
1. Dermatology Subcommittee of the Anti-Infective and Topical Drugs Advisory Committee.	April 10, 9 a.m. Conference room C, Parklawn Bldg., 5600 Fishers Lane, Rockville, Md.	Open public hearing, 9 a.m. to 10 a.m.; open committee discussion 10 a.m. to 5 p.m., Mary K. Bruch (HFD-140), 5600 Fishers Lane, Rockville, Md. 20857, 301-443-4310.

General function of the Committee. The Committee reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational prescription drugs for use in infectious diseases, dermatological disorders, and ocular disease.

Agenda—Open public hearing. Any interested persons may present data, information, or views, orally or in writing, on issues pending before the Committee.

Open committee discussion. The Subcommittee will consider adrenal suppression studies as part of guidelines for testing topical corticosteriods; sulfones and sulfapyridine—addition of "Dermatitis Herpetiformis" to the indications section of the labeling of these drugs; and update on Psoralens ultra-violet A (PUVA).

Committee name	Date, time, and place	Type of meeting and contact person
2. Drug Abuse Advisory Committee	April 17, 9 a.m., Conference room G-H, Parklawn Bldg., 5600 Fishers Lane, Rockville, Md.	Open public hearing 9 a.m. to 10 a.m.; open committee discussion 10 a.m. to 4:30 p.m.; Robert C. Nelson (HFD-120), 5600 Fishers Lane, Rockville, Md. 20857, 301-443-3800.

General function of the Committee. The Committee advises on the scientific and medical evaluation of information gathered by the Department of Health, Education, and Welfare and the Department of Justice on the

safety, efficacy, and abuse potential of drugs and recommends actions to be taken on the marketing, investigation, and control of such drugs.

Agenda—Open public hearing. Any interested persons may present data, information, or views, orally or in writing, on issues pending before the Committee.

Open Committee discussion. The Committee will discuss Propoxyphene—conclusive evaluation to determine the appropriateness of current scheduling under the Controlled Substances Act (continuation of the February 13, 1979, meeting).

Committee name	Date, time, and place	Type of meeting and contact person
3. Miscellaneous Internal Drug Products Panel	April 17 and 18, 9 a.m., Conference room A, Parklawn Bldg., 5600 Fishers Lane, Rockville, Md.	Open public hearing 9 a.m. to 10 a.m.; open committee discussion April 17, 10 a.m. to 5 p.m., April 18, 8:30 a.m. to 4 p.m., Armond Welch (HFD-510), 5600 Fishers Lane, Rockville, Md. 20857, 301-443-6156.

General function of the Committee. The Committee reviews and evaluates available data concerning the safety and effectiveness of nonprescription drug products.

Agenda—Open public hearing. Any interested persons may present data, information, or views, orally or in writing, on issues pending before the Committee. Those who desire to make such a presentation should notify the contact person before April 12, 1979, and submit a brief statement of the general nature of the data, information, or views they wish to present, the names and addresses of proposed participants, and an indication of the approximate time desired for their presentation.

Open committee discussion. The Panel will review data submitted in response to the over-the-counter (OTC) review's call for data for this Panel (see also 21 CFR 330.10(a)(2)). The Panel will be reviewing, voting upon, and modifying the content of summary minutes and categorization of ingredients and claims.

Committee name	Date, time, and place	Type of meeting and contact person
4. Ad Hoc Subcommittee of the Drug Abuse Advisory Committee to Study the "Effects of Scheduling".	April 18, 9 a.m., Conference room L, Parklawn Bldg., 5600 Fishers Lane, Rockville, Md.	Open public hearing 9 a.m. to 10 a.m.; open committee discussion 10 a.m. to 4:30 p.m.; Robert C. Nelson (HFD-120), 5600 Fishers Lane, Rockville, Md. 20857, 301-443-3800.

General function of the Committee. The Committee advises on the scientific and medical evaluation of information gathered by the Department of Health, Education, and Welfare and the Department of Justice on the safety, efficacy, and abuse potential of drugs and recommends actions to be taken on the marketing, investigation, and control of such drugs.

Agenda—Open public hearing. Any interested persons may present data, information, or views, orally or in writing, on issues pending before the Committee.

Open committee discussion. This Subcommittee is charged with the study of "effects of scheduling" and will examine and discuss various information sources as they relate to data required in the area of abuse of prescription drug products.

Committee name	Date, time, and place	Type of meeting and contact person
5. Science Advisory Board	April 19 and 20, 9 a.m., Bldg. 13, National Center for Toxicological Research, Jefferson, Ar[12].	Open public hearing April 19, 9 a.m. to 10 a.m.; open committee discussion April 19, 10 a.m. to 4:30 p.m.; April 20, 9 a.m. to 4:30 p.m.; Ruth Magee, National Center for Toxicological Research, Jefferson, AR 72079, 501-541-4528.

General function of the Committee. The Committee advises on establishment and implementation of a research program that will assist the Commissioner of Food and Drugs and the Administrator, Environmental Protection Agency, in fulfilling their regulatory responsibilities.

Agenda—Open Public hearing. Any interested persons may present data, information, or views, orally or in writing, on issues pending before the Committee.

Open committee discussion. The Committee will discuss NCTR overview; National Toxicology Program; Toxicology Profile Master Plan; rotenone; saccharin; collaborative behavioral teraology study, heritable translocation document; and microlesions study status report.

Committee name	Date, time, and place	Type of meeting and contact person
6. Allergenic Extracts Panel	April 27 and 28, 9 a.m., room 719, 11140 Rockville Pike, Rockville, Md..	Open public hearing April 27, 9 a.m. to 10 a.m.; open committee discussion April 27, 10 a.m. to 4 p.m.; April 28, 9 a.m. to 4 p.m.; Clay Sisk (HFB-5), 8800 Rockville Pike, Bethesda, Md. 20014, 301-443-5455.

General function of the Committee. The Committee reviews and evaluates available data concerning the safety and effectiveness of biological products.

Agenda—Open public hearing. Any interested persons may present data, information, or views, orally or in writing, on issues pending before the Committee.

Open committee discussion. The Committee will discuss house dust extracts and will review and edit the panel report on the safety, effectiveness, and labeling of allergenic extracts.

Committee name	Date, time, and place	Type of meeting and contact person
7. Antimicrobial Panel	April 27 and 28, 9 a.m., Conference room C, Parklawn Bldg., 5600 Fishers Lane, Rockville, Md., (April 27); Holiday Inn, Bethesda, Md., (April 28).	Open public hearing April 27, 9 a.m. to 10 a.m.; open committee discussion April 27, 10 a.m. to 4:30 p.m.; April 28, 9 a.m. to 4:30 p.m.; Lee Geismar (HFD-512), 5600 Fishers Lane, Rockville, Md. 20857, 301-443-6057.

General function of the Committee. The Committee reviews and evaluates available data concerning the safety and effectiveness of nonprescription drug products.

Agenda—Open public hearing. Any interested persons may present data, information, or views, orally or in writing, on issues pending before the Committee. Those who desire to make such a presentation should notify the contact person before April 24, 1979, and submit a brief statement of the general nature of the data, information, or views they wish to present, the names and addresses of proposed participants, and an indication of the approximate time desired for their presentation.

Open committee discussion. The Panel will review data submitted in response to the over-the-counter (OTC) review's call for data for this Panel (see also 21 CFR 330.10(a)(2)). The Panel will be reviewing, voting upon, and modifying the content of summary minutes and categorization of ingredients and claims.

Committee name	Date, time, and place	Type of meeting and contact person
8. Miscellaneous External Drug Products Panel	April 29 and 30, 9 a.m., Pennsylvania Room, Holiday Inn, Bethesda, Md., (April 29); Conference room I, Parklawn Bldg., 5600 Fishers Lane, Rockville, Md., (April 30).	Open public hearing April 29, 9 a.m. to 10 a.m.; open committee discussion April 29, 10 a.m. to 4:30 p.m.; April 30, 9 a.m. to 4:30 p.m.; John T. McElroy (HFD-515), 5600 Fishers Lane, Rockville, Md. 20857, 301-443-4960.

General function of the Committee. The Committee reviews and evaluates available data concerning the safety and effectiveness of nonprescription drug products.

Agenda—Open public hearing. Any interested persons may present data, information, or views, orally or in writing, on issues pending before the Committee. Those who desire to make such a presentation should notify the contact person before April 25, 1979, and submit a brief statement of the general nature of the data, information, or views they wish to present, the names and addresses of proposed participants, and an indication of the approximate time desired for their presentation.

Open committee discussion. The Panel will review data submitted in response to the over-the-counter (OTC) review's call for data for this Panel (see also 21 CFR 330.10(a)(2)). The Panel will be reviewing, voting upon, and modifying the content of summary minutes and categorization of ingredients and claims.

FDA public advisory committee meetings may have as many as four separable portions: (1) An open public hearing, (2) an open committee discussion, (3) a closed presentation of data, and (4) a closed committee deliberation. Every advisory committee meeting shall have an open public hearing portion. Whether or not it also includes any of the other three portions will depend upon the specific meeting involved. There are no closed portions for the meetings announced in this notice. The dates and times reserved for the open portions of each committee meeting are listed above.

The open public hearing portion of each meeting shall be at least 1 hour long unless public participation does not last that long. It is emphasized, however, that the 1 hour time limit for an open public hearing represents a minimum rather than a maximum time for public participation, and an open public hearing may last for whatever longer period the committee chairman determines will facilitate the committee's work.

Meetings of advisory committees shall be conducted, insofar as is practical, in accordance with the agenda published in this FEDERAL REGISTER notice. Changes in the agenda will be announced at the beginning of the open portion of a meeting.

Any interested person who wishes to be assured of the right to make an oral presentation at the open public hearing portion of a meeting shall inform the contact person listed above, either orally or in writing, prior to the meeting. Any person attending the hearing who does not in advance of the meeting request an opportunity to speak will be allowed to make an oral presentation at the hearing's conclusion, if time permits, at the chairman's discretion.

Persons interested in specific agenda items to be discussed in open session may ascertain from the contact person the approximate time of discussion.

A list of committee members and summary minutes of meetings may be obtained from the Public Records and Documents Center (HFC-18), 5600

Fishers Lane, Rockville, Md. 20857, between the hours of 9 a.m. and 4 p.m., Monday through Friday. The FDA regulations relating to public advisory committees may be found in 21 CFR Part 14.

The Commissioner approves the scheduling of meetings at locations outside of the Washington, D.C., area on the basis of the criteria of 21 CFR 14.22 of FDA's regulations relating to public advisory committees.

Dated: March 12, 1979.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-7969 Filed 3-15-79; 8:45 am]

[1505-01-M]

[Docket No. 76N-0249]

BUCLIZINE HYDROCHLORIDE

Final Order on Objections and Request for a Hearing Regarding Approval of Supplemental New Drug Application

NOTE: This document originally appeared in the FEDERAL REGISTER for Monday, March 12, 1979. It is reprinted in this issue to meet requirements for publication on an assigned day of the week. (See OFR notice 41 FR 32914, August 6, 1976.)

Correction

In FR Doc. 79-1739 appearing at page 4012 in the issue for Friday, January 19, 1979, make the following correction: On page 4012, in the last column, under the heading, FOR FURTHER INFORMATION CONTACT, the telephone number given should be "(301-443-4020)".

[4110-03-M]

CONSUMER PARTICIPATION

Open Meeting

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: This document announces a forthcoming Consumer Exchange Meeting to be chaired by the Commissioner of Food and Drugs.

DATE: The meeting will be held at 1:30 p.m., Wednesday, March 21, 1979.

ADDRESS: The meeting will be held at: 200 C St. SW., FOB #8, Rm. 1409, Washington, DC.

FOR FURTHER INFORMATION CONTACT:

Alexander Grant, Special Assistant to the Commissioner for Consumer Affairs (HF-7), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1547.

SUPPLEMENTARY INFORMATION: The purpose of the meeting is to exchange information between FDA officials and consumer representatives concerning:

1. Compensation of Public Participants in Certain FDA Administrative Proceedings.

2. Depo-Provera:

a. Should Depo-provera be reapproved as a 3-month injectable contraceptive?

b. Can Depo-provera be legally exported—within the context of the report provision of the new drug bill?

3. Effectiveness of OTC Contraceptives.

4. Alpha-Fetoprotein: Discussion of public hearings held on 02/26/79.

Current FDA policy will be explained, issues discussed, and areas identified requiring action or followup.

Dated: March 12, 1979.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner to Regulatory Affairs.

[FR Doc. 79-7967 Filed 3-15-79; 8:45 am]

[1505-01-M]

[Docket No. 78N-0311]

DRUGS FOR VETERINARY USE; DRUG EFFICACY STUDY IMPLEMENTATION

Nitrofurazone Topical Preparations

NOTE: This document originally appeared in the FEDERAL REGISTER for Monday March 12, 1979. It is reprinted in this issue to meet requirements for publication on an assigned day of the week. (See CFR notice 41 FR 32914, August 6, 1976.)

Correction

In FR Doc. 79-1837 appearing at page 4014 in the issue for Friday, January 19, 1979, make the following corrections:

(1) On page 4014, in the middle column, under the heading, DATE, substitute "July 18, 1979" for "July 30, 1979".

(2) One page 4015, in the last column, in the 2nd full paragraph, in the 4th line, substitute "July 18, 1979" for "July 30, 1979".

[4110-03-M]

[Docket No. 78P-0143]

TOMATO JUICE DEVIATING FROM IDENTITY STANDARD

Temporary Permit for Market Testing

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: This notice announces that a temporary permit has been issued to Cliffstar Corp. to market test tomato juice from concentrate. The purpose of the temporary permit is to permit the applicant to measure consumer acceptance of the food.

DATES: This permit is effective for 15 months, beginning on the date the new food is introduced into or caused to be introduced into interstate commerce, but no later than June 14, 1979. However, the permit may terminate sooner, depending upon the final action on the Food and Drug Administration (FDA) published proposal to amend the standard of identity for tomato juice.

FOR FURTHER INFORMATION CONTACT:

F. Leo Kauffman, Bureau of Foods (HFF-414), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C St. SW., Washington, DC 20204, 202-245-1164.

SUPPLEMENTARY INFORMATION: In accordance with § 130.17 (21 CFR 130.17), concerning temporary permits to facilitate market testing of foods deviating from the requirements of the standards of identity promulgated under section 401 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341), the agency announces that a temporary permit has been issued to Cliffstar Corp., Dunkirk, NY 14048. This permit covers interstate marketing tests of tomato juice that deviates from the standard of identity prescribed in § 156.145 (21 CFR 156.145). The permit provides for the temporary marketing of a total of 100,000 cases of twelve 46-ounce cans and twelve 32-ounce bottles to be distributed in the States of Connecticut, Massachusetts, Michigan, New Jersey, New York, Ohio, Pennsylvania, and Rhode Island. Approximately half of the distribution in each State will be in cans and half in bottles.

The test product is prepared from concentrated tomato liquid that complies with the requirements of § 155.192(a)(1) (21 CFR 155.192(a)(1)). The finished product will be equivalent to a single-strength tomato juice normally found in the marketplace. The finished product will contain not

less than 5.5 percent tomato soluble solids.

The principal display panel of the label will state the product name as "tomato juice from concentrate." Each of the ingredients used will be stated on the label as required by the applicable sections of Part 101 (21 CFR Part 101), except that the tomato ingredient complying with the requirements of § 155.192(a)(1) will be declared as "tomato concentrate." This permit is effective for 15 months, beginning on the date the new food is introduced or caused to be introduced into interstate commerce, but no later than June 14, 1979. However, the permit may terminate sooner, depending upon the final action on the proposal to amend the standard of indentity for tomato juice, which was published in the FEDERAL REGISTER of May 9, 1978 (43 FR 19864). If the final action taken is to affirm the proposal, the permit shall terminate on the effective date of the final regulation. If the final action is to reject the proposed amendment, the permit shall expire 30 days following such negative ruling on the proposal.

Dated: March 12, 1979.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-7968 Filed 3-15-79; 8:45 am]

[4110-08-M]

National Institutes of Health

REPORT ON BIOASSAY OF TOXAPHENE FOR POSSIBLE CARCINOGENICITY

Availability

Toxaphene (CAS 8001-35-2) has been tested for cancer-causing activity with rats and mice in the Carcinogenesis Testing Program, Division of Cancer Cause and Prevention, National Cancer Institute. A report is available to the public.

Summary: A bioassay of technical-grade toxaphene for possible carcinogenicity was conducted by administering the test chemical in feed to Osborne-Mendel rats and B6C3F1 mice. Applications of the chemical include use as a pesticide.

It is concluded that under the conditions of this bioassay, toxaphene was carcinogenic in male and female B6C3F1 mice, causing increased incidences of hepatocellular carcinomas. The test results also suggest carcinogenicity of toxaphene for the thyroid of male and female Osborne-Mendel rats.

Single copies of the report, Bioassay of Toxaphene for Possible Carcinogenicity (T.R. 37), are available from the Office of Cancer Communications, National Cancer Institute, Building 31, Room 10A21, National Institutes of Health, Bethesda, Maryland 20014.

(Catalogue of Federal Domestic Assistance Program Number 13.393, Cancer Cause and Prevention Research)

Dated: March 8, 1979.

DONALD S. FREDRICKSON,
Director, National Institutes of Health.

[FR Doc. 79-7430 Filed 3-15-79; 8:45 am]

[4110-02-M]

Office of Education

LAW SCHOOL CLINICAL EXPERIENCE PROGRAM

Closing Date for Transmittal of Applications for Fiscal Year 1979; Funding Criteria

This Notice announces the closing date for applications for grants under the Law School Clinical Experience Program. It also announces the funding criteria the Commissioner applies in making the awards.

Authority for this program is contained in Section 1101 of the Higher Education Act of 1965, as amended (20 U.S.C. 1136, 1136a and b).

CLOSING DATE FOR TRANSMITTAL OF APPLICATIONS: Applications for awards must be mailed (postmarked) or hand-delivered by May 11, 1979.

A. APPLICATIONS DELIVERED BY MAIL: An application sent by mail must be addressed to the U.S. Office of Education, Application Control Center, Attention: 13:584, Washington, D.C. 20202.

Proof of mailing must consist of a legible U.S. Postal Service dated postmark or a legible receipt with the date of mailing stamped by the U.S. Postal Service. Private metered postmarks or mail receipts will not be accepted without a legible date stamped by the U.S. Postal Service. (Note: The U.S. Postal Service does not uniformly provide a dated postmark. Applicants should check with their local post office before relying on this method.) Applicants are encouraged to use registered or at least first class mail.

Each late applicant will be notified that its application will not be considered in the current competition.

B. APPLICATIONS DELIVERED BY HAND: An application that is hand delivered must be taken to the U.S. Office of Education, Application Control Center, Room 5673, Regional Office Building 3, 7th and D Streets, S.W., Washington, D.C.

The application Control Center will accept hand-delivered applications between 8:00 a.m. and 4:00 p.m. (Washington, D.C., time) daily, except Saturdays, Sundays, and Federal holidays.

Applications that are hand-delivered will not be accepted after 4:00 p.m. on the closing date.

C. PROGRAM INFORMATION:

1. *Eligible applicants.* Only accredited law schools may apply for awards. (20 U.S.C. 1136(a)).

2. *Available funds.* Approximately $2,000,000 is available for the Law School Clinical Experience Program in FY 1979.

It is estimated that these funds could support approximately 50 projects.

The anticipated award for new projects will be between $30,000 and $40,000.

These estimates do not bind the U.S. Office of Education except as may be required by the applicable statute and regulations.

3. *Funding criteria.* The funding criteria governing the Law School Clinical Experience Program, published in the FEDERAL REGISTER on July 12, 1978 (43 FR 29996) are applicable to awards made for fiscal year 1979. A copy is appended to this Notice.

These criteria were published as final funding criteria for fiscal year 1978, because the program was funded in FY 1978 as a one-time demonstration program. The funding criteria were published as a Notice of Proposed Rulemaking. Comments were received and considered. The final funding criteria were published without change.

An appropriation is now available for the program for FY 1979. In view of the fact that the criteria for FY 1978 were adopted without change and have been favorably received. Proposed rulemaking is waived under authority of 5 U.S.C. 553(d)(3) to meet the demands of the funding cycle and to award grants for FY 1979 in a timely manner. The funding criteria published for FY 1978 are adopted as funding criteria for awards under the program in FY 1979.

D. APPLICATION FORMS: Application forms and program information packages are expected to be ready for mailing by March 26, 1979. They may be obtained by writing to the Graduate Training Branch, U.S. Office of Education (Room 3060, Regional Office Building 3), 400 Maryland Avenue, S.W., Washington, D.C. 20202.

Applications must be prepared and submitted in accordance with the criteria, instructions, and forms included in the program information packages.

FURTHER INFORMATION: For further information contact Dr. Donald N. Bigelow, Chief, Graduate Training Branch, U.S. Office of Education (Room 3060, Regional Office Building 3), 400 Maryland Avenue,

S.W., Washington, D.C. 20202, Telephone: (202) 245-2347.

(20 U.S.C. 1136, 1136a and b)

(Catalog of Federal Domestic Assistance Number 13.584, Law School Clinical Experience Program)

Dated: February 16, 1979.

ERNEST L. BOYER,
U.S. Commissioner of Education.

APPENDIX

FINAL FUNDING CRITERIA—LAW SCHOOL CLINICAL EXPERIENCE PROGRAM

Review of Applications and Administration of Awards—Funding Criteria for Evaluating Applications and Considerations for Awarding Grants. The U.S. Commissioner of Education shall take into account the following considerations when evaluating applications for grants under the Law School Clinical Experience Program:

(1) The application will assist in attaining a wider distribution throughout the United States of higher quality Law Clinical Experience Programs;

(2) The proposed project would provide a demonstration in training of law students by supervised use of legal skills on behalf of varied client groups, and;

(3) The extent to which the proposed project ranks high on the criteria set forth below, with the maximum point score for each criterion as shown:

(i) The proposed project indicates that the law school has a commitment to clinical legal education as demonstrated by the degree to which the institution's regular budget is devoted to continuing an existing program or will be devoted to the establishment of a new program. (15 points)

(ii) The proposed project will either establish for the first time a new program of clinical legal education or expand an existing program in which case these factors will be evaluated: developing new areas of practical experience, increasing the number of participating students, and providing appropriate and improved supervision. (20 points)

(iii) The proposed project will provide actual experience in legal skills such as the preparation and trial of actual cases, including administrative cases and the settlement of cases and controversies outside the courtroom. This experience may include, but not necessarily be limited to, the development of such skills as interviewing witnesses, counseling clients, negotiating compromises, drafting documents, trial preparation, advocacy, and training in professional responsibility. (20 points)

(iv) The law school administration and faculty have sufficient experience, time and resources (including a director) to provide adequate on-the-job supervision to students, while they are learning legal skills in the proposed program of clinical legal education. (15 points)

(v) The proposed program of law school clinical experience provides for the award of appropriate academic credits to participating students. (15 points)

(vi) The proposed project places emphasis on increasing the law school's involvement in clinical legal education while maintaining the quality of the supervision. (10 points)

(vii) The proposed project indicates that the law school plans to incorporate into its curriculum the experience and knowledge gained from the proposed demonstration project. (5 points)

General Provisions Regulations. Assistance under this program is subject to the provisions of 45 CFR Parts 100 and 100a (Office of Education General Provisions Regulations), except for the funding criteria set out at 45 CFR 100a.26(b).

(20 U.S.C. 1136-1136b)

[FR Doc. 79-8027 Filed 3-15-79; 8:45 am]

[4310-84-M]

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[INT DES 79-11]

PROPOSED GRAZING MANAGEMENT PROGRAM FOR THE EAST SOCORRO ENVIRONMENTAL STATEMENT AREA, SOCORRO, NEW MEXICO

Availability of Draft Environmental Statement and Hearing

In accordance with Section 102(2)(C) of the National Environmental Policy Act of 1969, the Bureau of Land Management (BLM) has prepared a Draft Environmental Statement on a proposed Range Management Program to improve forage for livestock, wild horses and wildlife, and construction of range developments.

The statement addresses an improved livestock grazing management program on 838,808 acres of public land. The proposed action includes grazing management plans designed to enhance the vegetation resources, improve range conditions, reduce erosion, improve water quality, provide quality habitat for wildlife and wild horses, protect archaeological and historical sites, and provide a continuous supply of livestock forage. Adjustments in livestock grazing use and construction of water developments and fencing are also proposed.

Copies are available for inspection at the BLM District Office, 200 Neel Avenue, Socorro, New Mexico, and the BLM State Office, Federal Building, Santa Fe, New Mexico.

In addition to the above locations, reading copies are available at public and/or university libraries in Socorro, Albuquerque, Las Gruces, Belen, and Truth or Consequences, New Mexico.

Public hearings will be held in Socorro at the County Courthouse at 7 p.m. on April 24, 1979 and in Albuquerque at the Convention Center at 7 p.m. on April 25, 1979.

The hearing will provide the BLM, under Section 102(2)(C) of the National Environmental Policy Act of 1969, with the opportunity to receive additional comments and views of interested State and local agencies and the public.

Interested individuals, representatives of organizations, and public officials wishing to testify are requested to contact Steve Fischer, Public Affairs Office, at the BLM District Office in Socorro by April 19, 1979, phone (505) 835-0412. Written requests to testify should identify the organization represented, be signed by the prospective witness, and state a phone number for contact purposes. Because of time constraints, oral testimony will be limited to 10 minutes unless additional time is requested in advance.

Oral testimony can be supplemented with written statements at the time oral testimony is presented. Also, speakers with prepared speeches may file their text with the presiding officer whether or not they have been able to finish oral delivery in the allotted time. If time permits, following oral testimony by those who have given advance notice, the hearings office will give others an opportunity to be heard.

Dated: February 22, 1979.

FRANK GREGG,
Director.

Approved:

LARRY E. MEIEROTTO,
Deputy Assistant Secretary of the Interior.

[FR Doc 79—7966 Filed 3-15-79; 8:45 am]

[4310-84-M]

[M 35734 and M 35735]

MONTANA

Coal Lease Offering by Sealed Bid

MARCH 8, 1979.

U.S. Department of the Interior, Bureau of Land Management, Montana State Office, Granite Tower Building, 222 North 32nd Street, P.O. Box 30157, Billings, Montana 59107. Notice is hereby given that at 2 p.m., March 30, 1979, in the Conference Room on the 6th Floor of the Granite Tower Building, the coal resources in the tracts described below will be offered for competitive lease by sealed bid to the qualified bidder submitting the highest bid amount. The tracts are being offered separately and will result in two competitive leases. This offering is being made as a result of two applications filed by the Western Energy Company and in accordance with the provisions of the Mineral Leasing Act of 1920 (41 Stat. 437), as amended, and the Department of Energy Organization Act of August 4, 1977 (91 Stat. 565, 42 U.S.C. 7101). Bidders shall formulate their bids using one, but not both, of the following cash-bonus payment methods:

TRACT 1 (M 35734)

(1) The bidder may elect to accept a royalty figure of 21 percent of the production from surface mining, but not less than $1.47 per ton, and begin bidding at the minimum $25 per acre or fraction thereof, or

(2) The bidder may elect to accept a royalty figure of 12.5 percent of the production from surface mining and begin bidding at the minimum of $3,495 per acre.

TRACT 2 (M 35735)

(1) The bidder may elect to accept a royalty figure of 21 percent of the production from surface mining, but not less than $1.47 per ton, and begin bidding at the minimum $25 per acre or fraction thereof, or

(2) The bidder may elect to accept a royalty figure of 12.5 percent of the production from surface mining and begin bidding at the minimum of $3,422 per acre.

The bids will then be reviewed to calculate the highest bidder. No bids received after 2 p.m. on the day of the sale will be considered. Sealed bids may not be modified or withdrawn unless such modification or withdrawal is received before the date, time and place set for the opening of such bids. The successful bidder is obligated to pay for the newspaper publication of this Notice.

COAL OFFERED

TRACT 1 (M 35734)

T. 1 N., R. 41 E., P.M.M.,
Sec. 10, N½, N½S½.

480.00 acres.

TRACT 2 (M 35735)

T. 1 N., R. 41 E., P.M.M.,
Sec. 2, Lots 3, 4, S½NW¼, SW¼, W½SE¼, SE¼SE¼.

446.95 acres.

The tracts are located in Rosebud County near Colstrip, Montana.

The coal resources offered are limited to the Rosebud bed. The Conservation Division, Geological Survey, has reported that Tract 1 (M 34734) contains 11.8 million tons and Tract 2 (M 35735) contains 10.7 million tons of coal recoverable by surface mining methods under a maximum overburden depth of 150 feet at 94 percent recovery. The average coal thickness projected over the entire proposed leasehold is 24 feet. The heating value of the noncoking coal is about 9060 BTU's per pound with a sulfur content of about 0.7 percent. The coal resources are within the Powder River Known Recoverable Coal Resource Area.

RENTAL AND ROYALTY

The leases issued as a result of this offering will provide for payment of an annual rental of $3 per acre or fraction thereof and a royalty at the rate determined by the bidding procedure. The royalty shall be payable to the United States on the value of coal mined by strip mining methods. The value of coal shall be determined in accordance with 30 CFR 211.63.

PUBLIC COMMENTS

The public is invited to submit written comments to the Bureau of Land Management on the fair market value of the coal to be leased. Public comments should be sent to the State Director, Bureau of Land Management, at the address given above, to arrive no later than March 23, 1979.

DETAILED STATEMENT OF SALE

A detailed statement of the sale, including bidding instructions and the terms of the leases, is available at the office listed above. All case file documents and written comments submitted by the public on fair market value or royalty rates, except those portions identified as proprietary which meet the exemptions stated in the Freedom of Information Act, will be available for public inspection at the Bureau of Land Management Office at the address given above.

ROLAND F. LEE,
Chief, Branch of Lands and Minerals Operations.

[FR Doc. 79-7998 Filed 3-15-79; 8:45 am]

[4310-84-M]

[M 42697]

MONTANA

Application; Correction

MARCH 5, 1979.

Notice is hereby given that, pursuant to Sec. 28 of the Mineral Leasing Act of 1920, as amended (30 U.S.C. 185), Shell Oil company has applied for a 6-inch oil and gas pipeline right-of-way across the following Federal lands:

PRINCIPAL MERIDIAN, MONTANA

T. 22 N., R. 60 E.,
Sec. 20, Lot 4 and SE¼SW¼.

FIFTH PRINCIPAL MERIDIAN, NORTH DAKOTA

T. 148 N., R. 105 W.,
Sec. 10, Lots 3 and 4; and
Sec. 15, Lot 1.

This pipeline will convey natural gas across 0.22 of a mile of land in Richland County, Montana, administered by the Bureau of Land Management, and 0.58 of a mile of land in McKenzie County, North Dakota, administered by the United States Forest Service.

This notice is issued to supplement the original notice appearing in FEDERAL REGISTER Doc. 79-4306, page 8027, column three, in the issue for Thursday, February 8, 1979, in which the agency jurisdiction for the lands in the application was not shown.

The purpose of this notice is to inform the public that the Bureau will be proceeding with consideration of whether the application should be approved and, if so, under what terms and conditions.

Interested persons desiring to express their views should do so promptly. Persons submitting comments should include their name and address and send them to District Manager, Bureau of Land Management, P.O. Box 940, Miles City, Montana 59301.

ROLAND F. LEE,
Chief, Branch of Lands and Minerals Operations.

[FR Doc. 79-7999 Filed 3-15-79; 8:45 am]

[4310-84-M]

[NM 35843]

NEW MEXICO

Application

MARCH 9, 1979.

Notice is hereby given that, pursuant to Section 28 of the Mineral Leasing Act of 1920 (30 U.S.C. 185), as amended by the Act of November 16, 1973 (87 Stat. 576), El Paso Natural Gas Company has applied for one 4½-inch natural gas pipeline right-of-way across the following land:

NEW MEXICO PRINCIPAL MERIDIAN, NEW MEXICO

T. 30 N., R. 8 W.,
Sec. 34, E½NW¼ and SW¼NW¼.

This pipeline will convey natural gas across 0.199 of a mile of public land in San Juan County, New Mexico.

The purpose of this notice is to inform the public that the Bureau will be proceeding with consideration of whether the application should be approved, and if so, under what terms and conditions.

Interested persons desiring to express their views should promptly send their name and address to the District Manager, Bureau of Land Management, P.O. Box 6770, Albuquerque, New Mexico 87107.

FRED E. PADILLA,
Chief, Branch of Lands and Minerals Operations.

[FR Doc. 79-8000 Filed 3-15-79; 8:45 am]

[4310-84-M]

[NM 36204]

NEW MEXICO

Application

MARCH 9, 1979.

Notice is hereby given that, pursuant to Section 28 of the Mineral Leasing Act of 1920 (30 U.S.C. 185), as amended by the Act of November 16,

1973 (87 Stat. 576), Llano Incorporated has applied for one 4½-inch natural gas pipeline right-of-way across the following land:

NEW MEXICO PRINCIPAL MERIDIAN, NEW MEXICO

T. 19 S., R. 33 E.,
Sec. 7, lots 2 and 3.

This pipeline will convey natural gas across 0.26 of a mile of public land in Lea County, New Mexico.

The purpose of this notice is to inform the public that the Bureau will be proceeding with consideration of whether the application should be approved, and if so, under what terms and conditions.

Interested persons desiring to express their views should promptly send their name and address to the District Manager, Bureau of Land Management, P.O. Box 1397, Roswell, New Mexico 88201.

RAUL E. MARTINEZ,
Acting Chief, Branch of Lands and Minerals Operations.

[FR Doc. 79-8001 Filed 3-15-79; 8:45 am]

[4310-84-M]

[Wyoming 66897]

WYOMING

Application

MARCH 7, 1979.

Notice is hereby given that pursuant to Section 28 of the Mineral Leasing Act of 1920, as amended (30 U.S.C. 185), the Northwest Pipeline Corporation of Salt Lake City, Utah filed an application for a right-of-way to construct a 4½ inch O.D. pipeline and related facilities for the purpose of transporting natural gas across the following described public lands:

SIXTH PRINCIPAL MERIDIAN, WYOMING

T. 19 N., R. 112 W.,
Sec. 28, NE¼NW¼.

The proposed pipeline will transport natural gas southerly to a point of connection with an existing pipeline all within the NE¼NW¼ section 28, T. 19 N., R. 112 W., Lincoln County, Wyoming.

The purpose of this notice is to inform the public that the Bureau will be proceeding with consideration of whether the application should be approved and, if so, under what terms and conditions.

Interested persons desiring to express their views should do so promptly. Persons submitting comments should include their name and address and send them to the District Manager, Bureau of Land Management, Highway 187 N., P.O. Box 1869, Rock Springs, Wyoming 82901.

WILLIAM S. GILMER,
Acting Chief, Branch of Lands and Minerals Operations.

[FR Doc. 79-8002 Filed 3-15-79; 8:45 am]

[4310-84-M]

[Wyoming 66878]

WYOMING

Application

MARCH 9, 1979.

Notice is hereby given that pursuant to Section 28 of the Mineral Leasing Act of 1920, as amended (30 U.S.C. 185), the Northwest Pipeline Corporation of Salt Lake City, Utah filed an application for a right-of-way to construct a 4½ and 8⅝ inch O.D. pipeline and related facilities for the purpose of transporting natural gas across the following described public lands:

SIXTH PRINCIPAL MERIDIAN, WYOMING

T. 25 N., R. 110 W.,
Secs. 4, 5, 7, 8, 18 and 19.
T. 26 N., R. 110 W.,
Sec. 33.
T. 24 N., R. 111 W.,
Secs. 3 and 4.
T. 25 N., R. 111 W.,
Sec. 24, 25, and 35.

The proposed pipeline will transport natural gas from the No. 32-33 Ferguson Federal well located in the SW¼NE¼ section 33, T. 26 N., R. 110 W., to a point of connection with an existing line located in the NW¼SE¼ section 4, T. 24 N., R. 111 W., Sweetwater County, Wyoming.

The purpose of this notice is to inform the public that the Bureau will be proceeding with consideration of whether the application should be approved and, if so, under what terms and conditions.

Interested persons desiring to express their views should do so promptly. Persons submitting comments should include their name and address and send them to the District Manager, Bureau of Land Management, Highway 187 N., P.O. Box 1869, Rock Springs, Wyoming 82901.

WILLIAM S. GILMER,
Acting Chief, Branch of Lands and Minerals Operations.

[FR Doc. 79-8003 Filed 3-15-79; 8:45 am]

[4310-70-M]

National Park Service

GENERAL MANAGEMENT PLAN, REDWOOD NATIONAL PARK, CALIFORNIA

Intent to Prepare Environmental Impact Statement

Notice is hereby given that, in accordance with the National Environmental Policy Act of 1969, the U.S. Department of Interior, National Park Service has begun preparation of an Environmental Impact Statement to analyze impacts of various alternatives for the future management and development of Redwood National Park.

The statement will assess potential environmental impacts associated with the development of a general management plan including the reciprocal effects of regional development and adjacent land use and the effects of access and circulation, overnight accommodations, visitor services and facilities and natural and cultural resources management.

Alternatives which have been evaluated both by the Park Service and the public include no action, regional destination, and restructured use alternatives.

This project commenced in June 1978 with a series of public workshops. From those meetings, the previously identified alternatives were developed and reviewed during the first three months of 1979. The Draft Environmental Statement will be released for public and agency review the summer of 1979.

All interested agencies, organizations, or individuals are invited to submit comments or suggestions for consideration in the preparation of the Draft Environmental Statement. The availability of the document will be announced in the FEDERAL REGISTER and additional public comments will be solicited. Those who desire to submit comments or suggestions should submit them to Project Manager, Redwood National Park, General Management Plan, P.O. Drawer N, Crescent City, California 95531 on or before May 1, 1979.

Dated: March 9, 1979.

JOHN H. DAVIS,
Acting Regional Director, Western Region, National Park Service.

[FR Doc. 79-8038 Filed 3-15-79; 8:45 am]

[4510-30-M]

DEPARTMENT OF LABOR

Employment and Training Administration

EXTENDED BENEFITS

Availability of Extended Benefits in the State of Pennsylvania

This notice announces the beginning of a new Extended Benefit Period in the State of Pennsylvania, effective on March 11, 1979.

BACKGROUND

The Federal-State Extended Unemployment Compensation Act of 1970 (Title II of the Employment Security Amendments of 1970; Public Law 91-373; 26 U.S.C. 3304 note), established the Extended Benefit Program as a part of the Federal-State Unemployment Compensation Program. The Extended Benefit Program takes effect during periods of high unemployment in a State or the nation, to furnish up to 13 weeks of additional benefits to eligible individuals who have exhausted their rights to regular benefits under permanent State and Federal unemployment compensation laws. Part 615 of Chapter V, Title 20, Code of Federal Regulations, implements the statute.

In accordance with section 203(e) of the Act, the Pennsylvania unemployment compensation law provides that there is a State "on" indicator in the State for a week if the head of the State employment security agency determines, in accordance with 20 CFR 615.12(e), that, for the period consisting of that week and the immediately preceding 12 weeks, the rate of insured unemployment under the State unemployment compensation law equalled or exceeded 5.0 percent. 20 CFR 615.12(c)(2)(i). The Extended Benefit Period actually begins with the third week following the week for which there is an "on" indicator. A benefit period will be in effect for a minimum of 13 consecutive weeks, and will end the third week after there is an "off" indicator.

DETERMINATION OF "ON" INDICATOR

The head of the employment security agency of the State of Pennsylvania has determined that, for the period consisting of the week ending on February 24, 1979; and the immediately preceding 12 weeks, the rate of insured unemployment in the State equalled or exceeded 5.0 percent.

Therefore, an Extended Benefit Period commenced in that State with the week beginning on March 11, 1979.

INFORMATION FOR CLAIMANTS

The duration of Extended Benefits payable in the new Extended Benefit Period, and the terms and conditions on which they are payable, are governed by the Act and the State unemployment compensation law. The State employment security agency will furnish a written notice of potential entitlement to Extended Benefits to each individual who has established a benefit year in the State that will expire after the new Extended Benefit Period begins, and who has exhausted all rights under the State unemployment compensation law to regular benefits before the beginning of the new Extended Benefit Period. 20 CFR 615.13(d)(1). The State employment security agency also will provide such notice promptly to each individual who exhausts all rights under the State unemployment compensation law during the Extended Benefit Period, including exhaustion by reason of the expiration of the individual's benefit year. 20 CFR 615.13(d)(2).

Persons who believe they may be entitled to Extended Benefits in the State of Pennsylvania, or who wish to inquire about their rights under the Extended Benefit Program, should contact the nearest State Employment Office of the Pennsylvania Department of Labor and industry in their locality.

Signed at Washington, D.C., on March 13, 1979.

ERNEST G. GREEN,
Assistant Secretary for Employment and Training.

[FR Doc. 79-8060 Filed 3-15-79; 8:45 am]

[4510-43-M]

Mine Safety and Health Administration

[Docket No. M-79-8-M]

ATLAS MINERALS

Petition for Modification of Application of Mandatory Safety Standard

Atlas Minerals, P.O. Box 1207, Moab, Utah 84532, has filed a petition to modify the application of 30 CFR 57.19-22 (wire rope) to its Snow Mine and its Probe Mine, in Emery County, Utah. The petition is filed under section 101(c) of the Federal Mine Safety and Health Act of 1977, Pub. L. 95-164.

The substance of the petition follows:

1. Instead of turning the end of its hoisting rope at least one full turn on the hoist drum shaft, the petitioner proposes to use rope clips and a short, separate piece of wire rope of the same size and construction as the hoist rope to dead end the hoisting rope inside the hoist drum.

2. The petitioner states that this alternative method provides a greater measure of safety to personnel who actually perform the attachment of the hoisting rope. There is no danger of any "whipping" action by a rope slipping from position while being turned around the shaft because the alternative method requires no bending of the rope. Upon completion of the attachment of the short rope piece and clips to the end of the hoist rope, the hoist rope is simply pulled into position inside the drum, slack removed and the rope wound on the drum.

3. The petition states that this alternative method will achieve no less protection for its miners than that provided by the standard.

REQUEST FOR COMMENTS

Persons interested in this petition may furnish written comments on or before April 16, 1979. Comments must be filed with the Office of Standards, Regulations and Variances, Mine Safety and Health Administration, 4015 Wilson Boulevard, Arlington, Virginia 22203. Copies of the petition are available for inspection at that address.

Dated: March 8, 1979.

ROBERT B. LAGATHER,
Assistant Secretary for Mine Safety and Health.

[FR Doc. 79-8057 Filed 3-15-79; 8:45 am]

[4510-43-M]

[Docket No. M-79-19-C]

BISHOP COAL CO.

Petition for Modification of Application of Mandatory Safety Standard

Bishop Coal Company, 1800 Washington Road, Pittsburgh, Pa. 15241, has filed a petition to modify the application of 30 CFR 75.305 (weekly examinations), to its Dry Fork Mine, located in McDowell County, Virginia, in accordance with section 101(c) of the Federal Mine Safety and Health Act of 1977, Pub. L. 95-164.

The substance of the petition follows:

1. Due to adverse roof conditions, certain return air courses in the petitioner's mine are virtually impassable and extremely hazardous to travel and examine. A map of the mine supplied by the petition indicates these locations.

2. The existing falls have had no effect on the velocity or quality of air passing through the return air course.

3. The return air courses are not designated as return escapeways.

4. As a result of the existing roof falls and other potentially dangerous conditions in the specified return air courses, the petitioner considers weekly examinations for hazardous conditions too hazardous to be performed.

5. As an alternative, the petitioner proposes to establish two air monitoring stations to make air measurements where air enters and exists the area designated on the petition.

6. The air monitoring stations and approaches to them will be maintained in safe condition.

7. Examinations of air quality, quantity and direction, as required by 30 CFR 75.305, will be made daily by approved means.

8. The date, time and results of these examinations will be recorded in a book which shall be provided at each measuring station. Such results will also be recorded in a book kept on the surface and made available to all interested parties.

9. Methane or other harmful, noxious or poisonous gases will not be permitted to accumulate in these air courses in excess of legal limits. An increase of 0.5 percent methane above the last previous methane rating will require an immediate investigation of the affected airways. If at any time the air quality at either of the monitoring stations indicates a reduction of air quality of 10 percent, an immediate investigation of the affected area will be conducted.

10. The petitioner states that the proposed alternative will at all times guarantee no less than the same measure of protection to miners than that provided by the standard.

REQUEST FOR COMMENTS

Persons interested in this petition may furnish written comments on or before April 16, 1979. Comments must be filed with the Office of Standards, Regulations and Variances, Mine Safety and Health Administration, 4015 Wilson Boulevard, Arlington, Virginia 22203. Copies of the petition are available for inspection at that address.

Dated: March 8, 1979.

ROBERT B. LAGATHER,
Assistant Secretary for Mine Safety and Health.

[FR Doc. 79-8056 Filed 3-15-79; 8:45 am]

[4510-43-M]

[Docket No. M-79-12-C]

LOBO COAL CO.

Petition for Modification of Application of Mandatory Safety Standard

Lobo Coal Company, P.O. Box 64, Terra Alta, West Virginia, has filed a petition to modify the application of 30 CFR 75.1710 (canopies), to its No. 1 Mine, located in Preston County, West Virginia, in accordance with section 101(c) of the Federal Mine Safety and Health Act of 1977, Pub. L. 95-164.

The substance of the petition follows:

1. The petition concerns the use of cabs or canopies on electric face equipment in the petitioner's mine.

2. Because the mean height of the coal in the petitioner's mine is about 48 inches, the height of its equipment cannot exceed 36 inches to allow for undulating pavement and rolls in the roof line and clearance of roof supports.

3. When the petitioner has operated two of its scoops with canopies, these canopies have torn out roof bolts, wooden headers and steel plates causing roof falls. In addition, these canopies so reduce the equipment operator's visibility that he cannot see where he is traming. As a result, the operator constantly sticks his head outside the canopy to see, substantially increasing the danger of injuring his head.

4. The petitioner lists the following additional potential hazards concerning the use of canopies in low seam heights:

a. The cramped and confined space under a canopy restricts the operator from properly handling equipment controls and impedes his reaction to any emergency situation.

b. Canopies force the operator's head down in an unnatural position. The operator cannot see and observe the condition of the roof above him nor see his helper or other employees in the area at all times.

5. The petitioner states that for these reasons the application of the standard to its equipment in areas of the mine in which the mean height of the minable coal is 48 inches will result in diminution of safety to the miners affected and therefore requests relief from the application of the standard.

REQUEST FOR COMMENTS

Persons interested in this petition may furnish written comments on or before April 16, 1979. Comments must be filed with the Office of Standards, Regulations and Variances, Mine Safety and Health Administration, 4015 Wilson Boulevard, Arlington, Virginia 22203. Copies of the petition are available for inspection at that address.

Dated: March 8, 1979.

ROBERT B. LAGATHER,
Assistant Secretary for Mine Safety and Health.

[FR Doc. 79-8058 Filed 3-15-79; 8:45 am]

[4510-23-M]

Office of the Secretary

ALL ITEMS CONSUMER PRICE INDEX FOR ALL URBAN CONSUMERS, UNITED STATES CITY AVERAGE

Pursuant to Section 112 of the 1976 amendments to the Federal Election Campaign Act (Pub. L. 94-283, 2 U.S.C. 441a), the Secretary of Labor has certified to the Chairman of the Federal Election Commission, and publishes this notice in the FEDERAL REGISTER, the fact that the United States City Average All Items Consumer Price Index for All Urban Consumers (1967=100) increased 32.3 percent from its 1974 annual average of 147.7 to its 1978 annual average of 195.4. Using 1974 as a base (1974=100), I certify that the United States City Average All Items Consumer Price Index for All Urban Consumers thus increased 32.3 percent from its 1974 annual average of 100 to its 1978 annual average of 132.3.

Signed at Washington, D.C., on the 7th day of March 1979.

RAY MARSHALL,
Secretary of Labor.

[FR Doc. 79-8059 Filed 3-15-79; 8:45 am]

[4510-28-M]

[TA-W-4581, 4581a]

AFFINITY MINING CO., SOPHIA, WEST VIRGINIA

Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-4581 and 4581a: investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in Section 222 of the Act.

The investigation was initiated on January 8, 1979 in response to a worker petition received on December 18, 1978 which was filed by the United Mine Workers of Amercia on behalf of workers and former workers producing metallurgical coal at Affinity Mining Corporation's Keystone 5 Mine, Sophia, West Virginia. The investigation revealed that Affinity Mining Corporation is a wholly-owned subsidiary of Eastern Associated Coal Corportation. The investigation also revealed that there is a metallurgical coal preparation plant attached to the mine. The investigation was expanded to include that preparation plant (TA-W-4581a).

The Notice of Investigation was published in the FEDERAL REGISTER on January 19, 1979 (44 FR 4029-30). No

public hearing was requested and none was held.

The determination was based upon information obtained principally from officials of Eastern Associated Coal Corporation, its customers, the American Iron and Steel Institute, the U.S. Department of Interior, the U.S. Department of Energy, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of Section 222 of the Act must be met. It is concluded that all of the requirements have been met.

U.S. imports of metallurgical coal are negligible. However, coke is metallurgical coal in a later stage of processing, and is therefore "directly competitive" with metallurgical coal. U.S. imports of coke increased from 1,311 thousand tons in 1976 to 1,829 thousand tons in 1977, and from 1,057 thousand tons in the period from January to September, 1977 to 4,123 thousand tons in the same period in 1978. The ratio of imports to domestic coke production increased from 2.2. percent in 1976 to 3.4 percent in 1977, and from 2.6 percent in the period from January to September, 1977 to 11.5 percent in the same period in 1978.

The Department of Labor conducted a survey of Eastern Associated Coal Corporation's customers. From 1977 to 1978 some major customers surveyed decreased purchases of metallurgical coal from Eastern and increased purchases of imported coke.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increases of imports of articles like or directly competitive with the metallurgical coal produced at the Keystone 5 Mine and Preparation Plant, Sophia, West Virginia of Eastern Associated Coal Corporation contributed importantly to the decline in sales and production and to the total or partial separation of workers at the plants. In accordance with the provisions of the Act, I make the following certification:

All workers at the Keystone 5 Mine and Preparation Plant, Sophia, West Virginia, of Affinity Mining Company, a subsidiary of Eastern Associated Coal Corporation, who became totally or partially separated from employment on or after June 1, 1978, are eligible to apply for adjustment assistance under Title II Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C. this 9th day of March 1979.

JAMES F. TAYLOR,
Director, Office of Management, Administration, and Planning.

[FR Doc. 79-8061 Filed 3-15-79; 8:45 am]

[4510-28-M]

[TA-W-4641]

AMERICAN & EFIRD MILLS, INC., SPUN FIBER DIVISION, LENOIR, N.C., MOUNT HOLLY, N.C., CORPORATE OFFICE

Certificate Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-4641: investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in Section 222 of the Act.

The investigation was inititated on January 10, 1979 in response to a worker petition received on January 8, 1979 which was filed on behalf of workers and former workers producing long and short staple (synthetic yarns) at the Spun Fiber Division, of American and Efird Mills, Incorporated, Lenoir, North Carolina.

The Notice of Investigation was published in the FEDERAL REGISTER on January 19, 1979 (44 FR 4039-40). No public hearing was requested and none was held.

The determination was based upon information obtained principally from officials of American and Efird Mills, Incorporated, its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of Section 222 of the Act must be met. It is concluded that all of the requirements have been met.

The Spun Fiber Division of American and Efird Mills, Incoporated, Lenoir, North Carolina produced long staple and short staple. The petition alleges that imports of finished garments have adversely affected sales, production and employment at the Lenoir plant.

Imported finished garments cannot be considered to be like or directly competitive with long staple and short staple. Imports of staple must be considered in determining injury to workers producing long staple and short staple at the Spun Fiber Division of American and Efird Mills, Incorporated.

Imports of long and short staple are included in the market basket "Nylon, Polyester, Acrylic and Noncellulosic Staple and Tow Fiber." Imports of nylon, polyester, acrylic and noncellolosic staple and tow fiber increased from 41.8 million pounds in the first nine months of 1977 to 50.4 million pounds in the first nine months of 1978.

Long staple is the primary product of the Lenoir, North Carolina plant. A Department survey of American and Efird's customers revealed that customers had decreased their purchases of long staple from American and Efird and increased their purchases of imported long staple.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increases of imports of articles like or directly competitive with long staple produced at the Spun Fiber Division of American and Efird Mills, Incoporated, Lenoir, North Carolina contributed importantly to the decline in sales or production and to the total or partial separation of workers of that plant and at the Mount Holly, North Carolina corporate offices of American and Efird Mills, Incorporated. In accordance with the provisions of the Act, I make the following certification:

All workers of the Spun Fiber Division, Lenoir, North Carolina and clerical workers and salesmen in the Mount Holly, North Carolina corporate offices of American and Efird Mills, Incorporated who were engaged in employment related to the production of long staple who became totally or partially separated from employment on or after March 1, 1978 are eligible to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C. this 9th day of March 1979.

C. MICHAEL AHO,
Director, Office of Foreign Economic Research.

[FR Doc. 79-8062 Filed 3-15-79; 8:45 am]

[4510-28-M]

[TA-W-4642]

AMERICAN FELT AND FILTER, GLENVILLE STATION, GREENWICH, CONN.

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-4642: investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in Section 222 of the Act.

The investigation was initiated on January 10, 1979 in response to a worker petition received on January 5, 1979 which was filed by the Amalgamated Clothing and Textile Workers'

Union on behalf of workers and former workers producing industrial felt products at American Felt & Filter, Glenville Station, Greenwich, Connecticut.

The Notice of Investigation was published in the FEDERAL REGISTER on January 19, 1979 (44 FR 4039-40). No public hearing was requested and none was held.

The determination was based upon information obtained principally from officials of American Felt & Filter, the U.S. Department of Commerce, the U.S. International Trade Commission, the Felt Manufacturers Council industry analysts and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of Section 222 of the Act must be met. Without regard to whether any of the other criteria have been met, the following criterion has not been met:

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.

Total company sales, adjusted by utilizing the wholesale price index and production of industrial felt products by American Felt & Filter increased in 1978 compared with 1977. The company indicated that the Greenwich plant was phased out as part of a program of consolidation intended to improve operating efficiency. Production of felt and felt products was transferred from the Greenwich plant to company facilities in Newburgh, New York and Warren, Michigan.

CONCLUSION

After careful review, I determine that all workers of the Greenwich, Connecticut plant of American Felt & Filter are denied eligibility to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C. this 9th day of March 1979.

C. MICHAEL AHO,
Director, Office of Foreign Economic Research.

[FR Doc. 79-8063 Filed 3-15-79; 8:45 am]

[4510-28-M]

[TA-W-4584]

BISHOP COAL CO., McDOWELL COUNTY, W. VA.

In accordance with Section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-4584: investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in Section 222 of the Act.

The investigation was initiated on January 8, 1979, in response to a worker petition received on December 18, 1978 which was filed by the United Mine Workers of America on behalf of workers and former workers mining and preparing metallurgical coal at Bishop Coal Company, Pocahontas, Virginia. The investigation revealed that Bishop Coal Company's mines and preparation plant are located in McDowell County, West Virginia.

The Notice of Investigation was published in the FEDERAL REGISTER on January 19, 1979 (44 FR 4029-30). No public hearing was requested and none was held.

The determination was based upon information obtained principally from officials of Bishop Coal Company, its customers, the U.S. Department of the Interior, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of Section 222 of the Act must be met. Without regard to whether any of the other criteria have been met, the following criterion has not been met:

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.

Bishop Coal Company produces metallurgical coal which is used to produce coke. Coke is metallurgical coal at a later stage of production, and therefore, can be considered "like or directly competitive" with metallurgical coal.

The only domestic customer of Bishop Coal who purchased imported coke increased its purchases of metallurgical coal from Bishop in the period April through November, 1978 compared to the same period in 1977. No customer reported purchases of imported metallurgical coal.

CONCLUSION

After careful review, I determine that all workers of Bishop Coal Company, McDowell County, West Virginia are denied eligibility to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C. this 8th day of March 1979.

HARRY J. GILMAN,
Supervisory International Economist, Office of Foreign Economic Research.

[FR Doc. 79-8064 Filed 3-15-79; 8:45 am]

[4510-28-M]

[TA-W-4646]

BONANZA COAL COMPANY, INC. RUPERT, West Virginia

In accordance with Section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-4646: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in Section 222 of the Act.

The investigation was initiated on January 10, 1979 in response to a worker petition received on January 2, 1979 which was filed by the United Mine Workers of America, District 29, on behalf of workers and former workers mining metallurgical coal at Bonanza Coal Company, Incorporated, Lexington, Kentucky. The investigation revealed that Bonanza Coal Company's mine is located at Rupert, West Virginia.

The Notice of Investigation was published in the FEDERAL REGISTER on January 19, 1979 (44 FR 4039-40). No public hearing was requested and none was held.

The determination was based upon information obtained principally from officials of Bonanza Coal Company, Incorporated, its customers, American Iron and Steel Institute, the U.S. Departments of Energy, Interior and Commerce, the U.S. International Trade Commission, industry analysts and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of Section 222 of the Act must be met. It is concluded that all of the requirements have been met.

While U.S. imports of metallurgical coal have been negligible, U.S. imports of coke increased from 1,311 thousands of tons in 1976 to 1,829 thousands of tons in 1977 and increased from 1,057 thousands of tons in the first nine months of 1977 to 4,123 thousands of tons in the first nine months of 1978.

The ratio of imports to domestic production for coke increased from 2.2 percent in 1976 to 3.4 percent in 1977 and increased from 2.6 percent in the first nine months of 1977 to 11.5 percent for the first nine months of 1978.

Coke is metallurgical coal at a later stage of processing. Since a domestic article may be "directly competitive

with" an imported article at a later stage of processing, imports of coke can be considered in determining import injury to workers producing metallurgical coal at Bonanza Coal Company's Rupert, West Virginia mine.

As a contract mining operation, Bonanza sells all coal to one firm. A Labor Department survey of the customers of that firm revealed that some major customers significantly decreased purchases of metallurgical coal from that firm and increased purchases of imported coke from 1977 to 1978.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increases of imports of articles like or directly competitive with metallurgical coal mined at the Rupert, West Virginia mine of the Bonanza Coal Company, Incorporated contributed importantly to the decline in sales or production and to the total or partial separation of workers of that firm. In accordance with the provisions of the Act, I make the following certification:

All workers of the Rupert, West Virginia mine of the Bonanza Coal Company, Incorporated who became totally or partially separated from employment on or after March 27, 1978 are eligible to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C. this 9th day of March 1979.

JAMES F. TAYLOR,
Director, Office of Management Administration and Planning.

[FR Doc. 79-8065 Filed 3-15-79; 8:45 am]

[4510-28-M]

[TA-W-4586, 4586a, 4587, 4587a, 4588, 4589, 4589a, 4593, 4593a, 4594, 4595, 4595a, 4596, 4597, 4598, 4599, 4600]

EASTERN ASSOCIATED COAL CORP.

Negative Determinations Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-4586, 4586a, 4587, 4587a, 4588, 4589, 4589a, 4593, 4593a, 4594, 4595, 4595a, 4596-9, 4600: investigations regarding certification of eligibility to apply for worker adjustment assistance as prescribed in Section 222 of the Act.

The investigation was initiated on January 8, 1979, in response to a worker petition received on December 18, 1978 which was filed by the United Mine Workers of America, in part on behalf of workers and former workers producing metallurgical coal at the following plants of Eastern Associated Coal Corporation:

Keystone 1 Mine, Keystone, West Virginia (TA-W-4586); Keystone 2 Mine, Herndon, West Virginia (TA-W-4587); Keystone 3 Mine, Herndon, West Virginia (TA-W-4588); Keystone 4 Mine, Sophia, West Virginia (TA-W-4589); Kopperston 1 Mine, Kopperston, West Virginia (TA-W-4593); Kopperston 2 Mine, Kopperston, West Virginia (TA-W-4594); Wharton 2 Mine, Barrett, West Virginia (TA-W-4595); Wharton 4 Mine, Barrett, West Virginia (TA-W-4597); Wharton 11 Mine, Wharton, West Virginia (TA-W-4596); Lightfoot 1 Mine, Wharton, West Virginia (TA-W-4598); Lightfoot 2 Mine, Wharton, West Virginia (TA-W-4599); Wells Preparaton Plant, Wharton, West Virginia (TA-W-4600).

The investigation revealed that metallurgical coal preparation plants are attached to the Keystone 1 (TA-W-4576a) Keystone 2 and 3 (TA-W-4587a), Keystone 4 (TA-W-4589a), Kopperston 1 and 2 (TA-W-4593a), and Wharton 2 (TA-W-4595a) mines. The investigation was expanded to include those preparation plants.

The Notice of Investigation was published in the FEDERAL REGISTER on January 19, 1979 (44 FR 4029-30). No public hearing was requested and none was held.

The determination was based upon information obtained principally from officials of Eastern Associated Coal Corporation, its customers, the American Iron and Steel Institute, the U.S. Department of the Interior, the U.S. Department of Energy, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligilibity requirements of Section 222 of the Trade Act of 1974 must be met. With respect to workers at the Keystone 1 Mine and Preparation Plant, Wharton 4 Mine, Kopperston 1 and 2 Mines and Preparation Plant, and Lightfoot 2 Mine, without regard to whether any of the other critieria have been met, the following criterion has not been met:

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 decline in sales or production.

The Department's investigation revealed that decreases in sales or production at the facilities listed above are attributable to factors unrelated to imports and would have occurred regardless of the influence of increased imports.

The United Mine Workers of America, which represents all workers in Eastern's mines, was on strike from December 6, 1977 to March 27, 1978. When the period from April to November, 1978, during which miners were not on strike, is compared with the same period in 1977, sales and production of metallurgical coal at the Wharton 4 Mine and the Kopperston 1 and 2 mines and Preparation Plant increased. Workers at the Norfolk and Western Railroad, which transports all coal produced at the Keystone 1 mine and Preparation Plant, were on strike from July 7 to October 10, 1978. Production at the mine decreased in the third quarter of 1978 because of this strike. When the period not affected by the two strikes—April-June and October-November 1978—is compared to the same period of 1977, production and sales at the mine increased.

Mining of coal at the Lightfoot 2 Mine began in April, 1977. From April, 1977 to July, 1978, coal was extracted through one tunnel. Since July 1978, production has been discontinued at the mine to allow construction on a second tunnel. This construction was planned at the time the mine was designed, and is necessary for future production at the mine.

With respect to workers at the Keystone 2 and 3 Mines and Preparation Plant, the Keystone 4 Mine and Preparation Plant, the Wharton 2 Mine and Preparation Plant, the Wharton 11 Mine, the Lightfoot 1 Mine and the Wells Preparation Plant, without regard to whether any of the other criteria have been met, the following criterion has not been met:

That sales of production, or both, of the firm or subdivision have decreased absolutely.

Both sales and production of coal at the above mentioned mines and preparation plants, with the exception of the Wells Preparation Plant, increased in quantity in 1978 compared with 1977. Cleaning of coal at the Wells Preparation Plant began in June 1978. Production at the plant was higher in the fourth quarter of 1978 than in the third quarter.

CONCLUSION

After careful review, I determine that all workers at the Keystone 1 Mine and Preparation Plant, Keystone, West Virginia (TA-W-4586, 4586a); Keystone 2 and 3 Mines and Preparation Plant, Herndon, West Virginia (TA-W-4587, 4588, 4587a); Keystone 4 Mine and Preparation Plant, Sophia, West Virginia (TA-W-4589, 4589a); Wharton 2 Mine and Preparation Plant, Barrett, West Virginia (TA-W-4595, 4595a); Wharton 4 Mine, Wharton, West Virginia (TA-W-4597); Kopperston 1 and 2 Mines and Preparation Plant, Kopperston, West Virginia (TA-W-4593, 4594, 4593a); Lightfoot 1 Mine, Wharton, West Virginia

(TA-W-4598); Lightfoot 2 Mine, Wharton, West Virginia (TA-W-4599); and the Wells Preparation Plant, Wharton, West Virginia (TA-W-4600) of Eastern Associated Coal Corporation are denied eligibility to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C. this 9th day of March 1979.

JAMES F. TAYLOR,
Director, Office of Management Administration and Planning.

[FR Doc. 79-8066 Filed 3-15-79; 8:45 am]

[4510-28-M]

[TA-W-4712]

KNITCAPERS, INC., JAMAICA, NEW YORK

Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-4712: investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in Section 222 of the Act.

The investigation was initiated on January 16, 1979 in response to a worker petition received on January 12, 1979 which was filed on behalf of workers and former workers producing ladies', children's and men's sweaters at Knitcapers, Incorporated, Jamaica, New York. The investigation revealed that Knitcapers, Incorporated produces primarily women's knitted sweaters at the Jamaica facility.

The Notice of Investigation was published in the FEDERAL REGISTER on January 26, 1979 (44 FR 5534). No public hearing was requested and none was held.

The determination was based upon information obtained principally from officials of Knitcapers, Incorporated, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of Section 222 of the Act must be met. It is concluded that all of the requirements have been met.

U.S. imports of women's, misses' and children's sweaters increased absolutely and relative to domestic production in 1976 compared to 1975 and increased absolutely in 1977 compared to the average level of imports for the 1973-1976 period. The ratio of imports of domestic production in 1976 and 1977 exceeded 140 percent. The ratio of imports to domestic production in 1977 exceeded the average I/P ratio for the 1973 through 1976 period.

Customers surveyed accounting for a significant proportion of the decline in Knitcapers sales in 1978 compared to 1977 indicated that they had increased purchases of imported women's knitted sweaters.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increases of imports of articles like or directly competitive with women's knitted sweaters produced at Knitcapers, Incorporated, Jamaica, New York contributed importantly to the decline in sales or production and to the total or partial separation of workers of that firm. In accordance with the provisions of the Act, I make the following certification:

All workers of Knitcapers, Incorporated, Jamaica, New York who became totally or partially separated from employment on or after January 6, 1978 are eligible to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C. this 12th day of March 1979.

HARRY J. GILMAN,
Supervisory International Economist, Office of Foreign Economic Research.

[FR Doc. 79-8067 Filed 3-15-79; 8:45 am]

[4510-28-M]

[TA-W-4756]

LEVI STRAUSS & COMPANY, INC., LAREDO, TEXAS

Certification Regarding Eligibility to Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-4756: investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in Section 222 of the Act.

The investigation was initiated on January 29, 1979 in response to a worker petition received on January 22, 1979 which was filed by the Amalgamated Clothing and Textile Workers Union on behalf of workers and former workers producing ladies' jeans at the Laredo, Texas plant of Levi Strauss & Company, Incorporated.

The Notice of Investigation was published in the FEDERAL REGISTER on February 6, 1979 (44 FR 7249). No public hearing was requested and none was held.

The determination was based upon information obtained principally from officials of Levi Strauss & Company, Incorporated, its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, the National Cotton Council of America, industry analysts and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of Section 222 of the Act must be met. It is concluded that all of the requirements have been met.

Imports of women's, misses' and children's slacks and shorts (which includes jeans) increased from 11,040,000 dozen units in 1976 to 11,622,000 dozen units in 1977 and increased from 9,080,000 dozen units in the first nine months of 1977 to 11,431,000 units in the first nine months of 1978.

Customers who reduced purchases of jeans from Levi Strauss were surveyed. The survey revealed that customers increased purchases of imported jeans in the first six months of 1978 compared to the same period in 1977.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increases of imports of articles like or directly competitive with ladies' jeans produced at Levi Strauss & Company, Incorporated contributed importantly to the decline in sales or production and to the total or partial separation of workers at the Laredo, Texas plant. In accordance with the provisions of the Act, I make the following certification:

All workers of the Laredo, Texas plant of Levi Strauss & Company, Incorporated who became totally or partially separated from employment on or after January 18, 1978 are eligible to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C. this 8th day of March 1979.

C. MICHAEL AHO,
Director, Office of Foreign Economic Research.

[FR Doc. 79-8068 Filed 3-15-79; 8:45 am]

[4510-28-M]

[TA-W-4704]

MOREHOUSE GARMENT CORP., BASTROP, LOUISIANA

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-4704: investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in Section 222 of the Act.

The investigation was initiated on January 15, 1979, in response to a worker petition received on January 9, 1979, which was filed by the United Paperworkers' International Union on

behalf of workers and former workers producing men's and boys' trousers at the Morehouse Garment Corporation, Bastrop, Louisiana.

On November 30, 1976, the Department issued a certification of eligibility to apply for adjustment assistance for all workers of Morehouse Garment Corporation (TA-W-1082). The certification expired on November 30, 1978.

The Notice of Investigation was published in the FEDERAL REGISTER on January 26, 1979 (44 FR 5533-4). No public hearing was requested and none was held.

The determination was based upon information obtained principally from officials of Morehouse Garment Corporation, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of Section 222 of the Act must be met. Without regard to whether any of the other criteria have been met, the following criterion has not been met:

That sales or production, or both, of the firm or subdivision have decreased absolutely.

The Department's investigation revealed that Morehouse Garment produces trousers on a contract basis. Therefore sales equals production. Production of men's and boys' trousers at Morehouse Garment Corporation increased in 1978 compared with 1977.

CONCLUSION

After careful review, I determine that all workers of Morehouse Garment Corporation, Bastrop, Louisiana are denied eligibility to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C. this 8th day of March 1979.

HARRY J. GILMAN,
Supervisory International Economist, Office of Foreign Economic Research.

[FR Doc. 79-8069 Filed 3-15-79; 8:45 am]

[4510-28-M]

[TA-W4616-4618, 4620-4623]

RANGER FUEL CORP., BOLT, WEST VIRGINIA

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-4616-4618, 4620-4623: investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in Section 222 of the Act.

The investigation was initiated on January 8, 1979 in response to a worker petition received on December 18, 1978 which was filed by the United Mine Workers of America on behalf of workers and former workers mining coal at the Beckley No. 2 Mine (TA-W-4616) and the Beckley No. 4 Mine (TA-W-4617), Beckley, West Virginia and at the F-Mine (TA-W-4618), the K-Mine (TA-W-4620) the AA-Mine (TA-W-4621) and the Cove Creek Mine (TA-W-4622), Bolt, West Virginia, and cleaning coal at the Bolt Preparation Plant (TA-W-4623), Bolt, West Virginia of Ranger Fuel Corporation, Beckley, West Virginia. The investigation revealed that the Beckley No. 4 Mine is correctly referred to as the Beckley No. 1 Mine, and that the Beckley No. 1 Mine and the Beckley No. 2 Mine are located in Bolt, West Virginia.

The Notice of Investigation was published in the FEDERAL REGISTER on January 19, 1979 (44 FR 4029-30). No public hearing was requested and none was held.

The determination was based upon information obtained principally from officials of Ranger Fuel Corporation, The Pittston Company, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of Section 222 of the Act must be met. Without regard to whether any of the other criteria have been met, the following criterion has not been met by workers at the Beckley No. 1 Mine of Ranger Fuel Corporation:

That sales or production, or both, of the firm or dubdivision have decreased absolutely.

Sales and production of coal at the Beckley No. 1 Mine increased in quantity in 1977 compared with 1976 and increased again in 1978 compared with 1977. The value of sales also increased over the same periods.

Without regard to whether any of the other criteria have been met, the following criterion has not been met by workers at the Beckley No. 2 Mine, the F-Mine, the K-Mine, the AA-Mine, the Cove Creek Mine and the Bolt Preparation Plant:

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.

BEKLEY NO. 2 MINE

Evidence developed during the course of the investigation indicated that U.S. imports of bituminous coal are insignificant. The ratio of imports to domestic production has remained below one half of one percent in every year from 1973 through 1977, and in the first three quarters of 1978.

Coal mined at the Beckley No. 2 Mine was not sold to domestic coke producers until the fourth quarter of 1978. Prior to that time, domestic sales were made to utility companies. Those customers burned the coal and did not process it into coke. Imports of bituninous coal must therefore be considered in determining import injury to workers at the Beckley No. 2 Mine.

F-MINE, K-MINE, AA-MINE AND COVE CREEK MINE

Evidence developed during the course of the investigation indicated that all of the sales declines at these mines are accounted for by decreases in export sales. No domestic sales were made from these mines in 1976 or 1977. Consequently, increased imports of coke into the United States did not affect sales and production levels at these mines.

BOLT PREPARATION PLANT

Evidence developed during the course of the investigation indicated that the production declines at the Bolt Preparation Plant are similarly accounted for by decreases in export sales. Domestic sales of coal cleaned at the plant increased in 1977 compared with 1976 and increased in April through November, 1978 compared with April through November, 1977.

CONCLUSION

After careful review, I determine that all workers of the Beckley No. 1 Mine, the Beckley No. 2 Mine, the F-Mine, the K-Mine, the AA-Mine, the Cove Creek Mine and the Bolt Preparation Plant, Bolt, West Virginia of Ranger Fuel Corporation are denied eligibility to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C. this 8th day of March 1979.

C. MICHAEL AHO,
Director, Office of Foreign Economic Research.

[FR Doc. 79-8070 Filed 3-15-79; 8:45 am]

[4510-28-M]

[TA-W-4649, 4649A]

RONALD COAT CO. AND SELDIN COAT CO., BALTIMORE, MARYLAND

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-4649, 4649A: investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in Section 222 of the Act.

The investigation was initiated on January 10, 1979 in response to a worker petition received on January 2, 1979 which was filed by the International Ladies' Garment Workers' Union on behalf of workers and former workers producing ladies' coats at the Ronald Coat Company, Baltimore, Maryland. The investigation revealed that Ronald Coat is owned by Seldin Coat. Both companies occupy the same physical facilities. The investigation was expanded to include workers at the Seldin Coat Company, Baltimore, Maryland.

The Notice of Investigation was published in the FEDERAL REGISTER on January 19, 1979 (44 FR 4039). No public hearing was requested and none was held.

The determination was based upon information obtained principally from officials of the Seldin Coat Company, its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of Section 222 of the Act must be met. Without regard to whether any of the other criteria have been met, the following criterion has not been met:

That increases of imports of articles like or directly competitive with articles produced by the firm or subdivision have contributed importantly to the total or partial separation, or threat thereof, and to the absolute decline in sales or production.

Imports of women's, misses' and children's coats and jackets increased absolutely in 1977 compared to 1976. Imports in the first nine months of 1978 declined absolutely compared to the first nine months of 1977.

The Department conducted a survey of some of the customers of the Seldin Coat Company. Responses to the survey indicated that no customers decreased their purchases from the Seldin Coat Company and increased their purchases of imported women's coats in 1978 compared to 1977.

CONCLUSION

After careful review, I determine that all workers of the Ronald Coat Company and Seldin Coat Company, Baltimore, Maryland are denied eligibility to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C. this 9th day of March 1979.

HARRY J. GILMAN,
Supervisory International Economist, Office of Foreign Economic Research.

[FR Doc. 79-8071 Filed 3-15-79; 8:45 am]

[4510-28-M]

[TA-W-4742]

SAXWOOD SPORTSWEAR, DEER PARK, NEW YORK

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-4742: investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in Section 222 of the Act.

The investigation was initiated on January 24, 1979 in response to a worker petition received on January 19, 1979 which was filed by the International Ladies' Garment Workers' Union on behalf of workers and former workers producing ladies' jackets at Saxwood Sportswear, Deer Park, New York. The investigation revealed that ladies' slacks and skirts were produced.

The Notice of Investigation was published in the FEDERAL REGISTER on January 30, 1979 (44 FR 5952). No public hearing was requested and none was held.

The determination was based upon information obtained principally from officials of Saxwood Sportswear, its manufacturers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of Section 222 of the Act must be met. Without regard to whether any of the other criteria have been met, the following criterion has not been met:

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.

The manufacturer for which Saxwood Sportswear performed contract work does not use foreign sources or purchase imported ladies' slacks or skirts. The value of the work contracted by this manufacturer increased from 1976 to 1977 and from 1977 to 1978.

CONCLUSION

After careful review, I determine that all workers of Saxwood Sportswear, Deer Park, New York are denied eligibility to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C. this 8th day of March 1979.

HARRY J. GILMAN,
Supervisory International Economist, Office of Foreign Economic Research.

[FR Doc. 79-8072 Filed 3-15-79; 8:45 am]

[4510-28-M]

[TA-W-3781]

SHELLER-GLOBE CORP., HARDY DIVISION, UNION CITY, INDIANA

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 the Department of labor herein presents the results of TA-W-3781: investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in Section 222 of the Act.

The investigation was initiated on May 25, 1978 in response to a worker petition received on May 22, 1978 which was filed by the Allied Industrial Workers of America on behalf of workers and former workers producing zinc die casting and plastic molders for decorative hardware at Sheller-Globe Corporation, Hardy Division, Union City, Indiana. The investigation revealed that the plant primarily produces zinc die casted and plastic injection molded components, assemblies and decorative trim for automobiles, and zinc die casted and plastic injection molded bezels for television sets.

The Notice of Investigation was published in the FEDERAL REGISTER on June 9, 1978 (43 FR 25197). No public hearing was requested and none was held.

The determination was based upon information obtained principally from officials of Sheller-Globe Corporation-Hardy Division, its customers, industry sources, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment as-

sistance each of the group eligibility requirements of Section 222 of the Act must be met. Without regard to whether any of the other criteria have been met, the following criterion has not been met with respect to the production of television bezels:

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.

A survey conducted by the Department revealed that the major customers purchasing television bezels from Sheller-Globe Corporation, Hardy Division, did not purchase any imported zinc or plastic television bezels in 1976, 1977 or the first quarter of 1978. These customers indicated either increased purchases of television bezels from other domestic sources, or increased in-house production of bezels during the surveyed time period.

With respect to the production of automotive components, assemblies and decorative trim, without regard to whether any of the other criteria have been met, the following criterion has not been met:

That sales or production, or both, of the firm or subdivision have decreased absolutely.

The investigation revealed that Division sales or zinc and plastic automotive components, assemblies and decorative trim increased in 1977 compared to 1976 and increased in the first five months of 1978 compared to the same period in 1977.

Both total Division sales and total Division production, the majority of which is accounted for by automotive parts, increased in 1977 compared to 1976 and increased in the first ten months of 1978 compared to the same period in 1977.

CONCLUSION

After careful review, I determine that all workers of Sheller-Globe Corporation, Hardy Division, Union City, Indiana are denied eligibility to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C. this 9th day of March 1979.

JAMES F. TAYLOR,
Director, Office of Management, Administration and Planning.

[FR Doc. 79-8073 Filed 3-15-79; 8:45 am]

[4510-28-M]

[TA-W-4580]

V.T.M. FINISHING CO., PATERSON, NEW JERSEY

Notice of Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-4580: investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in Section 222 of the Act.

The investigation was initiated on January 2, 1979 in response to a worker petition received on December 26, 1978 which was filed on behalf of workers and former workers engaged in dyeing and finishing fabrics at V.T.M. Dyeing and Finishing Corporation, Paterson, New Jersey.

The investigation revealed that the correct company name is the V.T.M. Finishing Company, division of Vitromar, Inc.

The Notice of Investigation was published in the FEDERAL REGISTER on January 9, 1979 (44 FR 2033). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of V.T.M. Finishing Company, its customers, the Amercian Textile Manufacturers Institute, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of Section 222 of the Act must be met. Without regard to whether any of the other criteria have been met, the following criterion has not been met:

That increases of imports of articles like or directly competitive with articles produced by the firm or subdivision have contributed importantly to the total or partial separation, or threat thereof, and to the absolute decline in sales or production.

V.T.M. Finishing Company produced dyed and finished fabric for the apparel industry. The petitioners appear to allege that increased imports of finished garments contributed importantly to the closing of V.T.M. Finishing Company. Imported wearing apparel cannot be considered like or directly competitive with finished fabric. Imports of all types of finished fabric must be considered in determining import injury to workers producing dyed and finished fabric at V.T.M. Finishing Company, Paterson, New Jersey.

The ratio of imports of all finished fabric (bleached, dyed, and printed) to domestic production was less than 2 percent in each of the years 1974-1977.

Customers of V.T.M. Finsihing Company were surveyed and reported that they did not purchase imported finished fabric.

CONCLUSION

After careful review, I determine that all workers of V.T.M. Finishing Company, Paterson, New Jersey are denied eligibility to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C. this 9th day of March 1979.

JAMES F. TAYLOR,
Director, Office of Management, Administration, and Planning.

[FR Doc. 79-8074 Filed 3-15-79; 8:45 am]

[TA-W-4657-4663-B; 4685; 4688-4694-A; et al.]

WESTMORELAND COAL CO.

Certifications Regarding Eligibility To Apply for Worker Adjustment Assistance

In the matter of Eccles, West Virginia (TA-W-4657, 4658, 4662), East Gulf, West Virginia (TA-W-4659, 4661, 4663), Macalpin, West Virginia (TA-W-4660), Tams, West Virginia (TA-W-4663—A), Maben, West Virginia (TA-W-4663-B), Clothier, West Virgina (TA-W-4685, 4688, 4688-A), Quinwood, West Virginia (TA-W-4689-4694, 4694-A).

In accordance with Section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-4657-4663-B; 4685; 4688-4694-A: investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in Section 222 of the Act.

The investigation was initiated on January 11, 1979 in response to a worker petition received on December 18, 1978 which was filed by the United Mine Workers of America, in part on behalf of workers and former workers mining metallurgical coal at the Westmoreland Coal Company facilities listed in the attachment.

The Notice of Investigation was published in the FEDERAL REGISTER on January 19, 1979 (44 FR 4040-42). No public hearing was requested and none was held.

The determination was based upon information obtained principally from officials of Westmoreland Coal Company, its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility

requirements of Section 222 of the Act must be met. It is concluded that all of the requirements have been met.

U.S. imports of metallurgical coal are negligible. However, in accordance with Section 222 of the Trade Act of 1974 and 29 CFR 90.2, a domestic article may be "directly competitive" with an imported article at a later stage of processing. Coke is metallurgical coal at a later stage of processing. Therefore, imports of coke as well as imports of metallurgical coal should be considered in determining import injury to workers producing metallurgical coal.

U.S. imports of coke increased from 1,311 thousands of tons in 1976 to 1,829 thousands of tons in 1977 and increased from 1,057 thousands of tons in the first nine months of 1977 to 4,123 thousands of tons in the first nine months of 1978.

The ratio of imports to domestic production for coke increased from 2.2 percent in 1976 to 3.4 percent in 1977 and increased from 2.6 percent in the first nine months of 1977 to 11.5 percent for the first nine months of 1978.

The Department of Labor conducted a survey of the major customers purchasing metallurgical coal from Westmoreland Coal Company. Several of these customers reduced purchases from Westmoreland and increased imports of metallurgical coal and/or coke from 1977 to 1978.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increases of imports of articles like or directly competitive with metallurgical coal produced at the Westmoreland Coal Company facilities listed in the attachment, contributed importantly to the decline in sales or production and to the total or partial separation of workers of those facilities.

In accordance with the provisions of the Act, I make the following certification:

All workers of Westmoreland Coal Company facilities listed in the attachment, who became totally or partially separated from employment on or after the respective impact dates are eligible to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C. this 9th day of March 1979.

C. MICHAEL AHO,
Director, Office of Foreign Economic Research.

ATTACHMENT

TA-W-	Facility	Location	Impact date
4657	Eccles #6	Eccles, W. Va.	October 1, 1978.
4658	Eccles #5	Eccles, W. Va.	October 1, 1978.
4659	Winding Gulf #4	East Gulf, W. Va	October 1, 1978.
4660	MacAlpin	MacAlpin, W. Va	October 1, 1978.
4661	East Gulf	East Gulf, W. Va	October 1, 1978.
4662	Eccles Preparation Plant	Eccles, W. Va.	October 1, 1978.
4663	East Gulf Preparation Plant	East Gulf, W. Va	October 1, 1978.
4663-A	Winding Gulf Central Shop	Tams, W. Va.	October 1, 1978.
4663-B	Maben Preparation Plant	Maben, W. Va	March 27, 1978.
4685	Hampton #6	Clothier, W. Va.	November 1, 1978.
4688	Hampton #4 Preparation Plant	Clothier, W. Va.	October 1, 1978.
4688-A	Hampton Central Shop	Clothier, W. Va.	November 1, 1978.
4689	Imperial #7	Quinwood, W. Va.	October 1, 1978.
4690	Imperial #2	Quinwood, W. Va.	October 1, 1978.
4691	Imperial #8	Quinwood, W. Va.	October 1, 1978.
4692	Imperial #29	Quinwood, W. Va.	October 1, 1978.
4693	#1 Carl Preparation Plant	Quinwood, W. Va.	October 1, 1978.
4694	#6 Clifftop Preparation Plant	Quinwood, W. Va.	October 1, 1978.
4694-A	Imperial Central Shop	Quinwood, W. Va.	November 1, 1978.

[FR Doc. 79-8075 Filed 3-15-79; 8:45 am]

[4510-28]

[TA-W-4672-76, 4680-81]

WESTMORELAND COAL CO., BIG STONE GAP, VIRGINIA

Negative Determinations Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-4672-76, 4680-81: investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in Section 222 of the Act.

The investigation was initiated on January 11, 1979 in response to a worker petition received on December 18, 1978 which was filed by the United Mine Workers of America, in part on behalf of workers and former workers producing metallurgical coal at the Wentz #1 mine, (TA-W-4672), the Wentz #2 mine (TA-W-4673), the Wentz #1-B, mine (TA-W-4674), the Pine Branch #1 mine (TA-W-4675), the Pine Branch #2 mine (TA-W-4676), the Wentz Preparation Plant (TA-W-4680) and the Pine Branch Preparation Plant (TA-W-4681) of Westmoreland Coal Company. All of these facilities are located in Big Stone Gap, Virginia.

The Notice of Investigation was published in the FEDERAL REGISTER on January 19, 1979 (44 FR 4040-42). No public hearing was requested and none was held.

The determination was based upon information obtained principally from officials of Westmoreland Coal Company, its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of Section 222 of the Act must be met. Without regard to whether any of the other criteria have been met, the following criterion has not been met with respect to workers at the facilities listed below.

That a significant number or proportion of the workers in the workers' firm, or an appropriate subdivision thereof, have become totally or partially separated, or are threatened to become totally or partially separated.

No layoffs occurred at the following facilities of Westmoreland Coal Company in 1978:

TA-W-	Facility	Location
4672	Wentz #1	Big Stone Gap, Virginia.
4673	Wentz #2	Big Stone Gap, Virginia.
4674	Wentz #1-B	Big Stone Gap, Virginia.
4675	Pine Branch #1	Big Stone Gap, Virginia.
4676	Pine Branch #2	Big Stone Gap, Virginia.
4680	Wentz Preparation Plant	Big Stone Gap, Virginia.
4681	Pine Branch Preparation Plant	Big Stone Gap, Virginia.

The average weekly hours worked per employee did not change significantly during this period. There is no immediate threat of separation of workers at these facilities.

CONCLUSION

After careful review, I determine that all workers of the Westmoreland Coal Company facilities listed below are denied eligibility to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

TA-W-	Facility	Location
4672	Wentz #1	Big Stone Gap, Virginia.
4673	Wentz #2	Big Stone Gap, Virginia.
4674	Wentz #1-B	Big Stone Gap, Virginia.
4675	Pine Branch #1	Big Stone Gap, Virginia.
4676	Pine Branch #2	Big Stone Gap, Virginia.
4680	Wentz Preparation Plant	Big Stone Gap, Virginia.
4681	Pine Branch Preparation Plant	Big Stone Gap, Virginia.

Signed at Washington, D.C. this 9th day of March 1979.

C. MICHAEL AHO,
Director, Office of
Foreign Economic Research.

[FR Doc. 79-8076 Filed 3-15-79; 8:45 am]

[4510-28-M]

[TA-W-4683, 4684, 4686, 4687]

WESTMORELAND COAL CO., CLOTHIER, WEST VIRGINIA

Negative Determinations Regarding Eligibility to Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-4683, 4684, 4686, 4687: investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in Section 222 of the Act.

The investigation was initiated on January 11, 1979 in response to a worker petition received on December 18, 1978 which was filed by the United Mine Workers of America, in part on behalf of workers and former workers producing metallurgical coal at the Ferrell #17 mine (TA-W-4683), the Hampton #3 mine (TA-W-4684), the Ferrell Preparation Plant (TA-W-4686) and the Hampton #3 Preparation Plant (TA-W-4687) of Westmoreland Coal Company. All of these facilities are located in Clothier, West Virginia.

The Notice of Investigation was published in the FEDERAL REGISTER on January 19, 1979 (44 FR 4040-42). No public hearing was requested and none was held.

The determination was based upon information obtained principally from officials of Westmoreland Coal Company, its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of Section 222 of the Act must be met. Without regard to whether any of the other criteria have been met, the following criterion has not been met with respect to workers at the facilities listed below.

That sales or production, or both, of the firm or subdivision have decreased absolutely.

Sales and production of metallurgical coal mined and processed at the Westmoreland Coal Company facilities listed below increased from 1977 to 1978.

TA-W-	Facility	Location
4683	Ferrell #17	Clothier, West Virginia
4684	Hampton #3	Clothier, West Virginia
4686	Ferrell Preparation Plant	Clothier, West Virginia
4687	Hampton #3 Preparation Plant	Clothier, West Virginia

CONCLUSION

After careful review, I determine that all workers of the Westmoreland Coal Company facilities listed below are denied eligibility to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

TA-W-	Facility	Location
4683	Ferrell #17	Clothier, West Virginia
4684	Hampton #3	Clothier, West Virginia
4686	Ferrell Preparation Plant	Clothier, West Virginia
4687	Hampton #3 Preparation Plant	Clothier, West Virginia

Signed at Washington, D.C. this 9th day of March 1979.

C. MICHAEL AHO,
Director, Office of
Foreign Economic Research.

[FR Doc. 79-8077 Filed 3-15-79; 8:45 am]

[4510-28—M]

WORKER ADJUSTMENT ASSISTANCE

Investigations Regarding Certifications of Eligibility To Apply

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, Bureau of International Labor Affairs, has instituted investigations pursuant to Section 221(a) of the Act and 29 CFR 90.12.

The purpose of each of the investigations is to determine whether absolute or relative increases of imports of articles like or directly competitive with articles produced by the workers' firm or an appropriate subdivision thereof have contributed importantly to an absolute decline in sales or production, or both, of such firm or subdivision and to the actual or threatened total or partial separation of a significant number or proportion of the workers of such firm or subdivision.

Petitioners meeting these eligibility requirements will be certified as eligible to apply for adjustment assistance under Title II, Chapter 2, of the Act in accordance with the provisions of Subpart B of 29 CFR Part 90. 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.

Pursuant to 29 CFR 90.13, the petitioners or any other persons 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 March 26, 1979.

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 March 26, 1979.

The petitions filed in this case are available for inspection at the Office of the Director, Office of Trade Adjustment Assistance, Bureau of International Labor Affairs, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, D.C. 20210.

Signed at Washington, D.C. this 5th day of March 1979.

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
Experimental Mining of West Virginia (U.M.W.A.).	Richlands, Va	2/23/79	2/16/79	TA-W-4,879	Mining & selling of coal.
F & D Ladies' Coats & Suits, Inc. (workers).	Brooklyn, N.Y	2/12/79	2/8/79	TA-W-4,880	Ladies' coats, raincoats and some jackets.
McKnight Mining, Inc. (U.M.W.A.)	Fayette County, W. Va	2/23/79	2/16/79	TA-W-4,881	Mining and selling of coal.
Sandra Coat Co. (workers)	Hoboken, N.J	2/28/79	2/15/79	TA-W-4,882	Ladies' coats and jackets.
Sterling Smokeless Coal Co. #10 Mine (U.M.W.A.).	Raleigh County, W. Va	2/23/79	2/17/79	TA-W-4,883	Mining of coal.
Sterling Smokeless Coal Co. #12 Mine (U.M.W.A.).	Raleigh County W. Va	2/23/79	2/17/79	TA-W-4,884	Mining of coal.
Sterling Smokeless Coal Co. #17 Mine (U.M.W.A.).	Raleigh County, W. Va	2/23/79	2/17/79	TA-W-4,885	Mining of coal.
Sterling Smokeless Coal Co. #13 Mine (U.M.W.A.).	Raleigh County, W. Va	2/23/79	2/17/79	TA-W-4,886	Mining of coal.
Sterling Smokeless Coal Co. Preparation Plant (U.M.W.A.).	Raleigh County, W. Va	2/23/79	2/17/79	TA-W-4,887	Cleaning of coal.
The New River Co., Skelton Mine (U.M.W.A.).	Raleigh County, W. Va	2/23/79	2/16/79	TA-W-4,888	Mining of coal.
The New River Co., Siltix Mine (U.M.W.A.).	Fayette County, W. Va	2/23/79	2/16/79	TA-W-4,889	Mining of coal.
The New River Co., Lockgelly Tipple (U.M.W.A.).	Lockgelly, W. Va	2/23/79	2/16/79	TA-W-4,890	Cleaning of coal.
The New River Co., Garden Ground Tipple (U.M.W.A.).	Fayette County, W. Va	2/23/79	2/16/79	TA-W-4,891	Cleaning of coal.
The New River Co., Machine Shop (U.M.W.A.).	Fayette County, W. Va	2/23/79	2/16/79	TA-W-4,892	Repairing mining equipment.
U.S. Steel Corp., Fairfield Works, Ensley Division (workers).	Birmingham, Ala	2/22/79	2/8/79	TA-W-4,893	Steel rails for railroad industry.

[FR Doc. 79-7623 Filed 3-15-79; 8:45 am]

[7510-01-M]

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice 79-31]

JAPAN ENGINEERING DEVELOPMENT CO.

Intent To Grant Foreign Exclusive Patent License

In accordance with the NASA Foreign Licensing Regulations, 14 CFR 1245.405(e), the National Aeronautics and Space Administration announces its intention to grant to the Japan Engineering Development Company, Tokyo, Japan, a limited, exclusive patent license in Japan for the seven NASA-owned inventions covered by the Japanese counterparts of (1) U.S. Patent No. 3,620,784 for "Potassium Silicate Zinc Coating", issued to NASA on November 16, 1971; (2) U.S. Application Serial No. 623,561 for "Plastic Lens Antireflection Coating", filed by NASA on October 20, 1975; (3) U.S. Application Serial No. 728,369 for "Bio-Medical Ultrasonoscope", filed by NASA on September 30, 1976; (4) U.S. Patent No. 3,493,401 for "Fire Resistant Coating Composition", issued to NASA on February 3, 1970; (5) U.S. Application Serial No. 862,880 for "Alkali-Metal Silicate Binders and Methods of Manufacture", filed by NASA on December 21, 1977; (6) U.S. Application Serial No. 914,260 for

"Electrochemical Cell for Rebalancing Redox Flow system", filed by NASA on June 9, 1978; (7) U.S. Application Serial No. 928,130 for "A Phase Insensitive Ultrasonic Transducer", filed by NASA on July 26, 1978. Copies of the above U.S. Patent Applications can be purchased from the National Technical Information Services, Springfield, Virginia, 22161, at a cost of $3.75 a copy. Copies of the U.S. Patents may be purchased from the U.S. Patent and Trademark Office, Washington, D.C., 22030, for $.50 a copy. Interested parties should submit written inquiries or comments on or before May 15, 1979, to the Assistant General Counsel for Patent Matters, Code GP-4, National Aeronautics and Space Administration, Washington, D.C., 20546.

Dated: March 9, 1979.

S. NEIL HOSENBALL,
General Counsel.

[FR Doc. 79-7971 Filed 3-15-79; 8:45 am]

[6820-49-M]

NATIONAL COMMISSION ON THE INTERNATIONAL YEAR OF THE CHILD, 1979

CANCELLATION OF HEARING

MEETING AND HEARINGS, MARCH 22-23, 1979

DETROIT, MICHIGAN

MARCH 13, 1979.

Amend the Hearings for Friday, March 23, 1979 (44 FR 12783) to read as follows:

Friday, March 23, 1979, 2:30 to 5:30 p.m., City-County Bldg., 2 Woodward Avenue, 13th Floor Auditorium, Detroit, Michigan.

The session originally planned for 7:00-9:00 p.m. has been cancelled.

BENEDICT J. LATTERI.

[FR Doc. 79-7965 Filed 3-15-79; 8:45 am]

[7590-01-M]

NUCLEAR REGULATORY COMMISSION

PRIVACY ACT OF 1974

New System of Records

AGENCY: U.S. Nuclear Regulatory Commission (NRC).

ACTION: Notice of new system of records.

SUMMARY: The Nuclear Regulatory Commission has established a new system of records identified as Property and Supply System (PASS). It will consist of information concerning items of property, other than real property, which are owned by, acquired by, or leased to the NRC, and information about the individuals having custody of those items.

EFFECTIVE DATE: This amendment to the NRC Notices of Systems of Records becomes effective on April 16, 1979.

FOR FURTHER INFORMATION CONTACT:

Ms. Betty L. Wagman, Privacy Act Officer, Division of Rules and Records, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, telephone (301) 492-8133.

SUPPLEMENTARY INFORMATION: The Nuclear Regulatory Commission published a notice of a proposed new system of records in the FEDERAL REGISTER on November 9, 1978 (43 FR 52305). The notice invited comments on the proposed new system of records by December 11, 1978. No comments were received on the proposed new system of records identified as Property and Supply System (PASS).

PASS will consist of information concerning items of property, other than real property, which are owned by, acquired by, or leased to the NRC, and information about the individuals having custody of those items. The purpose of the system is to enable the agency to maintain inventory controls over NRC personal property which is in the custody of individual employees, consultants, or contractors. These include major items of equipment (e.g., office furnishing, automobiles, etc.) as well as items of sensitive personal property (e.g., items of equipment desirable for personal use which are easily lost or stolen (such as portable calculators and cassette recorders)).

Notice is hereby given that the Commission has established the new system of records Property and Supply System (PASS), NRC-24. Except for minor editorial changes the text of NRC-24 is identical with the text of the proposed NRC-24 published on November 9, 1978.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and sections 552, 552a, and 553 of Title 5 of the United States Code, the following notice of NRC Systems of Records, Property, and Supply System (PASS), NRC-24 is published as a document subject to publication in the annual compilation of Privacy Act Documents.

Effective date: This amendment to the NRC Notices of Systems of Records becomes effective on April 16, 1979.

Dated at Bethesda, Maryland this 2nd day of March 1979.

For the Nuclear Regulatory Commission.

LEE V. GOSSICK,
Executive Director for Operations.

NRC-24

System name:

Property and Supply System (PASS)—NRC

System location:

Property Management Section, Property and Supply Branch, Division of Facilities and Operations Support, NRC, 4922 Fairmont Avenue, Bethesda, Maryland.

Categories of individuals covered by the system:

NRC employees, consultants, and contractors who have custody of items of personal property, including major items of equipment (e.g. office furnishings, automobiles, etc.) and items of sensitive property (e.g., cameras, portable calculators, and cassette recorders).

Categories of records in the system:

These records contain information about the equipment (type, make, model, serial number, etc.); and information about the custodians of the equipment (name, office, and office location).

Authority for maintenance of the system:

a. The Federal Property and Administrative Services Act of 1949, as amended, 40 U.S.C. 483 (b) and (c) (1976).

b. 31 U.S.C. 66a(a)(3) (1976).

c. 40 U.S.C. 487(a) (1976).

Routine uses of records maintained in the system, including categories of users and the purposes of such uses:

Information in these records may be used:

a. To provide information to maintain inventory of equipment;

b. To provide information for clearances of employees who separate from the NRC;

c. For any of the routine uses specified in the Prefatory Statement.

Policies and practices for storing, retrieving, accessing, retaining, and disposing of records in the system:

Storage:

Maintained on NRC forms and magnetic tape systems, with history and audit files.

Retrievability:

Accessed by name, office, or office location.

Safeguards:

Doors are alarmed during non-working hours. Access to and use of these records are limited to those persons whose official duties require such access.

Retention and disposal:

Retained for three years after an individual's responsibility for the assigned equipment terminates; destroyed by regular trash disposal system or deleted from the data bank.

System manager and address:

Chief, Property and Supply Branch, Division of Facilities and Operations Support, Office of Administration, United States Nuclear Regulatory Commission, Washington, D.C. 20555.

Notification procedure:

Office of Administration, United States Nuclear Regulatory Commission, Washington, D.C. 20555.

Record access procedures:

Same as "Notification procedure."

Contesting record procedures:

Same as "Notification procedure."

Record source categories:

Information in this system of records comes from NRC forms signed by the individuals having custody of the items, or from reports and memoranda received by the Division of Facilities and Operations Support.

[FR Doc. 79-7898 Filed 3-15-79; 8:45 am]

[3190-01-M]

OFFICE OF THE SPECIAL REPRESENTATIVE FOR TRADE NEGOTIATIONS

ADVISORY COMMITTEE FOR TRADE NEGOTIATIONS

Notice of Meeting

Pursuant to the Federal Advisory Committee Act, 5 U.S.C. App. (the Act), notice is hereby given that a meeting of the Advisory Committee for Trade Negotiations will be held Wednesday, April 4, 1979, from 1:00 p.m. to 5:00 p.m. at the Office of the Special Representative for Trade Negotiations, 1800 G Street, N.W., Washington, D.C.

The purpose of this meeting will be to review and discuss the status of, and the United States strategy and objectives for, the multilateral trade negotiations currently underway in Geneva.

In accordance with section 10(d) of the Act, the meeting will not be open to the public because information falling within the purview of 5 U.S.C. 552b(c)(1) (the exception to the Government in the Sunshine Act for matters specifically required by Executive order to be kept secret in the interest of foreign policy) will be reviewed and discussed.

More detailed information can be obtained by contacting Phyllis O. Bonanno, Executive Director, Advisory Committee for Trade Negotiations, Office of the Special Representative for Trade Negotiations, 1800 G Street, Room 725, Washington, D.C. 20506.

PHYLLIS O. BONANNO,
Executive Director, Advisory Committee for Trade Negotiations.

ADVISORY COMMITTEE FOR TRADE NEGOTIATIONS

DETERMINATION OF CLOSING OF MEETING

The meeting of the Advisory Committee for Trade Negotiations (the Advisory Committee) to be held Wednesday, April 4, 1979, from 1:00 p.m. to 5:00 p.m. at the Office of the Special Representative for Trade Negotiations, 1800 G Street, N.W., Washington, D.C., will involve a review and discussion of the status of, and United States strategy and objectives for, the multilateral trade negotiations currently underway in Geneva. Such review and discussion will deal with information properly classified pursuant to Executive Order 11652 and specifically required by such order to be kept secret in the interests of national security (i.e., the conduct of foreign relations) of the United States. All members of the Advisory Committee have appropriate security clearances. Accordingly, I hereby determine that this meeting of the Advisory Committee will be concerned with matters listed in section 552b(c)(1) of Title 5 of the United States Code.

ROBERT S. STRAUSS,
Special Representative for Trade Negotiations.

[FR Doc. 79-8037 Filed 3-15-79; 8:45 am]

[8025-01-M]

SMALL BUSINESS ADMINISTRATION

[Proposed License No. 02/02-0357]

ATALANTA INVESTMENT CO.

Application for a License To Operate as a Small Business Investment Company

Notice is hereby given that an application has been filed with the Small Business Administration pursuant to § 107.102 of the Regulations governing small business investment companies (13 CFR 107.102 (1978)), under the name of Atalanta Investment Company, Inc. (Applicant), for a license to operate as a Small Business Investment Company under the provisions of the Small Business Investment Act of 1958, as amended, (the Act) (15 U.S.C. 661 et seq.), and the Rules and Regulations promulgated thereunder.

The Applicant was incorporated under the laws of the State of Delaware and it will commence operations with a capitalization of $8,100,000 which will be raised through a private placement of 47,500 shares of Class A Preferred Stock, 95,000 shares of Class B Preferred Stock, and 7,500 shares of Common Stock.

The Applicant will have its principal place of business at 450 Park Avenue, New York, New York 10022, and it intends to conduct operations primarily in the State of New York.

The proposed officers, directors, and stockholders are as follows:

Lewis Mark Newman, 720 Highland Avenue, Westfield, New Jersey 07091. Chairman of the Board, Chief Executive Officer, Director, 50% common stock.

Alan W. Livingston, 945 North Alpine Drive, Beverly Hills, California 90210. Director and Secretary, may own less than 10% of common stock.

Howard Traubner, 465 Martin Lane, Beverly Hills, California 90210. Director, may own less than 10% of common stock.

Matters involved in SBA's consideration of the Applicant include the general business reputation and character of the proposed owners and management, and the probability of successful operations of the Applicant, under their management, including adequate profitability and financial soundness in accordance with the Act and SBA Regulations.

Notice is hereby given that any person may not later than April 2, 1979, submit written comments on the Applicant to the Deputy Associate Administrator for Investment, Small Business Administration, 1441 "L" Street, N.W., Washington, D.C. 20416.

A copy of the Notice shall be published by the Applicant in a newspaper of general circulation in New York, New York.

(Catalog of Federal Domestic Assistance Program No. 59.011, Small Business Investment Companies.)

Dated: March 8, 1979.

PETER F. MCNEISH,
Deputy Associate Administrator for Investment.

[FR Doc. 79-7977 Filed 3-15-79; 8:45 am]

[8025-01-M]

[Proposed License No. 01/01-0299]

BOSTON HAMBRO CAPITAL CO.

Application for a License to Operate as a Small Business Investment Company

An application for a license to operate as a Small Business Investment

Company under the Small Business Investment Act of 1958, as amended, (Act) (15 U.S.C. 661 et seq.), has been filed with the Small Business Administration pursuant to § 107.102 (1978) by Boston Hambro Capital Company (BHCC), (a Massachusetts Limited Partnership), One Boston Place, Boston, Massachusetts 02106.

It is proposed to raise private capital in the minimum amount of $2,500,000 and a maximum of $5,000,000 through the sale of shares of limited partnership units at $250,000 per unit. The Corporate General Partner will be capitalized at $500,000.

The General Partner of the Partnership is Boston Hambro Corp. (BHC), a corporation jointly owned by The Boston Company Financial Strategies Group, Inc., and Hambro America Incorporated.

The principal officers, directors and stockholders of BHC, the managing partner, are as follows:

Name and Title

James F. Stone, President, Director, 11 Albion Road, Wellesley Hills, MA 02181.

Enrique F. Gittes, Executive Vice President, Director, 26 West 71 Street, New York, New York 10023.

Jeremy B. Greenhalgh, Vice President, Director, 1365 York Avenue, New York, New York 10021.

Edward J. Stewart III, Vice President, Treasurer, Director, 53 Temple Road, Wellesley, Massachusetts 02181.

Michael W. Christian, Director, Hugh Cargill Road, Concord, Massachusetts 01742.

Harold E. Fitzgibbons, Jr., Director, 25 Phillimore Gardens, London, W. 8, U.K.

Edward I. Rudman, Director, 60 Kensington Circle, Chestnut Hill, Massachusetts 02167.

Boston Company Financial Strategies Group, Inc., 50% of Common Stock, 1 Boston Place, Boston, Massachusetts 02106.

Hambro America Incorporated, 50% of Common Stock, 100% of Preference Stock, 645 Madison Avenue, New York, New York 10022.

Matters involved in SBA's consideration of the application include (1) the general business reputation and character of the proposed General Partner, (2) the reasonable prospects for successful operation of the new SBIC under the management of BHC including adequate profitability and financial soundness, and (3) whether the proposed licensing of BHCC would be in furtherance of the purposes of the Act.

Notice is hereby given that any person may, not later than April 2, 1979, submit to SBA, in writing, comments on the proposed SBIC to: Deputy Associate Administrator for Investment, Small Business Administration, 1441 "L" Street N.W., Washington, D.C. 20416.

A copy of this Notice will be published in a newspaper of general circulation in Boston, Massachusetts.

(Catalogue of Federal Domestic Assistance Program No. 59.011 Small Business Investment Companies.)

Dated: March 12, 1979.

PETER F. MCNEISH,
Deputy Associate Administrator for Investment.

[FR Doc. 79-7978 Filed 3-15-79; 8:45 am]

[8025-01-M]

[Application No. 04/04-5154]

CUBAN INVESTMENT CAPITAL CO.

Application for License to Operate as a Small Business Investment Company

An application for a license to operate as a small business investment company under the provisions of Section 301(d) of the Small Business Investment Act of 1958, as amended (15 U.S.C. 661 *et seq.*), has been filed by Cuban Investment Capital Co. (applicant) with the Small Business Administration (SBA), pursuant to 13 CFR 107.102 (1978).

The officers, directors and stockholders of the applicant are as follows:

Anthony G. Marina, President, Director, 43.33% Stockholder, 520 Savona Avenue, Coral Gables, Florida 33166.

Jorge de la Torriente, Vice President, Secretary, Treasurer, Director, 43.33% Stockholder, 10350 S.W. 38 Terrace, Miami, Florida 33165.

Giulio L. Mondello, Director, 13.34% Stockholder, 520 Savona Avenue, Coral Gables, Florida 33166.

Warren L. Miller, Director, 10387 N. Kendall Drive, Miami, Florida 33173.

The applicant, a Florida corporation, with its principal place of business at 7545 N.W. 79th Street, Miami, Florida 33166, will begin operations with $300,000 of paid-in capital and paid-in surplus derived from the sale of 300 shares of common stock.

The applicant will conduct its activities principally in the State of Florida, and in other areas within the United States of America.

Applicant intends to provide assistance to all qualified socially or economically disadvantaged small business concerns as the opportunity to profitably assist such concerns is presented.

As a small business investment company under Section 301(d) of the Act, the applicant has been organized and chartered solely for the purpose of performing the functions and conducting the activities contemplated under the Small Business Investment Act of 1958, as amended, from time to time, and will provide assistance solely to small business concerns which will contribute to a well-balanced national economy by facilitating ownership in such concerns by persons whose participation in the free enterprise system is hampered because of social or economic disadvantages.

Matters involved in SBA's consideration of the applicant include the general business reputation and character of the proposed managment, and the probability of successful operation of the applicant under their management, including adequate profitability and financial soundness, in accordance with the Small Business Investment Act and SBA Rules and Regulations.

Any person may, not later than April 2, 1979, submit to SBA written comments on the proposed applicant. Any such communication should be addressed to the Deputy Associate Administrator for Investment, Small Business Administration, 1441 L Street, N.W., Washington, D.C. 20416.

A copy of this notice shall be published in a newspaper of general circulation in Miami, Florida.

(Catalog of Federal Domestic Assistance Program No. 59.011 Small Business Investment Companies.)

Dated: March 8, 1979.

PETER F. MCNEISH,
Deputy Associate Administrator for Investment.

[FR Doc. 79-7979 Filed 3-15-79; 8:45 am]

[8025-01-M]

[License No. 04/04-5139]

M VENTURE CAPITAL CORP.

Issuance of a License to Operate as a Small Business Investment Company

On August 9, 1978, a notice was published in the FEDERAL REGISTER (43 FR 35419), stating that M Venture Capital Corporation, located at 1309 Brickell Avenue, Miami, Florida 33130, had filed an application with the Small Business Administration pursuant to 13 CFR 107.102 (1978) for a license to operate as a small business investment company under the provisions of Section 301(d) of the Small Business Investment Act of 1958, as amended.

The period for comment expired on August 24, 1978, and no comments were received.

Notice is hereby given that having considered the application and other pertinent information, SBA has issued License No. 04/04-5139 to M Venture Capital Corporation.

(Catalog of Federal Domestic Assistance Program No. 59.011, Small Business Investment Companies.)

Dated: March 8, 1979.

PETER F. MCNEISH,
Deputy Associate Administrator for Investment.

[FR Doc. 79-7980 Filed 3-15-79; 8:45 am]

[8025-01-M]

[Declaration of Disaster Loan Area No. 1580, Amdt, No. 1]

MARSHALL ISLANDS OF THE PACIFIC

Declaration of Disaster Loan Area

The above numbered Declaration (see FR 44 12529) is amended in accordance with the President's declaration of February 12, 1979, to include Enewetak Island and Medren Island in Marshall Islands District and extending the filing date for physical damage until the close of business on April 26, 1979, and for economic injury until the close of business on November 25, 1979.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008.)

Dated: March 5, 1979.

A. VERNON WEAVER,
Administrator.

[FR Doc. 79-7974 Filed 3-15-79; 8:45 am]

[8025-01-M]

[Declaration of Disaster Loan Area No. 1571, Amdt. No. 1]

NEW YORK

Declaration of Disaster Loan Area

The above numbered Declaration (See 43 FR 10170) is amended by extending the filing date for physical damage until the close of business on April 16, 1979, and for economic injury until the close of business on November 14, 1979.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008.)

Dated: February 26, 1979.

WILLIAM H. MAUK, Jr.,
Acting Administrator.

[FR Doc 79-7975 Filed 3-15-79; 8:45 am]

[8025-01-M]

[Declaration of Disaster Loan Area No. 1576, Amdt. No. 1]

NEW YORK

Declaration of Disaster Loan Area

The above numbered Declaration (See 43 FR 11019) is amended by extending the filing date for physical damage until the close of business on April 16, 1979, and for economic injury until the close of business on November 14, 1979.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008.)

Dated: February 26, 1979.

WILLIAM H. MAUK, Jr.,
Acting Administrator.

[FR Doc. 79-7976 Filed 3-15-79; 8:45 am]

[4710-10-M]

DEPARTMENT OF STATE

PRESIDENTIAL ADVISORY BOARD ON AMBASSADORIAL APPOINTMENTS

Determination of a Closed Meeting

In accordance with Section 10(d) of the Federal Advisory Committee Act, as amended (86 Stat. 770, 5 U.S.C. App. § 10(d)), I hereby determine that the March 31, 1979, meeting of the Presidential Advisory Board on Ambassadorial Appointments set up by Executive Order 11970 and extended by Executive Order 12110 will necessarily discuss information of a personal nature and that disclosure of such information about candidates for Ambassadorial appointments would constitute a clearly unwarranted invasion of their personal privacy. The participants in the meeting will discuss the professional performance, personal characteristics, and other personal details bearing on the suitability and relative ranking of candidates. In order for the Advisory Board to be able to respond to the President's request, there must be full and free discussion of such personal information throughout the meeting. Accordingly, the meeting will be closed in its entirety.

Dated: March 13, 1979.

BEN H. READ,
Under Secretary for Management.

[FR Doc. 79-8080 Filed 3-15-79; 8:45 am]

[4710-05-M]

[Public Notice 651]

PRIVACY ACT OF 1974

Proposed New Systems of Records

Notice is hereby given that the Department of State proposes to alter a system of records pursuant to the provisions of the Privacy Act of 1974 (5 U.S.C. 552a (o)) and the Office of Management and Budget Circular No. A-108, Transmittal Memorandum No. 1, dated September 30, 1975 (40 FR 45877, October 3, 1975).

The Department proposes to alter the "Overseas Records, STATE-25", by automating portions of this record system which are currently maintained in a manual mode. The primary purposes of the Overseas Records are to facilitate assistance to U.S. citizens abroad and to document overseas post administration.

The proposed modification would not alter the personal or property rights of the individuals covered by the Overseas Records and would simply automate the present record-keeping system to ensure more efficient operation of the overseas posts.

The present overseas post records system is primarily manual in concept and operation. The proposed amendment of the present system essentially replaces several of the present time and space consuming operations with more facile procedures based on computer techniques.

The proposed automation program will improve service to the public and the posts by providing more rapid, accurate, and reliable filing and retrieval of records. Personal information contained in the automated records will be identical in content and format to the present manual records; however, a large percentage of this information will be stored on magnetic disks or tapes.

Not all categories of records will be impacted by automation. Nor will all posts be automated. Only those posts with medium to large size record holdings which lend themselves to management improvement by the use of computer technology will be affected. The sections of an Embassy which have been identified as logical candidates for automation are: the Commercial section, the Consular section, and the Administrative section. Traditionally these sections are the large volume record holders and automation would bring such benefits as increased accuracy, space and equipment savings, greater security and ease of destruction in posts where social upheavel and terrorism are constant threats.

The automated system will continue to be operated by the present employees who have proper authorizations and security clearances. All employees of the Department of State and of overseas posts have undergone a background security investigation. All records containing personal information on a computerized data base are accessible only through computer media under Department of State jurisdiction and placed in restricted areas to which only authorized personnel are admitted. Access to all computerized files is password protected and under the direct responsibility of the system manager. The system manager also has the capability of printing audit trails of access from the computer media thereby permitting regular or ad hoc monitoring of computer usage.

The record systems affected by the proposed change in equipment configuration are already in existence in a manual mode and computerization will provide for more highly controllable access. None of the applications are considered sensitive but every effort is being made to protect personal data commensurate with what is available with the computer state-of-the-art.

Any person interested in commenting on the proposed change to the

Overseas Records may do so by submitting comments in writing to the Director of the Foreign Affairs Document and Reference Center, Room 1239, Department of State, 2201 C Street, N.W., Washington, D.C. 20520. If no comments are received by April 16, 1979, the proposed change will go into effect.

Dated: February 27, 1979.

FOR THE SECRETARY OF STATE.

BEN H. READ,
Under Secretary for Management.

STATE-25

System name: Overseas Records

System location: United States Embassies, Consulates, and Missions overseas.

A list of overseas posts can be obtained by writing to the Director, Foreign Affairs Document and Reference Center, Department of State, 2201 C Street, N.W., Washington, D.C. 20520.

Categories of individuals covered by the system: U.S. Government employees assigned to the post; individuals seeking or obtaining consular or passport services; individuals living or visiting abroad who have registered their place of residence at the embassy or consulate; businessmen who have had official contacts with embassy economic and commerical sections; seamen; persons who are overseas on U.S. cultural or educational grants; individuals working overseas under U.S. government contracts; officials of Federal, state, or local governments, members of their staff or delegation travelling overseas on official business; individuals involved in the discussion, establishment, execution, or definition of United States foreign policy; military personnel; Members of legislative or judical branches of government; individuals employed by or seeking employment with international organizations.

Categories of records in the system: The categories of records maintained in the overseas records system are primarily information of working copies of records already on file at the Department of State and are described in the other system notices published in this issue of the FEDERAL REGISTER.[1]

Among those categories of records maintained at the Department's overseas establishments which may not be on file in the Department of State are:

1. Consular records used in the protection and assistance of individuals abroad including;

a. Address registration lists of U.S. citizens visiting or residing overseas;

b. Visa applications;

c. Educational and Cultural Grantee Records;

d. Assistance to Americans Records;

2. Administrative records including;

a. Travel Records;

b. Shipment, importation, licensing, registration and sale of property records;

c. Customs duties records;

d. Change of address records;

e. Blood donor lists;

f. Bad check records;

g. Accommodations exchange records;

h. Personnel locator records;

i. Individual work order requests;

j. Time and attendence cards;

k. W-2 forms;

l. Employment applications and related data;

m. Post diplomatic personnel lists;

n. Post administrators and technical personnel list;

o. Visual identification records;

p. Marriage records;

q. Allowance records;

r. General properties inventory records;

s. Commissary records;

t. Protection of Property files (complaints regarding damage to and seizure of property);

u. Restitution claims records;

v. Headstone records;

3. Commercial records including;

a. Procurement/Contract records;

b. Registration lists of U.S. businessmen;

c. Trade promotion records;

d. Trade complaint records;

e. Lists of American attorneys abroad;

f. Trust fund records;

4. Political records including;

a. Congressional delegation and important visitor recorders;

b. Registration cards for refugee and migration programs;

c. Mutual security records;

5. Ambassadorial records including;

a. Host government requests for jurisdiction in legal matters involving U.S.;

b. Records involving other legal matters (deportation, letters rogatory, subpoenas);

c. Clemency records;

d. Selective Service records;

Authority for maintenance of the system: The authorities for maintaining this record system are the following: 8 USC 1101-1503; Status of Forces Agreements; 28 USC 1781-1784; 50 App. USC 543; Presidential Proclamation 4313, September 16, 1974; 22 USC 501, 811a, 1131-1159, 1431, 1621-1643, 2054-2057, 2451-2458, 2601-2605.

Routine uses of records maintained in the system, including categories of users and the purposes of such uses: These correspond to the "Routine Uses" appearing in the other system notices appearing in this issue of the FEDERAL REGISTER.[1] Also see "Routine Uses" paragraphs in the Prefatory Statement.

Policies and practices for storing, retrieving, accessing, retaining, and disposing of records in the system:

Storage: Hard copy, microfilm, magnetic computer media.

Retrievability: By individual name.

Safeguards: All employees of the Department of State and of overseas posts have undergone a background security investigation. All records containing personal information are maintained in secured file cabinets or in restricted areas, access to which is limited to authorized personnel. All records containing personal information on a computerized data base are accessible only through computer media under Department of State jurisdiction and placed in restricted areas access to which is limited to authorized personnel. Access to computerized files is password protected and under the direct responsibility of the system manager. The system manager has the capability of printing audit trails of access from the computer media thereby permitting regular or *ad hoc* monitoring of computer usage.

Retention and disposal: These records are retired or destroyed in accordance with published schedules of the Department of State. More specific information may be obtained by writing the Director, Foreign Affairs Document and Reference Center, Room 1239, Department of State, 2201 C Street NW, Washington, D.C. 20520.

System manager(s) and address: The ambasssador, principal officer, deputy principal officer, or consular officer at each overseas post.

Notification procedure: Individuals who have reason to believe that an Overseas Record System might have information pertaining to them should write to the Chief, Privacy Staff, Foreign Affairs Document and Reference Center, Room 1239, Department of State, 2201 C Street NW, Washington, D.C. 20520. The individual must specify which embassy, consulate, or mission, he/she wishes to be checked. Or, the individual may contact the verseas post(s) directly. At a minimum, the individual must include: name; date and place of birth; current mailing address and zip code; signature; the specific post which the individual believes might have a record of him/her; the approximate dates when the record might have been created; a brief description of the circumstances which would have led to the creation of a record.

Examples of the kinds of information which would assist the Department of State in determining whether or not an overseas record system contains a record on an individual are: the individual's approximate dates of travel or residency in a foreign country or the approximate dates and

[1] See 42 FR 49699, September 27, 1977.

nature of an individual's contact with a U.S. diplomatic or consular post.

Record access procedures: Individuals who wish to gain access to or amend records pertaining to them should write to the specific overseas post or to the Chief, Privacy Staff, Foreign Affairs Document and Reference Center (address above). Access to routine unclassified administrative records may be granted at the overseas establishment. Requests involving other records will be referred to the Chief, Privacy Staff, Foreign Affairs Document and Reference Center (address above).

Contesting record procedures: (See above).

Record source categories: These correspond to the "Sources" described in the other system notices appearing in this issue of the FEDERAL REGISTER.[1]

Systems exempted from certain provisions of the act: Certain records contained within this system of records are exempted from 5 U.S.C. 552a (c)(3), (d), (e)(1), (e)(4)(G), (H), and (I) and (f). See Department of State Rules published in the FEDERAL REGISTER.[2]

[FR Doc. 79-8055 Filed 3-15-79; 8:45 am]

[4910-06-M]

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[FRA Docket No. EP-1, Notice 2]

PROCEDURES FOR CONSIDERING ENVIRONMENTAL IMPACTS

Final Procedures

AGENCY: Federal Railroad Administration, Department of Transportation.

ACTION: Final procedures.

SUMMARY: This Notice sets forth procedures to be followed by the Federal Railroad Administration (FRA) in order to insure full consideration of the environmental impacts of all major FRA actions as required by the National Environmental Policy Act ("NEPA", 42 U.S.C. 4321 *et seq.*), the Department of Transportation Act ("DOT Act", 49 U.S.C. 1651 *et seq.*), other environmental statutes and executive orders, and DOT Order 5610.1B (39 FR 35234, September 30, 1974). These Procedures revise the proposed Procedures published by FRA on January 27, 1977 (42 FR 5171).

EFFECTIVE DATE: These Procedures become effective March 16, 1979.

FOR FURTHER INFORMATION CONTACT:

Principal Program Person: Marilyn W. Klein, Office of Policy and Program Development, Federal Railroad Administration, Washington, D.C. 20590; (202) 426-9684. Principal Attorney: Brigid Hynes-Cherin, Office of the Chief Counsel, Federal Railroad Administration, Washington, D.C. 20590; (202)472-5438.

EXAMINATION OF WRITTEN COMMENTS: All written comments received on the Procedures are available for examination in Public Docket EP-1 during regular business hours in Room 4406, Transpoint Building, 2100 2nd Street, SW., Washington, D.C.

SUPPLEMENTARY INFORMATION: FRA is aware that the President's Council on Environmental Quality (CEQ) has issued new regulations which as of July 30, 1979 supersede its existing Guidelines, DOT Order 5610.1B, and these Procedures. FRA recognized these regulations in the preparation of these Procedures. It is our intention that to the extent these Procedures are not inconsistent with the new CEQ regulations they will continue to operate until the new DOT Order is issued and these Procedures are amended.

In response to comments received, FRA has made several changes in the "Proposed Procedures for Considering Environmental Impacts" published on January 27, 1977. These changes are described below in a section-by-section analysis.

GENERAL

Several statutory and regulatory references have been added in response to comments received. FRA has also made editorial revisions and deletions, either to clarify the Procedures or to make the language of the Procedures consistent with DOT Order 5610.1B and other laws and regulations. These editorial changes do not affect the substance of the proposed Procedures. The addition and deletion of several sections and subsections has necessitated the renumbering of certain sections and subsections.

The Proposed Procedures included an Appendix which was designed to tailor staff responsibilities to the special needs of the Northeast Corridor Project (NECP) office. In particular, the Appendix delegated final approval authority for NECP-prepared 4(f) determinations to the Director of the NECP instead of retaining that authority in the Administrator, as is the practice for 4(f) determinations prepared by other program offices. The Department of the Interior (DOI) questioned the wisdom of assigning responsibility for both preparation and approval of 4(f) determinations to the same office. On reconsideration, FRA concurs with DOI's view. The Procedures have been recast to provide that the Administrator retains authority to finally approve all 4(f) determinations, negative declarations, and environmental impact statements. Although the Appendix has been eliminated, FRA has sought to provide for the special procedural needs of the NECP and the Alaska Railroad, where appropriate, throughout the body of the text.

The New York Department of Transportation (NY DOT) suggested that the Procedures should include a "grandfather clause" exempting from the need to conduct an environmental review, all actions initiated prior to the issuance of these Procedures. FRA does not agree. These Procedures are intended only to implement DOT Order 5610.1B, which has applied to FRA actions since 1974. These Procedures are not intended to add any substantive regulatory burden to those imposed by existing law. Insofar as these Procedures require transitional procedural changes to be made by FRA and its applicants and consultants. FRA intends to apply these Procedures so as not to frustrate activities undertaken in reliance on preexisting practice and procedures.

BACKGROUND (FORMER SECTION 2)

This section has been omitted because it merely repeated the citations included in DOT Order 5610.1B, section 2.

DEFINITIONS (SECTION 3, FORMER SECTION 4)

This section has been revised and expanded. In response to a DOI comment, the definition of "4(f) determination" has been redrafted to reflect as exactly as possible the language of section 4(f) of the DOT Act. Because there are provisions in the text referring only to part of the language of section 4(f), and to avoid repeating cumbersome statutory language in each such provision, FRA has added a new definition of "4(f)-protected properties" which includes the appropriate language of section 4(f) and can be conveniently incorporated into the definition of "4(f) determination".

The definition of "Major Federal Action Significantly Affecting the Quality of the Human Environment" has been deleted and a definition of "significant" has been substituted. FRA believes that the criteria for identifying a "major federal action" more appropriately belong in Section 4 "Actions Covered". (See below.) On the other hand, the term "significant" is used throughout these Procedures and so is appropriately defined in this section.

In response to a comment by the Environmental Protection Agency (EPA), the definitions of "Environmental Impact Statement" and "Negative

[1] See 42 FR 49791, September 27, 1977.

Declaration" have been revised to stress purpose and content rather than administrative procedures.

Finally, definitions of "Draft EIS", "Final EIS", "Environmental Document", "FRA Action", "FRA Program Office", "Administrator", "EPA" and "ARR" were added to ensure the clarity of these terms as used in the text.

ACTIONS COVERED (SECTION 4, FORMER SECTION 5)

In response to NY DOT's and EPA's concern that section 5 was unclear as to whether an assessment would be prepared for actions not described in proposed section 5(b), and their request that the Procedures identify areas where no assessment will be required, FRA has extensively revised this section. It now lists thirteen categories of exempt actions (subsection (c)) and criteria for exempting other actions (subsection (d)). Any action which is not categorically exempt and is not otherwise exempted by application of the criteria will require an environmental assessment. This section retains the concept of preparing one environmental assessment for a class of actions and adds a similar provision for programmatic actions.

The Association of American Railroads (AAR) suggested the addition of safety rulemaking to the list of actions requiring an environmental assessment. No such list has been carried over to the revised Procedures, and FRA has not included safety rulemaking actions among the categorically exempted actions listed in subsection (c). Safety rulemaking, like other FRA actions, will therefore require an environmental assessment unless a particular rulemaking falls within categorial exemption (c)(5) as a technical or minor amendment to an existing regulation or is exempted by application of the criteria listed in subsection (d).

DOI and EPA objected to the proposed subsection (c)(6) as it placed contruction activities undertaken by the Northeast Corridor Improvement Program (NECIP) in a separate category and injected cost considerations as the basis for determining whether environmental documentation should be prepared. This subsection has been deleted.

NY DOT suggested that maintenance, rehabilitation or reconstruction of railroad facilities at existing locations should be exempt from the Procedures or be subject to only minimal environmental analysis. FRA has added an exempt category for maintenance activities, but believes that a blanket exemption for rehabilitation or reconstruction activities would be too broad, and therefore intends that they be subjected to the normal criteria for exemption of actions found in subsection (d).

JOINT ACTIONS (SECTION 5)

A new section 5 "Joint Actions" has been added to the Procedures in response to a DOI comment. This section describes FRA's role when it joins with one or more Federal agencies in the performance of an environmental assessment of an action. It supports the concept that one document should serve the needs of all the involved agencies and recognizes that the procedural requirements of the lead agency can be substituted for FRA's to avoid duplication of effort.

APPLICANTS (SECTION 6)

A new section 6 "Applicants" has been added to the Procedures in response to the NY DOT comment concerning the responsibility of applicants for FRA programs to submit environmental information. FRA has incorporated the policies contained in DOT Order 5610.1B, Section (7)(e), which authorize an agency to request an applicant to submit environmental information, or a draft negative declaration or environmental impact statement. The present section seeks to clarify, however, that FRA, not the applicant, is ultimately responsible for substantive and procedural compliance with the requirements of these Procedures.

NY DOT also suggested that the Procedures outline the type of information which applicants may be required to submit. FRA administers several programs of financial assistance to various entities involved in rail transportation and has provided specific instructions to an applicant as to what type of information is required for a particular assistance program in the regulations governing that program. For the convenience of potential applicants, those regulations are cross-referenced in these Procedures. Each FRA program office will interpret the specific regulations in light of these Procedures, and any further amendments to those regulations will conform to these Procedures. In addition, although there are no outstanding regulations, the program office may request a party seeking adoption of a safety rule to provide environmental information consistent with these procedures.

CONSULTANTS (SECTION 7)

A new section 7 "Consultants" has been added which incorporates the policies contained in DOT Order 5610.1B, Section 7(f), regarding the use of consultants and reiterates FRA's ultimate responsibility for substantive and procedural compliance with these Procedures.

ENVIRONMENTAL ASSESSMENTS (SECTION 8, FORMER SECTION 6)

This section has been revised to provide more guidance on the scope and depth of the environmental assessment. In particular, a "checklist" has been added in subsection (b), intended to suggest in one place the universe of areas for consideration in an assessment. FRA does not intend that an assessment is required to deal with all the areas listed, or at the same level of detail.

NY DOT questioned the need for two documents—one, an environmental assessment; the second, a negative declaration—with respect to those actions which have no environmental effect. FRA wishes to clarify an apparent confusion of terms and concepts. An "environmental assessment" is a *process*, which will normally and incidentally generate reports, memoranda, and other written data. At some point in this process, the cognizant FRA program office will be able to make certain decisions regarding the environmental impacts of the proposed action. These are set out in subsection (e). Chief among these determinations is whether or not the impacts will be "significant". If not, FRA intends that the environmental assessment file be compiled into one *document*—a "negative declaration"—with little or no additional effort. If the impacts will be significant, the additional detail of a full-scale EIS is called for. The special cases of 4(f), wetlands and flood plain impacts are also provided for in subsection(e). As suggested by DOI and AAR, external coordination with appropriate Federal, State and local agencies has been included in these Procedures.

CITIZEN INVOLVEMENT PROCEDURES (SECTION 9)

This section has been reformatted. EPA commented on the need to seek citizen participation in the environmental review process prior to the point in time when the FRA determines that an environmental impact statement is required. FRA acknowledges the usefulness of this approach, but, because there are times when public participation will have limited benefits or cause unwarranted delay, citizen involvement at this stage is encouraged but not required.

NEGATIVE DECLARATIONS (SECTION 10, FORMER SECTIONS 7 & 8)

This section has been reorganized and has expanded the list of required contents of a negative declaration in former section 8. New subsections (g) and (h) have been added to cover the special cases of legislative negative declarations and subsequent changes in the proposed action.

DOI, EPA and the American Waterways Operators (AWO) expressed opinions as to the need or advisability of circulating a negative declaration to other governmental organizations and providing the public with an opportunity to comment. There is no statutory or regulatory requirement for such circulation and FRA respectfuly declines to require such circulation in every case. However, a program office is not precluded from circulating a negative declaration (subsection (d)) and may be encouraged to do so in some cases (subsection (c)(2)).

4(F) DETERMINATIONS (SECTION 11)

A new section 11 "4(f) Determinations" has been added to clarify the special requirements of section 4(f) of the DOT Act. Since a 4(f) use is always a "major action", the 4(f) determination must accompany either an Environmental Impact Statement or a negative declaration. This section consolidates the 4(f) references which were spread throughout the proposed Procedures and specifies the content requirements of a 4(f) determination. The contents of the 4(f) determination consists of two distinct parts: (1) the analysis of alternatives and planning to minimize harm and, (2) the actual finding required by the statute. The latter is included only in a final EIS or a negative declaration since these documents include an identification of the FRA's tentative decision on the proposed action whereas the draft EIS is open to change based on the environmental review process. Finally, this section incorporates DOI's comment pointing out DOT's statutory obligation to consult with certain Federal agencies in the preparatation of 4(f) determinations.

ENVIRONMENTAL IMPACT STATEMENTS (SECTION 12, FORMER SECTION 10)

This section has been reorganized around subsection (c) which describes the sequence of steps involved with processing an EIS. In response to EPA's comment, these procedures now recognize that exceptions to shorten the customary time periods provided at various stages in the environmental review process should only be made after consultation with CEQ as provided in the CEQ guidelines (40 CFR 1500.11(e)). Subsection (d) covers the special case of a legislative EIS. Subsection (e) has been added to cover the case of post-EIS changes in a proposed action. The intent of this subsection is to guard against segmentation but at the same time to allow unchanged portions of the action which have independent utility (e.g., maintenance activities) to go forward while the supplement is being processed. Subsection (h) provides for flexibility in the format of the EIS.

CONTENTS OF ENVIRONMENTAL IMPACT STATEMENT (SECTION 13, FORMER SECTION 11)

This section has been changed in response to comments. The discussion of impacts has been shortened where possible by a general reference to the DOT order 5610.1B which contains much of the detail contained in the proposed Procedures.

FRA has accepted DOI's comment that subsection (o)(2), formerly subsection 11(b)(1), provide that the description of the proposed action include identification of any related funding or regulatory Federal actions, such as any permits which must be obtained for the proposed action.

Subsection (p), formerly subsection 11(b)(4), dealing with alternatives to a proposed action, has been revised and expanded in response to a comment by EPA. FRA intends that all reasonable alternatives to the proposed action be described in approximately the same detail as the proposed action, so that the environmental analysis of each alternative can be judged with as little bias as possible.

EPA suggested that subsection (r)(3), formerly subsection 11(b)(3)(i)(C), be expanded to provide more guidance on which noise standards would apply to particular types of actions. Because of the variety of programs it administers, FRA prefers not to articulate specific noise standards in these procedures. FRA has, however, revised the subsection to require consideration of any and all applicable environmental noise standards adopted by Federal, State, or local government.

DOI suggested that these Procedures refer to DOT Order 5660.1 "Preservation of the Nation's Wetlands". That DOT Order has been revised (5660.1A) to reflect Executive Order 11990, dated may 24, 1977, "Protection of Wetlands". New subsection (r)(6) complies with E.O. 11990 and DOT Order 5660.1A.

Subsection (r)(15) has been added in response to DOI's comment that the Proposed Procedures should be expanded to reflect the 1975 amendment to NEPA, section 102(2)(D)(iv), (42 U.S.C. 4322(2)(D)(iv)), concerning a Federal Agency's responsibility to notify and solicit the views of State and Federal land management entities with respect to any action or alternatives thereto that may have a significant impact on that entity.

Finally, DOI suggested that FRA require or perform professionally-acceptable cultural resource surveys to identify properties eligible for inclusion on the National Register of Historic Places. Although such surveys may be desirable for some assessments, FRA declines to require them in every case. FRA intends to conduct such surveys when deemed appropriate in a particular situation, after consultation with State historic Preservation Officers and other State and local authorities.

ENVIRONMENTAL IMPACT OF THESE PROCEDURES.

FRA has determined that publication of these Procedures does not itself constitute a major FRA action necessitating environmental assessment.

This proposal has been evaluated in accordance with the policies for evaluation of regulatory impacts contianed in Executive Order 12044 on the matter of "Improving Government Regulations" which was issued March 23, 1978 (43 FR 12661) and the existing and proposed policies of the Department of Transportation issued on June 1, 1978 (43 FR 23925). On the basis of that evaluation, FRA has concluded that this proposal constitues a "non-significant" and "non-major" regulatory proposal as those terms are used in the Executive Order and Departmental policy statements.

In consideration of the foregoing, the Federal Railroad Administration's "Procedures for Considering Environmental Impacts" are issued as set forth below.

This notice is issued under the authority of the National Environmental Policy Act, 42 U.S.C. 4321 *et seq.*; Executive Order 11514 (35 FR 4247, March 5, 1970); Council on Environmental Quality Guidelines, 40 CFR Part 1500; and DOT Order 5610.1B (39 FR 35234, Sept. 30, 1974).

Issued in Washington, D.C. on _____.

JOHN M. SULLIVAN,
Administrator.

FEDERAL RAILROAD ADMINISTRATION

PROCEDURES FOR CONSIDERING ENVIRONMENTAL IMPACTS

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1. PURPOSE

This Order establishes procedures for the assessment of environmental impacts of actions and legislation proposed by the Federal Railroad Admin-

istration (FRA) and for the preparation and processing of documents based on such assessments.

2. AUTHORITY

This Order implements the requirements of section 4 of Department of Transportation (DOT) Order 5610.1B (39 FR 35234, September 30, 1974). This Order establishes procedures for compliance by the FRA with the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*, hereinafter "NEPA"), especially section 102(2)(C) of that Act (42 U.S.C. 4332(2)(C)); section 4(f) of the Department of Transportation Act (49 U.S.C. 1653(f), hereinafter the "DOT Act"); section 106 of the National Historic Preservation Act (16 U.S.C. 470(f)); section 309(a) of the Clean Air Act (42 U.S.C. 7609(a)); section 307(c)(2) of the Coastal Zone Management Act (16 U.S.C. 1456(c)(2)); section 2(a) of the Fish and Wildlife Coordination Act (16 U.S.C. 662(a)); section 7 of the Endangered Species Act (16 U.S.C. 1536); and various Executive Orders, regulations and guidelines relating to environmental assessment and environmental documentation.

3. DEFINITIONS

The following definitions shall apply throughout this Order:

(a) *Administrator.* "Administrator" means the Federal Railroad Administrator.

(b) *ARR.* "ARR" means the Alaska Railroad.

(c) *EPA.* "EPA" means the U.S. Environmental Protection Agency.

(d) *Environmental Assessment.* This is the process of identifying and analyzing the probable impacts of a proposed action on the quality of the human environment, and the administrative record generated by that process.

(e) *Environmental Impact Statement (EIS).* This is a report required by section 102(2)(C) of NEPA which contains a detailed evaluation of the environmental impacts of proposed legislation or other major Federal action significantly affecting the quality of the human environment, and which shall accompany the proposal through the decision-making process.

(f) *Draft EIS.* This is an EIS approved by the FRA for distribution for agency and public comment.

(g) *Final EIS.* This is an EIS which has incorporated agency and public comment.

(h) *Negative Declaration.* This is a report which documents a determination that a proposed major FRA action will not have a significant impact on the quality of the human environment.

(i) *4(f)-Protected Properties.* These are any publicly-owned land from a public park, recreation area, or wildlife and waterfowl refuge of national, State, or local significance as determined by the Federal, State, or local officials having jurisdiction thereof, or any land from an historic site of national, State, or local significance as so determined by such officials within the meaning of section 4(f) of the DOT Act (49 U.S.C. 1653(f)).

(j) *4(f) Determination.* This is a report which must be prepared prior to the Federal Railroad Administrator's approval of any FRA action which requires the use of any 4(f)-protected properties. This report documents both the supporting analysis and the finding required by section 4(f) of the DOT Act (49 U.S.C. 1653(f)), that (1) there is no feasible and prudent alternative to the use of such land, and (2) the proposed FRA action includes all possible planning to minimize harm to such park, recreational area, wildlife and waterfowl refuge, or historic site resulting from such use.

(k) *Environmental Document.* This is any of the following: a 4(f) determination, a final EIS, a draft EIS, a negative declaration, or the record of an environmental assessment.

(l) *FRA Action.* This is an action taken by the Federal Railroad Administrator or his delegate. FRA actions include grants, loans, financing through redeemable preference shares and loan guarantees, contracts, purchases, leases, construction, research activities, rulemaking, regulatory actions, approvals, certifications, and licensing. FRA actions include renewals or reapprovals of FRA actions, and also include actions only partially funded by FRA. FRA actions also include FRA-sponsored proposals for legislation and favorable reports on proposed rail-related legislation, but do not include responses to Congressional requests for reports on pending legislation.

(m) *FRA Program Office.* This is an office within FRA which has been delegated the authority to administer a particular FRA action or program and which therefore bears primary responsibility for performing environmental assessments and preparing environmental documents in compliance with this Order. Examples of FRA Program offices are the Northeast Corridor Project, the Office of National Freight Assistance Programs, the Office of Passenger and Special Programs, the Office of State Assistance Programs, the Alaska Railroad, the Office of Safety, the Office of Research and Development, the Transportation Test Center, the Minority Business Resource Center, and the five Regional Offices.

(n) *Significant.* Whether an impact "significantly" affects the quality of the human environment shall be determined on a case-by-basis taking into consideration the following factors:

(1) Significance cannot be avoided by terming an impact temporary, although time may be a factor in quantifying the impact, or by breaking an action down into small component parts or by ignoring a close relationship between the proposed action and other actions with individually insignificant, but cumulatively significant, impacts;

(2) Unique characteristics of the geographic area such as proximity to historic sites, park lands, prime farm lands, floodplains, wetlands, wild or scenic areas, or ecologically critical areas;

(3) The likelihood that the impact will be very apparent or highly controversial;

(4) The extent to which the possible impact is uncertain or involves unique or unknown risks;

(5) Whether the action may establish a precedent for future actions with greater effects or represents a decision in principle about a future action or program;

(6) The extent to which the proposed action threatens public health or safety;

(7) Consistency of the proposed action with State, local and regional planning and established community patterns;

(8) The extent to which the proposed action affects air or water quality, level of ground water, flooding, erosion, sedimentation, ambient noise levels, or animal populations; and

(9) Whether the action threatens a violation of Federal, State, or local environmental law, regulation, ordinance, of judicial or administrative determination.

4. ACTIONS COVERED

(a) *General Rule.* An environmental assessment must be performed prior to all major FRA actions.

(b) *Major FRA Actions.* A major FRA action for purposes of this Order is any FRA action which does not come within one of the classes of actions categorically exempted in subsection (c) of this section, or which is not otherwise exempted by application of the criteria listed in subsection (d) of this section. The FRA program office shall consult with the Office of Chief Counsel (or, in the case of the ARR, with the Chief Counsel of the ARR) before determining that an FRA action is not a major FRA action. Any determination that an FRA action is not a major FRA action based on the application of the criteria is subsection (d) of this section shall be made in writing by the program office and reviewed for legal sufficiency by the Office of Chief Counsel (or in the case

of the ARR, by the Chief Counsel of the ARR).

(c) *Actions Categorically Exempted.* The following classes of FRA actions have been determined to be categorically exempt from the requirements of this Order:

(1) Quarterly financial assistance under section 601 and 602 of the Rail Passenger Services Act, as amended, (45 U.S.C. 601), where environmental documentation has been prepared as part of the FRA annual budget process for such assistance;

(2) Administrative procurements (e.g. for general supplies) and contracts for personal services;

(3) Personnel actions;

(4) Grants or procurements for planning or design activities which do not commit the FRA or its applicants to a particular course of action affecting the environment;

(5) Technical or other minor amendments to existing FRA regulations;

(6) Internal orders and procedures not required to be published in the FEDERAL REGISTER under the Administrative Procedure Act, 5 U.S.C. 552(a)(1);

(7) Changes in plans for an FRA action for which an environmental assessment has been performed, where the changes would not alter the environmental impacts of the action;

(8) Rulemakings issued under section 17 of the Noise Control Act of 1972, 42 U.S.C. 4916;

(9) Enforcement of safety regulations, including issuance of emergency orders;

(10) State rail assistance grants under section 5 of the Department of Transportation Act (49 U.S.C. 1654) for rail service continuation payments and acquisition, rehabilitation or improvement of rail lines as defined in 49 CFR 266;

(11) Report to the Interstate Commerce Commission as required by section 5(3)(f) of the Interstate Commerce Act (49 U.S.C. 5) on expedited merger procedures;

(12) Hearings, meetings, or public affairs activities; and

(13) Maintenance of: Existing railroad equipment; track and bridge structures; electrification, communication, signalling, or security facilities; stations; maintenance-of-way and maintenance-of-equipment bases, and other existing railroad-related facilities. For purposes of this exemption maintenance means normally periodic care which does not change the existing character of the facility.

(d) *Criteria for Exemption of Actions.* An FRA action not categorically exempted under subsection (c) of this section may nevertheless be exempted from the requirements for "major FRA actions" in this Order if it satisfies all of the following criteria:

(1) The action is not likely to be environmentally controversial from the point of view of people living within the environment affected by the action or controversial with respect to the availability of adequate relocation housing;

(2) The action is not inconsistent with any Federal, State, or local law, regulation, ordinance, or judicial or administrative determination relating to environmental protection;

(3) The action is not likely to have any significant adverse impact on any natural, cultural, recreational, or scenic environment(s) in which the action takes place, or on the air or water quality or ambient noise levels of such environment(s);

(4) The action will not: Use 4(f)-protected properties; adversely affect properties under section 106 of the National Historic Preservation Act; involve new construction located in a wetlands area; or affect a base floodplain;

(5) The action will not cause a significant short- or long-term increase in traffic congestion, or other significant adverse environmental impact on any mode of transportation;

(6) The action is not an integral part of a program of actions which, when considered separately, would not be classified as major FRA actions, but when considered together would be so classified; and

(7) Environmental assessment or documentation is not required by any Federal law, regulation, guideline, order, or judicial or administrative determination other than this Order.

(e) *Class of Actions.* A general class of major FRA actions, or a general class of Federally-related actions at least one of which is a major FRA action, may be covered by a single environmental assessment and subsequent documentation where the environmental impacts of all the actions (and their alternatives) are substantially similar.

(f) *Programmatic Actions.* (1) A programmatic FRA action, consisting of a group of FRA actions or a broad action composed of elements which are themselves FRA actions but where no single action would be taken except in conjunction with the other related actions, shall be treated as a separate major FRA action for purposes of this Order.

(2) A programmatic environmental assessment should identify program level alternatives and assess the program-wide environmental impacts. To the extent information is available, it should also identify the alternatives to and impacts of component FRA actions within the program.

(3) Where a programmatic assessment has been performed, the FRA program office shall examine each component FRA action making up the program to determine, in accordance with subsection (b) of this section, whether the component action is a major FRA action.

(4) For any component action which constitutes a major FRA action, the FRA program office shall perform an additional environmental assessment and shall make the four determinations required by section 8(e) of this Order. The program office shall prepare additional environmental documentation as required by this Order unless the documentation prepared for the programmatic action satisfies the requirements of this Order for the component FRA action.

5. JOINT ACTIONS

(a) *Joint Effort.* Where one or more Federal agencies together with FRA either co-sponsor an action, or are directly involved in an action through funding, licenses, or permits, or are involved in a group of actions directly related because of functional interdependence or geographical proximity or both, or are involved in a single program, the FRA program office shall seek to join all such agencies in performing a single joint environmental assessment and in preparing necessary environmental documentation.

(b) *Lead Agency.* Where the FRA joins with one or more other Federal agencies in the performance of an environmental assessment and in the preparation of environmental documentation, all agencies should agree to designate a single "lead agency" to supervise the effort. The lead agency should consult with the other participating agencies to ensure that the joint effort makes the best use of areas of jurisdiction and of special expertise of the participating agencies, that the views of participating agencies are considered in the course of the environmental assessment and documentation process, and that the substantive and procedural requirements of all participating agencies are met.

(c) *FRA Responsibility.* The FRA is responsible for substantive and procedural compliance with environmental laws, orders, and regulations. Where the FRA is not the lead agency of a joint effort of environmental assessment and documentation, the FRA program office shall review the work of the lead agency to ensure that its work product will satisfy the requirements of the FRA under this Order. The program office may enter into a memorandum of understanding with the lead agency substituting the lead agency's content requirements for those in sections 10(i) and 13(a)-(z) of this Order. If the lead agency is another component of DOT, the 4(f) content requirements in 11(d) may also be substituted. However, for every major

FRA action, the review and approval responsibilities of this Order must be met for any final environmental document.

6. APPLICANTS

(a) *General.* Each applicant for FRA financial assistance or other major FRA action may be requested to perform an environmental assessment of the proposed FRA action and to submit documentation of that assessment with the application. An applicant may also be requested to submit a proposed draft EIS or proposed negative declaration in connection with the application.

(b) *Cross References.* As of the date of this Order, the following FRA regulations deal with the responsibilities of applicants to submit environmental documentation with their applications:

(1) Financial assistance for railroad passenger terminals under subsection 4(i) of the DOT Act, as amended (49 U.S.C 1653(i)): 49 CFR 256.11(c)(9) (for Demonstration Funds) and 49 CFR 256.11(d)(5) (for Preservation Funds).

(2) Financial assistance for facilities rehabilitation and improvement under section 505 of the Railroad Revitalization and Regulatory Reform Act of 1976, as amended, (4R Act) (45 U.S.C. 825): 49 CFR 258.7(a)(8) and Appendix to 49 CFR Part 258.

(3) Financial assistance for the acquisition or rehabilitation and improvement of facilities or equipment or to develop or establish new railroad facilities under section 511 of the 4R Act (45 U.S.C. 831): 49 CFR 260.7(a)(12).

(4) Assistance to States for rail service under section 803 of the 4R Act (amending section 5(f) of the DOT Act) (49 U.S.C. 1654(f)): 49 CFR 266.21.

(c) *Information Required.* Where an applicant is required to submit environmental documentation, the FRA progrm office shall assist the applicant by specifying the types and amounts of information, consistent with this Order and the published regulations, if any, under which the application is being made.

(d) *Premature Action by Applicant.* The FRA program office shall inform an applicant that the applicant may not take any major action, in expectation of approval of the application, prior to compliance by the FRA with the appropriate requirements of this Order.

(e) *Applicant's Use of Consultants.* An applicant may use consultants in the performance of an environmental assessment and in the preparation of proposed environmental documents. The applicant shall exercise care in selecting consultants, and in reviewing their work, to ensure that their analysis is complete and objective.

(f) *FRA Responsibility.* The FRA is responsible for substantive and procedural compliance with environmental laws, orders, and regulations, and cannot delegate this responsibility to applicants. The FRA program office that processes an application shall make its own evaluation of the environmental issues raised by the application. The program office shall review environmental documentation submitted in connection with an application to insure that it satisfies the requirements of this Order. When necessary to perform its review, the program office shall seek the advice of the Office of Policy and Program Development and of the Office of Chief Counsel. An environmental document accepted by an FRA program office pursuant to this section shall be considered to have been prepared by that office for purposes of sections 8 through 13 of this Order.

7. CONSULTANTS

(a) *General.* An FRA program office may use consultants in the performance of environmental assessments and in the preparation of environmental documents.

(b) *Conflicts of Interest.* An FRA program office shall exercise care in selecting consultants, and in reviewing their work, to ensure that their analysis is complete and objective. This is a particularly important consideration where the consultant may expect further contracts based on the outcome of environmental assessment decisions.

(c) *FRA Responsibility.* The FRA is responsible for substantive and procedural compliance with environmental laws, orders, and regulations, and cannot delegate this responsiblity to consultants. The FRA program office that contracts with a consultant shall make its own evaluation of the environmental issues raised by the proposed action. The program office shall review any assessments performed and any documents prepared by a consultant to ensure that they satisfy the requirements of this Order. When necessary to the performance of its review, the program office shall seek the advice of the Office of Policy and Program Development and of the Chief Counsel (or, in the case of the ARR, of the Chief Counsel or the ARR). An environmental document accepted by an FRA program office pursuant to this section shall be considered to have been prepared by that office for purposes of sections 8 through 13 of this Order.

8. ENVIRONMENTAL ASSESSMENTS

(a) *Policy.* The environmental assessment of a proposed major FRA action should be begun by or under the supervision of the FRA program office at the earliest practical time in the planning process for the proposed action.

(b) *Scope.* The environmental assessment should begin by identifying all reasonable alternatives to the proposed action, including "no action" and including mitigation measures not incorporated into the design of the proposed action. It is entirely proper that the number of alternatives being considered should decrease as the environmental assessment proceeds and as analysis reveals that certain theoretical alternatives would in fact be unreasonable. The assessment should seek to identify the relevant environmental impacts of all alternatives discussed, including both beneficial and adverse impacts; impacts which are direct, indirect, and cumulative; and impacts of both long- and short-term duration. The assessment shall include consultation with appropriate Federal, State, and local authorities.

The following areas of impact should be among those considererd for the affected environment:

(1) Air quality;

(2) Water quality;

(3) Noise and vibration;

(4) Solid waste disposal;

(5) Ecological systems;

(6) Impacts on wetland areas;

(7) Impacts on endangered species of wildlife;

(8) Flood hazards and floodplain management;

(9) Coastal zone management;

(10) Use of energy resources;

(11) Use of other natural resources, such as water, minerals, or timber;

(12) Aesthetic and design quality impacts;

(13) Impacts on transportation: Of both passengers and freight; by all modes, including the bicycle and pedestrian modes; in local, regional, national, and international perspectives; and including impacts on traffic congestion;

(14) Possible barriers to the elderly and handicapped;

(15) Land use, existing and planned;

(16) Impacts on the socioeconomic environment, including the number and kinds of available jobs, the potential for community disruption and demographic shifts, the need for and availability of relocation housing, and impacts on commerce and on local government services and revenues;

(17) Public health;

(18) Public safety, including any impacts due to hazardous materials;

(19) Recreational opportunities;

(20) Locations of historic, archeological, architectural, or cultural, significance, including, if applicable, consultation with the appropriate State Historic Preservation Officer(s);

(21) Use of 4(f)-protected properties; and

(22) Construction period impacts.

(c) *Depth.* The environmental assessment should seek to quantify each impact identified as relevant to the proposed action and to each alternative. Such quantification should properly develop, over the course of the assessment process, from a rough order-of-magnitude estimate of impact to finer and more precise measurements. The depth of analysis of each impact should be determined at each point in the assessment process consistent with the following factors:

(1) The likely significance of the impact;

(2) The magnitude of the proposed action or an alternative action;

(3) Whether the impact is beneficial or adverse; and

(4) Whether and to what extent the impact has been assessed in a prior environmental document.

(d) *Documentation.* The administrative record produced in the course and as a result of an environmental assessment shall be maintained by or under the supervision of the FRA program office responsible for the assessment. This documentation shall be used to determine the need to prepare either a negative declaration or an environmental impact statement for the proposed action, and shall comprise the foundation for such documents if and when they are prepared. Evidence of consultation with appropriate Federal and State authorities is especially desirable as part of the documentation of an environmental assessment. The program office shall seek the advice of the Office of Policy and Program Development and of the Office of Chief Counsel (or, in the case of the ARR, of the Chief Counsel of the ARR) as to the sufficiency of the documentation.

(e) *Determination Based on the Environmental Assessment.* The environmental assessment is completed when sufficient information has been accumulated in the record for the FRA program office to make the following determinations: whether the proposed action will or will not have a foreseeable significant impact on the quality of the human environment; whether or not the proposed action will use 4(f)-protected properties; whether or not the proposed action will occur in a wetlands area; and whether or not the proposed action will occur in a base flood-plain. In making these four determinations, the program office shall seek the advice of the Office of Policy and Program Development and of the Chief Counsel (or, in the case of the ARR, of the Chief Counsel of the ARR) and shall inform these two advisory offices of the ultimate determinations. Based on these four determinations, the program office shall take action in accordance with paragraphs (1) through (4) below, as applicable:

(1) If the FRA program office determines that the proposed action will not have a foreseeable significant impact, the program office shall compile that determination and its supporting documentation into a negative declaration and proceed in accordance with section 10 of this Order.

(2) If the program office determines that there is a foreseeable significant impact, it shall begin to prepare a draft EIS and proceed in accordance with sections 9 and 12 of this Order.

(3) If the program office determines that the proposed action contemplates using 4(f)-protected properties, it shall proceed in accordance with section 11 of this Order.

(4) If the program office determines that the proposed action will occur in a wetlands area or in a base floodplain, the program office shall comply with subsection 13(r) (6) or (8) of this Order, as applicable. If a negative declaration is prepared, the reference in 13(r) (6) and (8) to final EIS should be read as negative declaration.

9. Citizen Involvement

(a) *Policy.* Citizen involvement is encouraged at every stage of the environmental assessment of a proposed FRA action, but shall only be required in the course of processing an EIS.

(b) *Procedures.* After an FRA program office made the decision to prepare a draft EIS, in accordance with section 8(e) of this Order, the program office has shall implement the following procedures:

(1) Develop, in cooperation with the FRA Public Affairs Officer, a list of interested parties, including Federal, regional, State, and local authorities, environmental groups, individuals, and business, public service, education, labor, and community organizations. A list of Federal and Federal-State agencies with jurisdiction by law or special expertise in environmental areas may be found in Attachment 4 to DOT Order 5610.1B.

(2) Notify interested parties of the decision to prepare an EIS. The notice shall include the name, title, address, and phone number of an FRA program official who may be contacted in connection with such preparation. The notice shall invite comments from the interested parties on the environmental impacts of the proposed action and on the scope and depth desirable for the discussion in the draft EIS.

(3) Circulate the draft EIS, to interested parties and to depositories, such as public libraries, together with an invitation to comment on the draft EIS. Such circulation should comply with OMB Circular A-95.

(4) Publicize the availability of the draft EIS by press release, in coordination with the FRA Public Affairs Officer, by advertisement in local newspapers of general circulation and by other suitable means. EPA will normally publish such notice in the Federal Register. If one or more alternative includes significant encroachment on a floodplain, the notice shall make reference to that fact.

(5) If necessary or desirable, as determined in consultation with the Office of Chief Counsel (or, in the case of the ARR, with the Chief Counsel of the ARR), using the criteria in section 5(e) of DOT Order 5610.1B, hold a hearing or hearings on the draft EIS.

(6) Respond to all responsible comments in the final EIS in accordance with section 12(c)(9) of this Order.

(c) *Lists of Actions.* The Office of Policy and Program Development shall maintain and make available on request a list of FRA actions for which 4(f) determinations or draft or final EIS's are being prepared. A list shall also be maintained and made available of negative declarations which have been prepared and approved in accordance with section 10 of this Order where the action covered by a negative declaration (1) has been identified as one nornally requiring preparation of an EIS; (2) is similar to another action for which an EIS has been or is being prepared; (3) has been previously announced to be the subject of an EIS; or (4) has been identified as particularly environmentally controversial. A current copy of both lists shall be submitted quarterly to the Administrator, to the Assistant Secretary of Transportation for Policy and International Affairs, and to the EPA.

10. Negative Declarations

(a) *General.* A negative declaration shall be prepared for all major FRA actions for which an environmental impact statement is not required, as determined in accordance with section 8(e) of this Order.

(b) *Decisionmaking on the Proposed Action.* No decision shall be made at any level of authority of the FRA to commit the FRA or its resources to a major FRA action for which a negative declaration must be prepared until a negative declaration covering the action has been prepared and approved in accordance with this section.

(c) *Staff Responsibilities.* (1) A negative declaration, when required, shall be prepared by the FRA program office and shall be signed by the official heading that office. The program office shall forward a copy to the Office of Policy and Program Development and a copy to the Office of Chief Counsel.

(2) When requested by the program office, the Office of Policy and Program Development shall review the

negative declaration and shall advise the program office of the consistency of the negative declaration with FRA policies and programs.

(3) The Office of Chief Counsel shall review every negative declaration and shall advise the program office in writing as to the legal sufficiency of the negative declaration.

(4) The program office shall submit the negative declaration to the Administrator concurrently with the advice obtained from the Office of Policy and Program Development, when applicable, and from the Office of Chief Counsel.

(5) A negative declaration may become final only upon approval by the Administrator.

(d) *Coordination.* An approved negative declaration need not be coordinated outside the FRA, but shall be made available to the public, to a Government agency, or to Congress upon request. A list of approved negative declarations shall be kept by the Office of Policy and Program Development as provided in section 9(c) of this Order.

(e) *4(f) Determinations.* A 4(f) determination, prepared according to section II of this Order, may be required for a proposed FRA action even though an EIS is not required. If so, the 4(f) determination shall be set forth in a separate document and shall accompany the negative declaration through the review process.

(f) *Representations of Mitigation.* Where a negative declaration has represented that certain measures would be taken to mitigate adverse environmental impacts of an action, the FRA program office shall monitor the action and, as necessary, take steps to enforce the implementation of such measures. Where applicable, the FRA program office shall include mitigation measures in grant and contract funding agreements.

(g) *Legislative Negative Declaration.* An approved negative declaration covering any FRA-sponsored proposal for legislation which will not significantly affect the quality of the human environment shall be forwarded to the appropriate Congressional committee(s) with the proposed legislation.

(h) *Changes and Supplements.* Where a significant change is made in the planning for an FRA action which would alter environmental impacts, or where significant new information becomes available regarding the environmental impacts of an FRA action, the FRA program office shall determine whether, because of the changes or the new information, the proposed action will or will not have a foreseeable significant impact on the quality of the human environment. In making this determination, the program office shall seek the advice of the Office of Chief Counsel (or, in the case of the ARR, of the Chief Counsel of the ARR). If not, the program office shall prepare an appropriate supplement to the original negative declaration. If so, it shall prepare a draft EIS and proceed in accordance with sections 9 and 12 of this Order.

(i) *Contents of a Negative Declaration.* There shall be no prescribed format for negative declarations. A negative declaration shall contain the following:

(1) Identification of the document as a negative declaration;

(2) Identification of the U.S. Department of Transportation, Federal Railroad Administration;

(3) The title of the action, including, if applicable, identification of the action as a legislative proposal;

(4) The FRA program office which prepared the document;

(5) The month and year of preparation of the document;

(6) The name, title, address, and phone number of the person in the program office who should be contacted to supply further information about the document;

(7) A list of those persons or organizations assisting the FRA program office in the preparation of the document;

(8) A description of the proposed action;

(9) A description of the alternatives considered;

(10) Environmental data;

(11) A discussion of mitigation measures that will be used;

(12) A conclusion that the proposed action will have no foreseeable significant impact on the quality of the human environment; and

(13) Signature and date indicating the approval of the Administrator required by subsection (c) of this section.

11. 4(f) Determinations

(a) *General.* The program office shall obtain the approval of the Administrator for a 4(f) determination before any FRA acton is taken which proposes to use 4(f)-protected properties. The 4(f) determination shall accompany either a negative declaration or an environmental impact statement.

(b) *Staff Responsibilities.*

(1) The FRA program office shall determine whether or not a proposed action contemplates the use of 4(f)-protected properties. The program office shall seek the advice of the Office of Chief Counsel (or, in the case of the ARR, of the Chief Counsel of the ARR) in making this determination.

(2) If it is determined that the proposed action would use 4(f)-protected properties, the FRA program office shall initiate consultations on the proposed action with the Department of the Interior and, if appropriate, with the Departments of Housing and Urban Development and of Agriculture. If State or locally-owned property is involved, the program office should also consult with the appropriate State or local authorities.

(3) The FRA program office shall incorporate into its environmental assessment of the proposed action an analysis of whether or not there are any feasible and prudent alternatives to the proposed use of 4(f)-protected properties and of all possible planning measures which could be taken to minimize harm to such 4(f)-protected properties resulting from such use.

(4) If the program office determines on the basis of its analysis that there is no feasible and prudent alternative to the use in the proposed action of 4(f)-protected properties, it shall prepare a 4(f) determination for the action. The document shall evidence consultation with the Department of the Interior and, where applicable, with the Departments of Housing and Urban Development and of Agriculture. The program office shall forward a copy of the 4(f) determination to the Office of Policy and Program Development and a copy to the office of Chief Counsel along with the appropriate negative declaration or EIS.

(5) When requested by the program office, the Office of Policy and Program Development shall review the 4(f) determination and shall advise the program office as to the consistency of the 4(f) determination with FRA policies and programs.

(6) The Office of Chief Counsel shall review every 4(f) determination and shall advise the program office in writing as to the legal sufficiency of the 4(f) determination.

(7) The program office shall submit the 4(f) determination to the Administrator concurrently with the advice obtained from the Office of Policy and Program Development, when applicable, and from the Office of Chief Counsel.

(8) A 4(f) determination may become final only upon approval by the Administrator.

(c) *Representations of Mitigation.* Where a 4(f) determination has represented that certain measures would be taken to implement the planning to minimize harm to 4(f)-protected properties, the FRA program office shall monitor the action and, as necessary, take steps to enforce the implementation of such measures. Where applicable, the FRA program office shall include mitigation measures in grant and contract funding agreements.

(d) *Contents of a 4(f) Determination.* There shall be no prescribed format for 4(f) determinations. A 4(f) determination shall contain the following:

(1) Identification of the document as a 4(f) determination made pursuant to section 4(f) of the Department of Transportation Act, 49 U.S.C. 1653(f);

(2) Identification of the U.S. Department of Transportation, Federal Railroad Administration;

(3) The title of the action;

(4) The program office which prepared the document;

(5) The month and year of preparation of the document;

(6) A description of the proposed action in its entirety, or reference to such description in an accompanying environmental document;

(7) A description of the 4(f)-protected properties proposed to be affected, including information about their size, uses, patronage, unique qualities, and relationship to other lands in the vicinity of the action; and an explanation of the significance of the properties as determined by the Federal, State, or local officials having jurisdiction thereof;

(8) A detailed description of the use which the FRA action proposes to make of the affected 4(f)-protected properties;

(9) A similarly detailed description of every reasonable alternative location, routing, or design to the one proposed, including the alternative of "no action". Each description should analyze, as appropriate, the technical feasibility, cost estimates (with figures showing percentage differences in total project costs), the possibility of community or ecosystem disruption, and other significant environmental impacts of each alternative, so as to evidence that the financial, social, or ecological costs or adverse environmental impacts of each alternative other than that proposed would present unique problems or reach extraordinary magnitudes;

(10) A description of all planning undertaken to minimize harm to the 4(f)-protected properties from the proposed action. This should include a description of actions which will be taken to mitigate adverse environmental impacts, such as beautification measures, replacement of land or structures of their equivalents on or near their existing site(s), tunneling, cut and cover, cut and fill, treatment of embankments, planting, screening, installation of noise barriers, or establishment of pedestrian or bicycle paths;

(11) Evidence of concurrence or of efforts to obtain concurrence of the public official or officials having jurisdiction over the 4(f)-protected properties regarding the proposed action and the planning to minimize its harm;

(12) In a final EIS or along with a negative declaration, evidence of consultation with the Department of the Interior and, where appropriate, with the Departments of Housing and Urban Development and of Agriculture;

(13) In a final EIS or along with a negative declaration, a conclusion that there is no feasible and prudent alternative to the proposed use of 4(f)-protected properties and that the proposal includes all possible planning to minimize harm to such properties resulting from such use; and

(14) In a final EIS or along with a negative declaration, signature and date indicating the approval of the Administrator as required by subsection (b)(8) of this section.

12. ENVIRONMENTAL IMPACT STATEMENTS

(a) *General.* The FRA shall prepare and include a final EIS in every recommendation on proposals for major FRA actions significantly affecting the quality of the human environment, as determined in accordance with section 8(e) of this Order.

(b) *Decisionmaking on the Proposed Action.* No decision shall be made at any level of FRA to commit the FRA or its resources to a major FRA action for which an EIS must be prepared until the later of the following dates:

(1) Thirty (30) days after a final EIS covering the action has been submitted to the EPA: or

(2) Ninety (90) days after a draft EIS has been made available to the public, as measured from the date the EPA publishes a notice of the draft EIS's availability in the FEDERAL REGISTER.

The FRA program office may seek a waiver to shorten these time limits from the Council on Environmental Quality in an emergency or where the delay imposed by these time limits would significantly raise the costs or seriously impair the effectiveness of the proposed action. Any proposed waiver of time limits should be requested only after consultation with the Office of Chief Counsel.

(c) *Staff Responsibilities and Timing.* (1) The FRA program office shall begin the preparation of a draft EIS as soon as the environmental assessment for the proposed action, performed in accordance with section 8 or 10(h) of this Order, discloses that the action will significantly affect the quality of the human environment.

(2) In preparing a draft EIS, the program office shall perform such further research and consultation as may be required to supplement the record of the environmental assessment. When completed, the draft EIS shall be signed by the head of the program office. The program office shall forward a copy to the Office of Policy and Program Development and a copy to the Office of Chief Counsel.

(3) When requested by the program office, the Office of Policy and Program Development shall review the draft EIS and shall advise the program office in writing as to the consistency of the draft EIS with FRA policies and programs.

(4) The Office of Chief Counsel shall review every draft EIS and shall advise the program office in writing as to the legal sufficiency of the draft EIS.

(5) The program office shall submit the draft EIS to the Administrator concurrently with the advice obtained from the Office of Policy and Program Development, when applicable, and from the Office of Chief Counsel.

(6) A draft EIS may be formally released outside the FRA only after approval by the Administrator.

(7) The Office of Policy and Program Development, in cooperation with the program office, shall direct distribution of the draft EIS as follows: ten copies to the EPA; two copies to the Office of the Assistant Secretary of Transportation for Policy and International Affairs; and copies to all Federal agencies which have jurisdiction by law or special expertise with respect to the environmental impacts of the proposed action; State and regional clearinghouses in accordance with OMB Circular A-95; State and local government authorities and public libraries in the area to be affected by the proposed action; and all other interested parties identified during the preparation of the draft EIS pursuant to section 9(b)(1) of this Order.

(8) The draft EIS shall be made available for public and agency comment for at least 45 days from the Friday following the week the draft EIS was received by EPA. The time period for comments on the draft EIS shall be specified in a prominent place in the document, but comments received after the stated time period expires should be considered to the extent possible.

(9) Where a public hearing is to be held on the draft EIS, as determined in accordance with section 9(b)(5) of this Order, the draft EIS shall be made available to the public at least 30 days prior to the hearing.

(10) The program office shall consider all comments received on the draft EIS, issues raised through the citizen involvement process, and new information, and shall revise the text into a final EIS accordingly. All responsible comments shall be included in the final EIS, either verbatim or in summary form. The final EIS shall be signed by the head of the program office and a copy forwarded to the Office of Policy and Program Development and a copy to the Office of Chief Counsel.

(11) When requested by the program office, the Office of Policy and Pro-

gram Development shall review the final EIS and shall advise the program office in writing as to the consistency of the final EIS with FRA policies and programs.

(12) The office of Chief Counsel shall review every final EIS and shall advise the program office in writing as to the legal sufficiency of the final EIS.

(13) The Office of Policy and Program Development, in cooperation with the program office, shall transmit two copies of the final EIS to the Office of the Assistant Secretary of Transportation for Policy and International Affairs for concurrence by that office. The final EIS may be deemed concurred in by that office unless that office notifies the FRA to the contrary within two weeks or if the decision whether or not to take the action has been reserved to the Secretary of Transportation, as provided in sections 9.c(5) and 9.e of DOT Order 5610.1B That office shall issue appropriate comments if it does not concur. The comments must be resolved and concurrence obtained prior to submission of the final EIS to the Administrator.

(14) The program office shall submit the final EIS to the Administrator concurrently with the advice obtained from the Office of Policy and Program Development, when applicable, and the Office of Chief Counsel, and along with any comments of the Assistant Secretary of Transportation for Policy and International Affairs.

(15) The final EIS may become final only upon approval by the Administrator.

(16) After approval by the Administrator, the Office of Policy and Program Development, in cooperation with the program office, shall direct distribution of the final EIS as follows: Ten copies to the EPA; and copies to FRA regional offices; State and local authorities and public libraries in the area affected by the proposed action; Federal agencies and other parties who commented substantively on the draft EIS in writing or at a public hearing; and all agencies, organizations, or individuals requesting copies.

(d) *Legislative EIS.* Notwithstanding the provisions of subsections (b) and (c) of this section, an approved draft EIS covering proposed legislation may be forwarded to the appropriate Congressional committee(s) with the proposed legislation before comments have been received and a final EIS prepared. If a final EIS is prepared, it shall be forwarded to the appropriate Congressional committee as soon as it becomes available.

(e) *Changes and Supplements.* Where a significant change is made in the planning for an FRA action which would alter environmental impacts, or where significant new information becomes available regarding the environmental impacts of an FRA action, the FRA program office shall prepare an appropriate supplement to the original draft or final EIS. Such a supplement shall be processed like a draft EIS for that portion of the FRA action affected. The program office, in consultation with the Office of Chief Counsel, shall determine whether and to what extent any portion of the proposed action is unaffected by the planning change or new information. FRA decisionmaking on portions of the proposed action having utility independent of the affected portion may go forward regardless of the concurrent processing of the supplement.

(f) *Representations of Mitigation.* Where a final EIS has represented that certain measures would be taken to mitigate the adverse environmental impacts of an action, the FRA program office shall monitor the action and, as necessary, take steps to enforce the implementation of such measures. Where applicable, the FRA program office shall include mitigation measures in grant and contract funding agreements.

(g) *4(f) Determinations.* Where a 4(f) determination as well as an EIS is required for a proposed FRA action, it should be prepared in accordance with Section 11 of this Order and should be incorporated into the draft and final EIS in an appropriate section.

(h) *Contents of an EIS.* The specific contents of both a draft and final EIS shall be as prescribed by section 13 of this Order. There shall be no prescribed format for or page limitations set on EIS's, but as EIS shall be prepared so as to focus on the significant issues, as identified by the environmental assessment and the process of public comment, and so as to avoid extraneous data and discussion. The text of an EIS should be written in plain language comprehenisble to a lay persons, with technical material gathered into appendices. Graphics and drawings, maps and photographs shall be used as necessary to clarify the proposal and its alternatives. The sources of all data used in an EIS shall be noted or referenced in the EIS.

13. Content of an Environmental Impact Statement

A draft or final EIS shall contain the following, subject to the general provisions of section 12(h) of this Order:

(a) Identification of the document as a draft or final, or supplement to a draft or final, environmental impact statement prepared pursuant to section 102(2)(C) of the National Environmental Policy Act, 42 U.S.C. 4332(2)(C).

(b) If appropriate, identification of the document as containing a 4(f) determination made pursuant to section 4(f) of the Department of Transportation Act, 49 U.S.C. 1653(f).

(c) If appropriate, a citation in addition to the identification in subsection (a) of this section to section 106 of the National Historic Preservation Act, 16 U.S.C. 470(f).

(d) Identification of the U.S. Department of Transportation, Federal Railroad Administration.

(e) The title of the action, including, if applicable, identification of the action as legislative proposal.

(f) The FRA program office which prepared the document.

(g) The month and year of preparation of the document.

(h) The name, title, address, and phone number of the person or persons in the FRA program office who can be contacted to supply further information about the document.

(i) In a draft EIS, the name and address of the person in the FRA to whom comments on the document should be addressed, and the date by which comments must be received to be considered.

(j) A list of those persons, organizations, or agencies assisting the FRA in the preparation of the document.

(k) In a draft EIS, a list of agencies, organizations, and persons to whom copies of the document are being sent.

(l) In a final EIS, a list of all agencies, organizations, or persons from whom comments were received on the draft EIS.

(m) A table of contents.

(n) A summary of the contents and conclusions of the document, stressing areas of significant environmental impact and in the draft EIS the issues to be resolved among alternatives to the proposed action. The final EIS should indicate how these issues have been resolved or considered in selecting the proposed alternative. The summary should be brief and no longer than 10 pages.

(o) A brief statement of the purpose and need to which the alternatives described in subsection (p) respond, including, where applicable, the legislative authority on which it is based; and the extent to which other Federal, State, or local agencies are funding or otherwise participating in or regulating the alternatives.

(p) A description of all reasonable alternative courses of action which could satisfy the purpose and need identified in subsection (o). The description should include the "no action" alternative and alternatives not currently within the authority of the FRA, as well as a description of feasible mitigation measures which have not been incorporated into the proposed action. The draft EIS may

and the final EIS shall identify which alternative is the proposed action.

(q) A short description of the environment likely to be affected by the proposed action, by way of introduction to the environmental impact analysis, including a list of all States, counties, and metropolitan areas likely to be so affected.

(r) An analysis of the environmental impacts of the alternatives, including the proposed action, if identified. The discussion under each area of impact should cover the proposed action and all alternatives, even if only to point out that one or more alternatives would have no impact of that kind. Under each area of impact, the discussion should focus on alternatives which might enhance environmental quality or avoid some or all adverse impacts of the proposed action. Attachment 2 to DOT Order 5610.1B shall provide guidance to the contents of this section. Analysis should be focused on areas of significant impact: Beneficial and adverse; direct, indirect, and cumulative; and both long and short-term. There should be evidence of consultation with appropriate Federal, State and local officials. At least the following areas of impact should be discussed:

(1) *Air quality.* There should be an assessment of the consistency of the alternatives with Federal and State plans for the attainment and maintenance of air quality standards.

(2) *Water quality.* There should be an assessment of the consistency of the alternatives with Federal and State standards concerning drinking water, storm sewer drainage, sedimentation control, and non-point source discharges such as runoff from construction operations. The need for any permits under sections 402 and 404 of the Federal Water Pollution Control Act (33 U.S.C. 1342, 1344) for the discharge of dredged or fill material shall be discussed.

(3) *Notice and vibration.* The alternatives should be assessed with respect to applicable Federal, State, and local noise standards, especially those enforced by the FRA for railroad equipment, yards and facilities including 49 CFR Part 210 "Railroad Noise Emission Compliance Regulations".

(4) *Solid waste disposal.* The alternatives should be assessed with respect to State and local standards for sanitary landfill and solid waste disposal.

(5) *Natural ecological systems.* The EIS should discuss both construction period and long-term impacts of the alternatives on wildlife and vegetation in the affected environment. Where an alternative proposes to control or modify a stream or other body of water in some way, there shall be evidence of consultation with the U.S. Fish and Wildlife Service of the Department of the Interior and with the agencies exercising administration over the wildlife resources of affected States, as required by section 2(a) of the Fish and Wildlife Coordination Act, 16 U.S.C. 662(a).

(6) *Wetlands.* In accordance with E.O. 11990 (May 24, 1977), and revised DOT Order 5660.1A (43 FR 45285, September 24, 1978), the program office shall determine whether any of the alternatives will be located in a wetland area. If so, the procedures in DOT Order 5660.1A should be followed including consultation with the appropriate representative of the Department of the Interior, and with responsible Federal, State or local officials with special expertise, concerning the impacts of the proposal on the wetland areas affected. If the proposed action is located in a wetland area, the final EIS shall document a determination that there is no practicable alternative to such location, and that the proposed action includes all practicable measures to minimize harm to wetlands which may result from such use.

(7) *Endangered species.* If applicable, the EIS shall discuss the impacts of the alternatives on endangered or threatened species of wildlife. The Department of the Interior lists such species in 50 CFR 17. There should be evidence of consultation with the Department of the Interior as required by section 7 of the Endangered Species Act, 16 U.S.C. 1536.

(8) *Flood hazard evaluation and floodplain management.* In accordance with E.O. 11988 (May 24, 1977), and DOT Order 5650.2, the program office shall determine whether any of the alternatives will affect a base floodplain. Base floodplain limits shall be determined by using Department of Housing and Urban Development floodplain maps, or, if one or more are not available for a particular area, on the best available information. If one or more alternatives will affect a base floodplain, the draft EIS shall discuss: any risk associated with each such alternative; the impacts on natural and beneficial floodplain values; the degree to which the alternative supports incompatible development in the base floodplain; and the adequacy of the methods proposed to minimize harm. In the final EIS, this discussion should concentrate on the proposed action. If the proposed action involves a significant encroachment on a base floodplain, the final EIS shall contain a finding, made in writing by the Administrator, that the proposed significant encroachment is the only practicable alternative. This finding shall be supported by a description of why the proposed action must be located in the floodplain, including the alternatives considered and why they were not practicable and accompanied by a statement that the action conforms to applicable State and/or local floodplain protection standards. This finding shall be provided to clearinghouse agencies designated under OMB Circular A-95 and to other interested parties. Guidance or the definition of significant encroachment and other matters is provided in DOT Order 5650.2.

(9) *Coastal zone management.* If applicable, the EIS should discuss to what extent the alternatives are consistent with approved coastal zone management programs in affected States, as required by section 307(c)(2) of the Costal Zone Management Act, 16 U.S.C. 1456(c)(2).

(10) *Production and consumption of energy.* The EIS shall discuss in detail any irreversible or irretrievable commitments of energy resources likely to be involved in each alternative.

(11) *Use of natural resources other than energy, such as water, minerals, or timber.* The EIS shall discuss in detail any irreversible or irretrievable commitment of these resources likely to be involved in each alternative.

(12) *Aesthetic environment and scenic resources.* The EIS should identify any significant changes likely to occur in the natural landscape and in the developed environment. The EIS should also discuss the consideration given to design art and architecture in project planning and development as required by DOT Order 5610.4.

(13) *Transportation.* The EIS should discuss the impacts on both passenger and freight transportation, by all modes, from local, regional, national, and international perspectives. The EIS should include a discussion of both construction period and long-term impacts on vehicular traffic congestion.

(14) *Elderly and handicapped.* The EIS shall discuss impacts of the alternatives on the transportation and general mobility of the elderly and handicapped.

(15) *Land use.* The EIS should discuss the impacts of each alternative on local land use controls and comprehensive regional planning as well as on development within the affected environment, including, where applicable, other proposed Federal actions in the area. Where inconsistencies or conflicts exist, this section should describe the extent of reconciliation and the reason for proceeding notwithstanding the absence of full reconciliation. As required by 42 U.S.C. 4332(2)(d)(iv), the program office shall provide early notification to, and solicit the views of, any State or Federal land management entity with respect to any alternative which may have significant impacts upon such entity and, if there is any disagreement on such impacts, prepare a written assessment

of such impacts and views for incorporation into the final EIS.

(16) *Socioeconomic environment.* The EIS should discuss the number and kinds of available jobs likely to be affected by the alternatives. Also discussed should be the potential for community disruption or cohesion, the possibility of demographic shifts, and impacts on commerce and on local government services and revenues. The need for and availability and adequacy of relocation housing should be assessed, using as a guide section 6 of Attachment 2 to DOT Order 5610.1B.

(17) *Public health.*

(18) *Public safety.* The EIS should discuss the transportation or use of any hazardous materials which may be involved in the alternatives, and the level of protection afforded residents of the affected environment from construction period and long-term operations associated with the alternatives.

(19) *Recreation areas and opportunities.* Impacts of the altenatives on sites devoted to recreational activities should be discussed, including impacts on non-site-specific activities such as hiking and bicycling and impacts on non-activity-specific sites such as designated "open space". Where land acquired with Federal grant money such as Department of Housing and Urban Development "open space" funds or Bureau of Outdoor Recreation land and water conservation" funds is involved, there should be evidence of consultation with the grantor agency concerning the proposed action. This discussion should reference but need not repeat any matter discussed in a 4(f) determination, if any, covering the same proposed action.

(20) *Sites of historical, archeological, architectural, or cultural significance.* In accordance with section 106 of the National Historic Preservation Act, 16 U.S.C. 470(f), the EIS shall identify all properties which may be affected by the alternatives that are included in or eligible for inclusion in the National Register of Historic Places. (For a property not included in the National Register, the criteria for inclusion may be found in 36 CFR Part 60. There should be evidence of consultation with the appropriate State Historic Preservation Officer and in case of disagreement with the Department of the Interior as to whether a property is eligible for the National Register). The criteria of effect on historic properties found in 36 CFR Part 800, should be discussed with regard to each alternative. In the final EIS, there should be evidence of consultation, concerning the impacts of the proposed action on historic properties, with the appropriate State Historic Preservation Officer(s), and with State or local historical societies, museums, or academic institutions having special expertise. In the event that a State Historic Preservation Officer finds that a proposed action will have an adverse effect on such property, there should also be evidence in the final EIS of subsequent consultation with the Advisory Council on Historic Preservation. A 4(f) determination may be required in addition to this discussion in the EIS, as provided in section 11 of this Order.

(21) *Construction impacts.* The EIS should identify and discuss the impacts associated with the construction period of each alternative, if any.

(s) A summary tabulation of unavoidable adverse impacts of the alternatives and a description of mitigation measures planned to minimize each adverse impact. Impacts and mitigation measures should be identified in this table as either long-term, short-term, or construction-period. If a proposed action will have an adverse effect on a property included in or eligible for inclusion in the National Register of Historic Places, this part of the final EIS shall include a copy of any Memorandum of Agreement with, or other response to comments by, the Advisory Council on Historic Preservation, in accordance with 36 CFR Part 800. This part of the EIS should also include a summary of any irreversible or irretrievable commitments of resources and any foreclosures of future options that would be likely to result from the alternatives.

(t) A brief discussion of the relationship between local short-term uses of the environment affected by the alternatives, and the maintenance and enhancement of long-term productivity in that environment.

(u) Any 4(f) determination covering the same proposed action as the EIS.

(v) In a final EIS, a compilation of all responsible comments received on the draft EIS, whether made in writing or at a public hearing, and responses to each comment. Comments may be collected and summarized except for comments by Federal agencies and where otherwise required by Federal law or regulation. Responses shall indicate how each issue raised by the comments has been resolved.

(w) An index, if possible and useful.

(x) A bibliography.

(y) Appendices of technical tables, graphs, maps, and other data not likely to be immediately helpful to a lay person reading the text but important to an expert's analysis of environmental impacts. Only that data generated in conjunction with the particular environmental assessment should be included; data or background information readily available from other sources should be referenced but should not ordinarily be reprinted in the EIS.

(z) Signature and date indicating the approval of the Administrator as required by section 12(c) of this Order.

[FR Doc. 79-8039 Filed 3-15-79; 8:45 am]

[8320-01-M]

VETERANS ADMINISTRATION

VETERANS ADMINISTRATION WAGE COMMITTEE

Availability of Annual Report

Pursuant to the provisions of section 10(d) of Pub. L. 92-463 (Federal Advisory Committee Act) and OMB Circular A-63 of March 27, 1974, notice is hereby given that the Annual Report of the Veterans Administration Wage Committee for calendar year 1978 has been issued.

The report summarizes activities of the Committee on matters related to wage surveys and pay schedules for Federal prevailing rate employees. It is available for public inspection at two locations:

Library of Congress, Microfilm Reading Room, Room MB-140B, Main Building, 10 First Street, SE., Washington, D.C. 20540.

Veterans Administration, Office of the Secretary, VA Wage Committee, Room 1102, 810 Vermont Avenue, NW., Washington, D.C. 20420.

Dated: March 12, 1979.

MAX CLELAND,
Administrator.

[FR Doc. 79-8023 Filed 3-15-79; 8:45 am]

[7035-01-M]

INTERSTATE COMMERCE COMMISSION

[Notice No. 46]

ASSIGNMENT OF HEARINGS

MARCH 13, 1979.

Cases assigned for hearing, postponement, cancellation or oral argument appear below and will be published only once. This list contains prospective assignments only and does not include cases previously assigned hearing dates. The hearings will be on the issues as presently reflected in the Official Docket of the Commission. An attempt will be made to publish notices of cancellation of hearings as promptly as possible, but interested parties should take appropriate steps to insure that they are notified of cancellation or postponements of hearings in which they are interested.

No. 37087, Clevepak Corporation V. Checker Express Co. and O.K. Motor Service, Inc., now being assigned for hearing on May 3, 1979 (2 days), at Chicago, IL, in a hearing room to be later designated.

MC 115331 (Sub-457F), Truck Transport Incorporated, now assigned for continued hearing on April 17, 1979 (4 days), at St. Francis Hotel, Union Square at Powell Street, San Francisco, California.

MC 117940 (Sub-281F), Nationwide Carriers, Inc., now assigned for hearing on April 23, 1979 (2 days), at Chicago, Illinois, in a hearing room to be later designated.
MC 133689 (Sub-215F), Overland Express, Inc., now assigned for hearing on April 25, 1979 (3 days), at Chicago, Illinois, in a hearing room to be later designated.
MC 123407 (Sub-478F), Sawyet Transport Inc, MC 128270 (Sub-33F), Rediehs Interstate, Inc., now assigned for hearing on June 25, 1979 (5 day), at Denver, Colorado, in a hearing room to be later designated.
MC 82063 (Sub-94F), Klipsch Hauling Co., now assigned for hearing on April 9, 1979 (2 days), at Dallas, Texas, in a hearing room to be later designated.
MC 124151 (Sub-8F), Vanguard Transportation, Incorporated, now assigned for hearing on May 9, 1979 (3 days), at New York, N.Y., in a hearing room to be later designated.

H. G. HOMME, Jr.
Secretary.

[FR Doc. 79-8053 Filed 3-15-79; 8:45 am]

[7035-01-M]

[I.C.C. Order No. 29 Under Service Order No. 1344]

MISSOURI-KANSAS-TEXAS RAILROAD CO.

Rerouting Traffic

In the opinion of Joel E. Burns, Agent, the Missouri-Kansas-Texas Railroad Company is unable to transport promptly all traffic offered for movement over its lines between Burkburnett, Texas, and Welon, Oklahoma, because of track conditions.

It is ordered,

(a) *Rerouting traffic.* The Missouri-Kansas-Texas Railroad Company, being unable to transport promptly all traffic offered for movement over its lines between Burkburnett, Texas, and Welon, Oklahoma, because of track conditions, is authorized to divert or reroute such traffic via any available route to expedite the movement. Traffic necessarily diverted by authority of this order shall be rerouted so as to preserve as nearly as possible the participation and revenues of other carriers provided in the original routing. The billing covering all such cars rerouted shall carry a reference to this order as authority for the rerouting.

(b) *Concurrence of receiving roads to be obtained.* The railroad rerouting cars in accordance with this order shall receive the concurrence of other railroads to which such traffic is to be diverted or rerouted, before the rerouting or diversion is ordered.

(c) *Notification of shippers.* Each carrier rerouting cars in accordance with this order, shall notify each shipper at the time each shipment is rerouted or diverted and shall furnish to such shipper the new routing provided under this order.

(d) Inasmuch as the diversion or rerouting of traffic is deemed to be due to carrier disability, the rates applicable to traffic diverted or rerouted by said Agent shall be the rates which were applicable at the time of shipment on the shipments as originally routed.

(e) In executing the directions of the Commission and of such Agent provided for in this order, the common carriers involved shall proceed even though no contracts, agreements or arrangements now exist between them with reference to the divisions of the rates of transportation applicable to said traffic. Divisions shall be, during the time this order remains in force, those voluntarily agreed upon by and between said carriers; or upon failure of the carriers to so agree, said divisions shall be those hereafter fixed by the Commission in accordance with pertinent authority conferred upon it by the Interstate Commerce Act.

(f) *Effective date.* This order shall become effective at 4:00 a.m., March 6, 1979.

(g) *Expiration date.* This order shall expire at 11:59 p.m., April 30, 1979, unless otherwise modified, changed or suspended.

This order shall be served upon the Association of American Railroads, Car Service Division, as agent of all railroads subscribing to the car service and car hire agreement under the terms of that agreement, and upon the American Short Line Railroad Association. A copy of this order shall be filed with the Director, Office of the Federal Register.

Issued at Washington, D.C., March 6, 1979.

INTERSTATE COMMERCE COMMISSION,
JOEL E. BURNS,
Agent.

[FR Doc. 79-8051 Filed 3-15-79; 8:45 am]

[7035-01-M]

[Notice No. 166]

MOTOR CARRIER BOARD TRANSFER PROCEEDINGS

The following publications include motor carrier, water carrier, broker, and freight forwarder transfer applications filed under Section 212(b), 206(a), 211, 312(b), and 410(g) of the Interstate Commerce Act.

Each application (except as otherwise specifically noted) contains a statement by applicants that there will be no significant effect on the quality of the human environment resulting from approval of the application.

Protests against approval of the application, which may include request for oral hearing, must be filed with the Commission within 30-days after the date of this publication. Failure seasonably to file a protest will be construed as a waiver of opposition and participation in the proceeding. A protest must be served upon applicants' representative(s), or applicants (if no such representative is named), and the protestant must certify that such service has been made.

Unless otherwise specified, the signed original and six copies of the protest shall be filed with the Commission. All protests must specify with particularity the factual basis, and the section of the Act, or the applicable rule governing the proposed transfer which protestant believes would preclude approval of the application. If the protest contains a request for oral hearing, the request shall be supported by an explanation as to why the evidence sought to be presented cannot reasonably be submitted through the use of affidavits.

The operating rights set forth below are in synopses form, but are deemed sufficient to place interested persons on notice of the proposed transfer.

MC-FC-77988, filed January 5, 1979. Tranferee: J & D AUTOMOTIVE, INC., 5415 Leavenworth Road, Kansas City, KS 66104. Transferor: KANSAS CITY TOW SERVICE, INC., 3305 Stadium Drive, Kansas City, MO 64129. Representative: James D. Howell, Jr., Attorney at Law, 110 Fox Hill Office Bldg., 4550 W. 109th St., Overland Park, KS 66211. Authority sought for purchase by transferee of the operating rights of transferor as set forth in Certificate No. MC-116109 issued February 26, 1974, as follows: Wrecked or disabled motor vehicles and trucks, from points in Kansas and Missouri to Kansas City, MO; and replacement motor vehicles for those wrecked or disabled, when transported by wrecker equipment, from Kansas City, MO, to points in Missouri and Kansas. Transferee presently holds no authority from this Commission. Application has not been filed for temporary authority under Section 210a(b).

H. G. HOMME, Jr.,
Secretary.

[FR Doc. 79-8052 Filed 3-15-79; 8:45 am]

[7035-01-M]

[Notice No. 39]

MOTOR CARRIER TEMPORARY AUTHORITY APPLICATIONS

MARCH 9, 1979.

The following are notices of filing of applications for temporary authority under Section 210a(a) of the Interstate Commerce Act provided for under the provisions of 49 CFR 1131.3. These rules provide that an original

and six (6) copies of protests to an application may be filed with the field official named in the FEDERAL REGISTER publication no later than the 15th calendar day after the date the notice of the filing of the application is published in the FEDERAL REGISTER. One copy of the protest must be served on the applicant, or its authorized representative, if any, and the protestant must certify that such service has been made. The protest must identify the operating authority upon which it is predicated, specifying the "MC" docket and "Sub" number and quoting the particular portion of authority upon which it relies. Also, the protestant shall specify the service it can and will provide and the amount and type of equipment it will make available for use in connection with the service contemplated by the TA application. The weight accorded a protest shall be governed by the completeness and pertinence of the protestant's information.

Except as otherwise specifically noted, each applicant states that there will be no significant effect on the quality of the human environment resulting from approval of its application.

A copy of the application is on file, and can be examined at the Office of the Secretary, Interstate Commerce Commission, Washington, D.C., and also in the ICC Field Office to which protests are to be transmitted.

NOTE.—All applications seek authority to operate as a common carrier over irregular routes except as otherwise noted.

MOTOR CARRIERS OF PROPERTY

MC 720 (Sub-62TA), filed February 12, 1979. Applicant: BIRD TRUCKING COMPANY, INC., P.O. Box 227, Waupun, WI 53963. Representative: Tom Westerman (same address as applicant). *Drugs, medicines and such commodities as are dealt in by wholesale and retail food chains, drugstores, hospitals, discount and variety stores, and grocery houses (except in bulk)* from the facilities of Bristol-Myers, Inc., at or near Bedford Park, IL to Milwaukee, WI and its commercial zone, for 180 days. Supporting shipper(s): Bristol Myers Co., P.O. Box 8528, Chicago, IL 60680. Send protests to: Gail Daugherty, Transportation Asst., Interstate Commerce Commission, Bureau of Operations, U.S. Federal Building and Courthouse, 517 East wisconsin Avenue, Room 619, Milwaukee, Wisconsin 53202.

MC 14252 (Sub-44TA), filed February 12, 1979. Applicant: COMMERCIAL LOVELACE MOTOR FREIGHT, INC., 3400 Refugee Road, Columbus, Ohio 43227. Representative: William C. Buckham, 3400 Refugee Road, Columbus, Ohio 43227. Common-regular. *General commodities (except those of unusual value, Classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment),* between Friendly, WV and Ravenswood, WV, over WV Hwy 2, serving all intermetiate points and all off-route points in Pleasants and Wood Counties, WV for 180 days. Supporting shipper(s): There are 16 shippers. Their statements may be examined at the office listed below and headquarters. Send protests to: Frank L. Calvary, District Supervisor, Interstate Commerce Commission, 220 Federal Building and U.S. Courthouse, 85 Marconi Boulevard, Columbus, Ohio 43215.

MC 25798 (Sub-358TA), filed February 13, 1979. Applicant: CLAY HYDER TRUCKING LINES, INC., P.O. Box 1186, Auburndale, FL 33823. Representative: Tony G. Russell (same address as applicant). *Part I—Petroleum* and *petroleum products, vehicle body sealer* and/or *sound deadener compounds* and *filters* (except in bulk, in tank vehicles) from points in Warren County, MS to points in AL, AR, FL, GA, KS, MO, NC, OK, SC, TN and TX. *Part II—Petroleum* and *petroleum products, vehicle body sealer* and/or *sound deadener compounds* and *filters, materials, supplies* and *equipment* as are used in the manufacture, sale and distribution of the commodities named in Part I above (except in bulk, in tank vehicles) from points in AL, GA and SC to points in Warren County, MS. Restricted in Parts I and II above to shipments originating at or destined to the facilities of Quaker State Oil Refining Corporation located in Warren County, MS. Supporting shipper(s): Quaker State Oil Refining Corp., P.O. Box 989, Oil City, PA 16301. Send protests to: Donna M. Jones, Transportation Assistant, Interstate Commerce Commission—BOp, Monterey Building, Suite 101, 8410 N.W. 53rd Terrace, Miami, FL 33166.

MC 43038 (Sub-476TA), filed February 13, 1979. Applicant: COMMERCIAL CARRIERS, INC., 10701 Middlebelt Rd., Romulus, MI 48174. Representative: Paul H. Jones, 29725 Shackett Ave., Madison Heights, MI 48071. *Trucks,* in truckaway service, between points in CA and NV, for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): Chrysler Corporation, P.O. Box 1976, Detroit, MI 48231; Nissan Motor Corporation, in U.S.A., 18501 S. Figueroa Carson, CA 90248; Mazda Motors of America (Central), Inc., 3040 E. Ana St., Compton, CA 90221; Toyota Motor, Sales, U.S.A., Inc., 2055 W. 190th St., Torrance, CA 90501. Send protests to: Tim Quinn, DS, ICC, 604 Federal Building and U.S. Courthouse, 231 W. Lafayette Blvd., Detroit, MI 48226.

MC 55896 (Sub-112TA), filed February 13, 1979. Applicant: R-W SERVICE SYSTEM, INC., 20225 Goddard Rd., Taylor, MI 48180. Representative: George E. Batty (same as applicant). *Iron and steel articles,* from the facilities of Inland Steel Company at East Chicago, IN, to points in IL, IA, MI, and OH, for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): Inland Steel Company, 30 W. Monroe St., Chicago, IL 60603. Send protests to: Tim Quinn, DS, ICC, 604 Federal Building and U.S. Courthouse, 231 W. Lafayette Blvd., Detroit, MI 48226.

MC 56244 (Sub-72TA), filed February 8, 1979. Applicant: KUHN TRANSPORTATION COMPANY, INC., P.O. Box 98, R.D. No. 2, Gardners, PA 17324. Representative: John M. Musselman, P.O. Box 1146, 410 North Third Street, Harrisburg, PA 17108. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Such merchandise as is dealt in by retail, wholesale, chain grocery and food business houses (except commodities in bulk), from facilities utilized by Musselman Food Products Division of Pet, Inc. at points in Berkeley and Jefferson Counties, WV, and from facilities utilized by Musselman Fruit Products Division of Pet, Inc. and Knouse Foods, Inc. at points in Adams, Cumberland, Dauphin, Franklin and York Counties, PA, to points in IL, IN, IA, KY, MI, MO, OH, PA, those in that part of WV on and north of U.S. Hwy 50, New York, NY and Baltimore, MD, and points in their commercial zones, restricted to transportation of shipments originating at said facilities and destined to the points indicated. Supporting shipper(s): Musselman Fruit Products Division of Pet, Inc., Biglerville, PA 17307. Send protests to: Charles F. Myers, District Supervisor, Interstate Commerce Commission, P.O. Box 869, Federal Square Station, 228 Walnut Street, Harrisburg, PA 17108.

MC 56244 (Sub-73TA), filed February 8, 1979. Applicant: KUHN TRANSPORTATION COMPANY, INC., P.O. Box 98, R.D. No. 2, Gardners, PA 17324. Representative: John M. Musselman, P.O. Box 1146, 410 North Third Street, Harrisburg, PA 17108. Common carrier, by motor vehicle, over irregular routes, transporting: *Foodstuffs* (except commodities in bulk and frozen foods), from the facilities of Lawry's Foods Inc. at Des Plaines, IL, to points in York County, PA, restricted to the transportation of shipments originating at said facilities and destined to the points named for 180 days. Supporting shipper(s):

Lawry's Foods, Inc., 568 San Fernando Rd., Los Angeles, CA 90065. Send protests to: Charles F. Myers, District Supervisor, Interstate Commerce Commission, P.O. Box 869, Federal Square Station, 228 Walnut Street, Harrisburg, PA 17108.

MC 57778 (Sub-24TA), filed February 12, 1979. Applicant: MICHIGAN REFRIGERATED TRUCKING SERVICE, INC., 6134 W. Jefferson Ave., Detroit, MI 48209. Representative: William B. Elmer, 21635 E. Nine Mile Rd., St. Clair Shores, MI 48080. *Foodstuffs,* from the facilities of Aunt Jane's Foods, Inc. at or near Croswell, MI to points in TX, OK, KS, MO, IA, IN, IL, and KY, for 180 days. Supporting shipper(s): Aunt Jane's Foods, Inc., 55 E. Sanborn, Croswell, MI 48422, James Kettlewell, Traffic Manager. Send protests to: Tim Quinn, DS, ICC, 604 Federal Building and U.S. Courthouse, 231 W. Lafayette Blvd., Detroit, MI 48226.

MC 82492 (Sub-223TA), filed February 8, 1979. Applicant: MICHIGAN & NEBRASKA TRANSIT CO., INC., 2109 Olmstead Road, P.O. Box 2853, Kalamazoo, MI 49003. Representative: Dewey R. Marselle (same address as applicant). *Zinc, Zinc Oxide, Zinc Dust and Cadmium,* from the facilities of St. Joe Zinc Co. located at Josephtown, (Potter Township, Beaver County), PA, to pts in IA, IL, IN, KS, MI, MN, MO, NE, and WI for 180 days. Supporting shipper(s): St. Joe Zinc Co., 2 Oliver Plaza, Pittsburgh, PA 15222. Send protests to: Mr. Clarence Flemming, District Supervisor, Interstate Commerce Commission, 225 Federal Building, 325 West Allegan Street, Lansing, MI 48933.

MC 82492 (Sub-224TA), filed February 2, 1979. Applicant: MICHIGAN & NEBRASKA TRANSIT CO., INC., 2109 Olmstead Road, P.O. Box 2853, Kalamazoo, MI 49003. Representative: Dewey R. Marselle (same address as applicant). *Frozen foods,* from the facilities of Banquet Foods Corp. at Carrollton, Marshall, Macon and Moberly, MO to pts in IL, IN, MI, OH, those pts in NY in west of Allegany, Livingston and Monroe Counties and those pts in PA on and west of U.S. Hwy 219 for 180 days. An underlying ETA has been granted. Supporting shipper(s): Banquet Foods Corp., 100 N. Broadway, St. Louis, MO 63102. Send protests to: Mr. Clarence Flemming, District Supervisor, Interstate Commerce Commission, 325 West Allegan Street, Lansing, MI 48933.

MC 105007 (Sub-46TA), filed February 12, 1979. Applicant: MATSON TRUCK LINES, INC., 1407 St. John Avenue, Albert Lea, MN 56007. Representative: Val M. Higgins, 1000 First National Bank Building, Minneapolis, MN 55402. *Fresh meat* from Ottumwa, IA to Crescent Springs, Ky, for 180 days. An underlying ETA seeks 90 days authority. Supporting Shipper(s): Geo. A. Hormel & Co., P.O. Box 800, Austin, MN 55912. Send protests to: Delores A. Poe, Transportation Assistant, Interstate Commerce Commission, 414 Federal Building & U.S. Court House, 110 South 4th Street, Minneapolis, MN 55401.

MC 105007 (Sub-47TA), filed February 12, 1979. Applicant: MATSON TRUCK LINES, INC., 1407 St. John Avenue, Albert Lea, MN 56007. Representative: Val M. Higgins, 1000 First National Bank Building, Minneapolis, MN 55402. *Animal fats* from Estherville, IA to Sioux Falls, SD, for 180 days. An underlying ETA seeks 90 days authority. Supporting Shipper(s): John Morrell & Co., 208 South LaSalle Street, Chicago, IL 60604. Send protests to: Delores A. Poe, Transportation Assistant, Interstate Commerce Commission, 414 Federal Building & U.S. Court House, 110 South 4th Street, Minneapolis, MN 55401.

MC 105120 (Sub-18TA), filed February 12, 1979. Applicant: FREIGHTWAYS EXPRESS, INC., 2700 Sterick Building, Memphis, TN 38103. Representative: James N. Clay III (same as applicant). *General commodities* (except those of unusual value, Classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment) between the facilities of American Greetings Corporation at Harrisburg, Osceola, McCrory, AR, on the one hand, and, on the other, Jonesboro, Forest City and Wynne, AR. Restricted to traffic having an immediately prior or subsequent movement by rail, for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): American Greetings Corporation, 10500 American Road, Cleveland, OH 44144. Send protests to: Floyd A. Johnson, District Supervisor, Interstate Commerce Commission, 100 North Main Building, Suite 2006, 100 North Main Street, Memphis, TN 38103.

MC 105813 (Sub-252TA), filed February 12, 1979. Applicant: BELFORD TRUCKING CO., INC., 1759 S.W. 12th Street, P.O. Box 2009, Ocala, FL 32670. Representative: Arthur J. Sibik, 7025 S. Pulaski Road, Chicago, IL 60629. *Liquid chocolate products in bulk, in tank vehicles,* from the facilities of M & M/Mars, a division of Mars, Inc., at or near Chicago, IL and Elizabethtown, PA, to the facilities of M & M/Mars, a division of Mars, Inc., at or near Cleveland, TN. Supporting shipper(s): M & M Mars, a division of Mars, Inc., High Street, Hackettstown, NJ 07840. Send prtests to: G. H. Fauss, Jr., DC, ICC, Box 35008, 400 West Bay Street, Jacksonville, FL 32202.

MC 107012 (Sub-343TA), filed February 9, 1979. Applicant: NORTH AMERICAN VAN LINES, INC., P.O. Box 988, Fort Wayne, IN 46801. Representative: Stephen C. Clifford (same as applicant). *Plastic plumbing fixtures and accessories, supplies and equipment used in the manufacture and distribution thereof,* from Walden (Bibb County), GA to points in IA, KS, MN, NC, ND, SD, VA and WV, for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): American Standard Inc., P.O. Box 2003, New Brunswick, NJ 08903. Send protests to: Beverly J. Williams, Transportation Assistant, Interstate Commerce Commission, 46 East Ohio Street, Room 429, Indianapolis, IN 46204.

MC 109584 (Sub-190TA), filed February 8, 1979. Applicant: ARIZONA-PACIFIC TANK LINES, 3980 Quebec St., P.O. Box 7240, Denver, CO 80207. Representative: Rick Barker (as above). *Sodium hydrosulfide,* in bulk, in tank vehicles, from Artesia, NM to Sahuarita, AZ for 180 days. Underlying ETA seeking 90 days filed. Supporting shipper(s): Kerley Chemical Co., 2801 W. Osborn Rd., Phoenix, AZ 85009. Send protests to: D/S Roger L. Buchanan, Interstate Commerce Commission, 721 19th St., 492 U.S. Customs House, Denver, CO 80202.

MC 113434 (Sub-122TA), filed January 31, 1979. Applicant: GRA-BELL TRUCK LINE, INC., A-5253 144th Ave., Holland, MI 49423. Representative: Wilhelmina Boersma, 1600 First Federal Bldg., 1001 Woodward Ave., Detroit, MI 48226. *Paper and Paper Products* (except commodities in bulk), from the facilities of Scott Paper (1) Philadelphia, PA and it's Commercial Zone to IL, IN, MI, OH; (2) Columbus, OH and it's Commercial Zone to IL, IN, MI, MO for 180 days. An underlying ETA has been granted. Supporting shipper(s): Scott Paper Co., Scott Plaza, Philadelphia, PA 19113. Send protests to: Mr. Clarence Flemming, District Supervisor, Interstate Commerce Commission, 325 West Allegan Street, Lansing, MI 48933.

MC 113434 (Sub-123TA), filed February 13, 1979. Applicant: GRA-BELL TRUCK LINE, INC., A-5253, 144th Avenue, Holland, MI 49423. Representative: Roger Van Wyk (same as applicant). *Such commodities as are dealt in by wholesale and retail food and drug business houses (except commodities in bulk)* from the facilities of A. E. Staley Manufacturing Company, at Chicago, IL and its commercial zone to points in MI, for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): A. E. Staley Manufacturing Company, 2200 East Eldorado Street, Decatur, IL 62525. Send protests to: C. R. Flemming, Dis-

trict Supervisor, 225 Federal Building, Lansing, MI 48933.

MC 114457 (Sub-476TA), filed February 12, 1979. Applicant: DART TRANSIT COMPANY, 2102 University Avenue, St. Paul, MN 55114. Representative: James H. Wills (same address as applicant). *Foodstuffs (except commodities in bulk)* from Albany, GA to IL, IN, IA, KS, KY, MO, TN and WI, for 180 days. Supporting shipper(s): Holsum Foods, Inc., 500 South Prairie Avenue, Waukesha, WI 53186. Send protests to: Delores A. Poe, Transportation Assistant, Interstate Commerce Commission, 414 Federal Building and U.S. Court House, 110 South 4th Street, Minneapolis, MN 55401.

MC 114569 (Sub-286TA), filed February 12, 1979. Applicant: SHAFFER TRUCKING, INC., P.O. Box 418, New Kingstown, PA 17072. Representative: N. L. Cummins, P.O. Box 418, New Kingstown, PA 17072. Common carrier, by motor vehicle, over irregular routes, transporting: Cleaning, scrubbing and scouring compounds, NOIBN in mechanically temperature controlled equipment from Milwaukee, WI and its commercial zone to Hurricane, WV; Knoxville and Maryville, TN; and Harrisburg, PA and their commercial zones. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper(s): U.S. Chemical Corp., 316 Hart Street, Watertown, WI 53094. Send protests to: Charles F. Myers, District Supervisor, Interstate Commerce Commission, P.O. Box 869, Federal Square Station, 228 Walnut Street, Harrisburg, PA 17098.

MC 115826TA (Sub-392TA), filed January 29, 1979. Applicant: W. J. DIGBY, INC., 6015 East 58th Ave., Commerce City, CO 80022. Representative: Howard Gore (address same as above). *Bananas,* from Ports of Entry in TX, LA, MS, AL to Denver, CO and its commercial zone, for 180 days. Underlying ETA seeks 90 days authority. Supporting shipper(s): Western Grocers, 4200 Wynkoop, Denver, CO. Send protests to: Herbert C. Ruoff, District Supervisor, 492 U.S. Customs House, 721 19th Street, Denver, CO 80202.

MC 115826TA (Sub-393TA), filed January 16, 1979. Applicant: W. J. DIGBY, INC., 6015 East 58th Ave., Commerce City, CO 80022. Representative: Howard Gore (address same as above). *Meats and packinghouse products,* from Pueblo, CO to Philadelphia, Pittsburgh, Springhouse and Pittston, PA; Harrington, DE; Syracuse, NY and South Kearny, NJ, for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): Alpha Beta Packing Co., 303 South Santa Fe, Pueblo, CO 81002. Send protests to: District Supervisor H. C. Ruoff, 492 U.S. Customs House, 721 19th Street, Denver, CO 80202.

MC 115826 (Sub-394TA), filed February 6, 1979. Applicant: W. J. DIGBY, INC., 6015 East 58th Avenue, Commerce City, CO 80022. Representative: Howard Gore (same address as above). *Shampoo, toilet preparations, hair mist and cosmetics,* from the facilities of Vidal Sassoon, Chatsworth, CA to Kansas City and St. Louis, MO; Dallas, TX; New York City, NY; Atlanta, GA; Chicago, IL; Philadelphia, PA and their commercial zones and points in NJ, for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): Vidal Sassoon, Inc., 9640 Owensmouth Avenue, Chatsworth, CA 91311. Send protests to: District Supervisor Herbert C. Ruoff, 492 U.S. Customs House, 721 19th Street, Denver, CO 80202.

MC 115826 (Sub-396TA), filed February 8, 1979. Applicant: W. J. DIGBY, INC., 6015 East 58th Avenue, Commerce City, CO 80022. Representative: Howard Gore (same address as above). *Freight,* all kinds moving on Southeastern Michigan Shipper's Cooperative bills of lading from (1) Detroit, MI to Dallas and Houston, TX, New York City, NY, Boston and Worcester, MA, Philadelphia, PA, Denver, CO, Omaha, NE, Minneapolis and St. Paul, MN, Portland, OR, Seattle, WA, Los Angeles and San Francisco, CA, Phoenix, AZ, Atlanta, GA and Charlotte, NC; from (2) New York City, NY and Philadelphia, PA to Detroit, MI, for 180 days. An underlying ETA seeks authority for 90 days. Both (1) and (2) restricted to transportation of traffic originating at and destined to facilities of Southeastern Michigan Shippers' Cooperative. Supporting shipper(s): Southeastern Michigan Shipper's Cooperative, 1448 Wabash St., No. 1, Detroit, MI 48216. Send protests to: District Supervisor Herbert C. Ruoff, 492 U.S. Customs House, 721 19th Street, Denver, CO 80202.

MC 115841 (Sub-679TA), filed February 12, 1979. Applicant: COLONIAL REFRIGERATED TRANSPORTATION, INC., 9041 Executive Park Drive, Suite 110, Bldg. 100, Knoxville, TN 37919. Representative: D. R. Beeler (same address as applicant). *Household, commercial & institutional kitchen and laundry equipment, fixtures, appliances, and parts; electrical appliances, equipment & parts (except commodities in bulk and commodities which require the use of special equipment because of size or weight)* from facilities of McGraw-Edison Company, located at or near Chattanooga, TN; Ripon, WI; Searcy, AR; Madisonville, KY; and Albion, MI, to points in TN, NC, SC, GA, FL, AL, MS, and points in the United States in and west of LA, AR, MO, IA, and MN, for 180 days. Supporting shipper(s): McGraw-Edison Company, 333 West River Road, Elgin, IL 60120. Send protests to: Glenda Kuss, TA, ICC, Suite A-422, U.S. Court House, 801 Broadway, Nashville, TN 37203.

MC 115841 (Sub-680TA), filed February 12, 1979. Applicant: COLONIAL REFRIGERATED TRANSPORTATION, INC., 9041 Executive Park Drive, Suite 110, Bldg. 100, Knoxville, TN 37919. Representative: D. R. Beeler (same address as applicant). *Garden tractors and attachments, lawn tractors, chain saws, lawn mowers, recreational vehicles, grills, and parts and accessories for all of the above* (1) between the facilities of Roper Corp at or near Bradley, IL; Williamsburg, KY; Orangeburg, SC; Swainsboro, & McRae, GA; and Nogales, AZ; and (2) between the facilities of Roper Corp at or near Bradley, IL; Williamsburg, KY; Orangeburg, SC, Swainsboro & McRae, GA; and Nogales, AZ, on the one hand, and, on the other, points in AZ, GA, IL, IN, MI, NY, OH, PA, SC, and TX, for 180 days. Supporting shipper(s): Roper Corp., Broadway & Schuyler, Bradley, IL 60915. Send protests to: Glenda Kuss, TA, ICC, Suite A-422, U.S. Court House, 801 Broadway, Nashville, TN 37203

MC 116073 (Sub-373TA), filed February 13, 1979. Applicant: BARRETT MOBILE HOME TRANSPORT, INC., 1825 Main Avenue, P.O. Box 919, Moorhead, MN 56560. Representative: John C. Barrett (same address as applicant). *Travel trailers and/or motor homes,* from the plantsites of Kit Manufacturing Company at or near McPherson, KS, to points in CO, AR, IA, KS, LA, MO, NE, NM, OK, SD, TX, and WY, for 180 days. Supporting shipper(s): Kit Manufacturing Company, P.O. Box 459, Caldwell, ID 83605. Send protests to: Ronald R. Mau, DS, ICC, Room 268 Federal Building and U.S. Post Office, 657 2nd Avenue North, Fargo, ND 58102.

MC 118142 (Sub-208TA), filed February 12, 1979. Applicant: M. BRUENGER & CO., INC., 6250 No. Broadway, Wichita, KS 67219. Representative: Lester C. Arvin, 814 Century Plaza Bldg., Wichita, KS 67202. *Bananas, and agricultural commodities exempt from regulation* under Section 203(b)(6) of the Interstate Commerce Act, in mixed loads with bananas; from Gulport, MS to the States of MI, IN, IL, WS, IA and St. Louis, MO. Restricted to the transportation of traffic having an immediately prior movement by water. Supporting shipper(s): Castle and Cooke, P.O. Box 8743, Metairie, LA 70011. Send protests to: M. E. Taylor, Dist. Supv., Interstate Com-

merce Commission, 101 Litwin Bldg., Wichita, KS 67202.

MC 118745 (Sub-24TA), filed January 18, 1979. Applicant: JOHN PFROMMER, INC., P.O. Box 307, Douglassville, PA 19518. Representative: Theodore Polydoroff, Suite 301, 1307 Dolley Madison Blvd., McLean VA 22101. Contract carrier, irregular routes, *petroleum coke*, in bulk, in dump vehicles, from Paulsboro, NJ to Alsen, NY, under contract with I.M.C. Carbon Products, Division of International Minerals & Chemical Corp., for 180 days. Supporting shipper(s): International Minerals & Chemical Corp., 421 E. Hawley, Mundelein, Ill. 60060. Send protests to: T. M. Esposito, Trans. Asst., 600 Arch St., Room 3238, Philadelphia, PA 19106.

MC 119789 (Sub-547 TA), filed January 15, 1979. Applicant: CARAVAN REFRIGERATED CARGO, INC., P.O. Box 226188, Dallas, TX 75266. Representative: James K. Newbold, Jr., (same as above). *Plastic Materials* (except in bulk), in mechanically refrigerated equipment from the facilities of Cosden Oil & Chemical Company, at or near Big Springs, TX to points in the U.S. except AK, CA, and HI, for 180 days. Supporting shipper(s): Cosden Oil & Chemical Company, P.O. Box 1311, Big Spring, TX 79720. Send protests to: Opal M. Jones, Trans. Asst., Interstate Commerce Commission, 1100 Commerce Street, Room 13C12, Dallas, TX 75242.

MC 120924 (Sub-5TA), filed February 1, 1979. Applicant: B & W CARTAGE CO., INC., 2932 W. 79th St., Chicago, IL 60652. Representative: Carl L. Steiner, 39 S. LaSalle St., Chicago, IL 60652. *Auto parts*, from LaPorte, IN to Lyons, MI for 180 days. An underlying ETA has been granted. Supporting shipper(s): Chrysler Corp., P.O. Box 1976, Detroit, MI 48288. Send protests to: TA Annie Booker, 219 S. Dearborn St., Rm. 1386, Chicago, IL 60604.

MC 123294 (Sub-60TA), filed February 2, 1979. Applicant: WARSAW TRUCKING CO., 1102 W. Winona, Warsaw, IN 46580. Representative: H. E. Miller, Jr., South Haven Square, U.S. Hwy 6, Valparaiso, IN 46383. *Paper and Paper Products*, from the facility of Miami Paper Corp. located at West Carrollton, OH, to pts in WI and MO for 180 days. An underlying ETA has been granted. Supporting shipper(s): Miami Paper Corp., P.O. Box 66, West Carrollton, OH 45449. Send protests to: TA Annie Booker, 219 S. Dearborn St., Rm. 1386, Chicago, IL 60604.

MC 123405 (Sub-64TA), filed February 9, 1979. Applicant: FOOD TRANSPORT, INC., R.D. No. 1, Thomasville, PA 17364. Representative: Christian V. Graf, Esquire, 407 North Front Street, Harrisburg, PA 17101. Common carrier, by motor vehicle, over irregular routes, transporting: Beverage preparations, non-refrigerated, from the facilities of Coca Cola Co., Foods Division, at Auburndale, FL to points in PA, NJ, NY, MD, DC, OH, and DE, for 180 days. An underlying ETA seeks 90 day authority. Supporting shipper(s): Coca Cola Co., Foods Division, Box 247, Auburndale, Florida 33823. Send protests to: Charles F. Myers, District Supervisor, Interstate Commerce Commission, P.O. Box 869 Federal Square Station, 228 Walnut Street, Harrisburg, PA 17108.

MC 123407 (Sub-542TA), filed February 8, 1979. Applicant: SAWYER TRANSPORT, INC., South Haven Square, U.S. Hwy 6, Valparaiso, IN 46383. Representative: H. E. Miller, Jr. (same address as applicant). *Paper Products*, from the facilities of Hexagon Honeycomb Corp. located in St. Clarie County, IL, to Tulsa, OK and PA, OH, NC, AR, MO, TX, TN, KY, NE, MN, SC; and from facilities of Hexagon Honeycomb Corp. located at Elkhart, IN to MI, IN, IL, OH and PA for 180 days. An underlying ETA has been granted. Supporting shipper(s): Hexagon Honeycomb Corp., 7803 Clayton Road, Suite 201, St. Louis, MO 63117. Send protests to: TA Annie Booker, 219 S. Dearborn St., Rm. 1386, Chicago, IL 60604.

MC 123685 (Sub-26TA), filed February 12, 1979. Applicant: PEOPLES CARTAGE, INC., 8045 Navarre Road SW., Massilon, OH 44646. Representative: Boyd B. Ferris, Muldoon, Pemberton & Ferris, 50 West Broad Street, Columbus, OH 43215. *Scrap paper* from points in Grand Rapids, Detroit, Pontiac, and points in their commercial zones in MI, to points in OH. An underlying ETA seeks 90 days authority. Supporting shipper: Container Corporation of America, 500 E. North Avenue, Carrol Stream, IL 60187. Send protests to: Frank L. Calvary, District Supervisor, Interstate Commerce Commission, 220 Federal Building and U.S. Courthouse, 85 Marconi Boulevard, Columbus, OH 43215.

MC 124896 (Sub-84TA), filed February 5, 1979. Applicant: WILLIAMSON TRUCK LINES, INC., P.O. Box 3485, Wilson, NC 27893. Representative: Jack H. Blanshan, Suite 205, 205 West Touhy Avenue, Park Ridge, IL 60068. *Bananas* for Del Monte Banana Company from Wilmington, DE to IA, MN, and MO for 180 days. An underlying ETA was filed seeking 90 days authority. Supporting shipper: Del Monte Banana Co., P.O. Box 011940, Miami, FL 33101. Send protests to: Mr. Archie W. Andrews, District Supervisor, Interstate Commerce Commission, P.O. Box 26896, Raleigh, NC 27611.

MC 125335 (Sub-50TA), filed February 13, 1979. Applicant: GOOD-WAY, INC., P.O. Box 2283, York, PA 17405. Representative: Gailyn L. Larsen, P.O. Box 82816, Lincoln, NE 68501. *Common carrier*, by motor vehicle, over irregular routes, transporting prunes, prune extract, and prune juice, in containers, from the facilities of Diamond/Sunsweet, Inc., at or near Middleboro, MA, to points in FL, for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper: Diamond/Sunsweet, Inc., P.O. Box 1727, Stockton, CA 95201. Send protests to: Charles F. Myers, District Supervisory, Interstate Commerce Commission, P.O. Box 869, Federal Square Station, 228 Walnut Street, Harrisburg, PA 17108.

MC 125368 (Sub-45TA), filed February 12, 1979. Applicant: CONTINENTAL COAST TRUCKING CO., INC., P.O. Box 26, Holly Ridge, NC 28445. Representative: C. W. Fletcher (same address as applicant). *Meats, meat products, meat by-products and articles distributed by meat packinghouses as described in Sections A and C of Appendix I to the report in Descriptions in Motor Carrier Certificates 61 MCC 209 and 766 (except hides and commodities in bulk), and supplies used in the manufacture of meat products* between the facilities of Dubuque Packing Company, at or near Dubuque, Denison and Sioux City, IA, on the one hand, and, on the other points in AL, AR, CT, DE, DC, FL, GA, IL, IN, DS, KY, LA, ME, MD, MA, MI, MS, MO, NH, NJ, NY, NC, OH, OK, PA, RI, SC, TN, TX, VT, VA, WV, and WI for 180 days. An underlying ETA was filed seeking 90 days authority. Supporting shipper: Dubuque Packing Company, P.O. Box 340, Le Mars, IA 51031. Send protests to: Mr. Archie W. Andrews, District Supervisor, Interstate Commerce Commission, P.O. Box 26896, Raleigh, NC 27611.

MC 126109 (Sub-8TA), filed February 12, 1979. Applicant: TRECHO TRANSPORT, INC., 2756 Short Street, York, NY 14592. Representative: S. Michael Richards/Raymond A Richards, P.O. Box 225, Webster, NY 14580. *Frozen foodstuffs*, from Brockport, NY to Buffalo, NY and Erie PA, for 180 days. Corresponding ETA under R-6 granted. Supporting shipper: Brockport Cold Storage Co., Inc., Joseph DeMarck, Vice-President, 98 Spring St.-Box C, Brockport, NY 14420. Send protests to: Interstate Commerce Commission, U.S. Courthouse & Federal Bldg., 100 S. Clinton St.-Rm. 1259, Syracuse, New York 13260.

MC 127042 (Sub-243TA), filed February 12, 1979. Applicant: HAGEN, INC., 3232 Highway 75 North, P.O. Box 98, Leeds Station, Sioux City, IA 51108.

Representative: Robert G. Tessar (same address as applicant). *Meats, meat products and meat by-products, and articles distributed by meat packinghouses, as described in Sections A and C of Appendix I to the report in Descriptions in Motor Carrier Certificates, 61 M.C.C. 209 and 766 (except hides and except commodities in bulk),* from Carroll, Iowa Falls, and Denison, IA to points in AZ, CA, OR, CO, ID, MT, NV, NM, TX, UT, WA, and WY, for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper: Dean D. Wilson, Farmland Foods, Inc., P.O. Box 403, Denison, IA 51442. Send protests to: Carroll Russell, ICC, Suite 620, 110 No. 14th St., Omaha, NE 68102.

MC 133095 (Sub-238TA), filed February 12, 1979. Applicant: TEXAS CONTINENTAL EXPRESS, INC., P.O. Box 434, Euless, TX 76039. Representative: Mark C. Ellison, P.O. Box 872, 235 Peachtree Street, Northeast, Atlanta, GA 30301. (1) *Reflective traffic control products, pavement marking compounds and materials, equipment and supplies used in the installation of the foregoing commodities,* from Cobb County, GA, to points in the U.S. (except AK and HI); and, (2) *equipment, machinery, materials, and supplies used in the manufacture, distribution and installation of the commodities named in (1) above,* from Baton Rouge, LA; Brownwood and Paris, TX; Jackson, MS; Savannah, GA; Apex, NC; Keyser, WV; and Cleveland, OH, to Cobb County, GA; commodities in (1) and (2) above restricted against the transportation of commodities in bulk, for 180 days. Supporting shipper: Pave-Mark Corporation, 1177 Hayes Industrial Drive, Marietta, GA 30060. Send protests to: Martha A. Powell, Transportation Asst., Interstate Commerce Commission, Room 9A27 Federal Building, 819 Taylor Street, Fort Worth, TX 76102.

MC 135007 (Sub-72TA), filed February 12, 1979. Applicant: AMERICAN TRANSPORT, INC., 7850 "F" Street, Omaha, NE 68127. Representative: Arthur J. Cerra, 2100 TenMain Center, P.O. Box 19251, Kansas City, MO 64141. *Contract carrier:* irregular routes: *Tallow, edible and inedible,* from the facilities of Spencer Foods, Inc., at or near Schuyler, NE to points in IL and IN, for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper: Don Brink, Spencer Foods, Inc., P.O. Box 544, Schuyler, NE 68661. Send protests to: Carroll Russell, ICC, Suite 620, 110 No. 14th St., Omaha, NE 68102.

MC 135410 (Sub-42TA), filed February 12, 1979. Applicant: Courtney J. Munson, d.b.a. MUNSON TRUCKING North Sixth Street Road, P.O. Box 266, Monmouth, IL 61462. Representative: Stephen H. Loeb, Attorney, suite 200, 205 West Touhy Avenue, Park Ridge, IL 60068. *Salt* (except in bulk), from the facilities of Morton Salt Co., at Manistee, Michigan to points in Illinois, Indiana, Iowa, Missouri and Wisconsin, for 180 days. An underlying ETA seeks 90 day authority. Supporting shipper: Morton Salt, Divison of Morton-Norwich Products, 110 North Wacker Drive, Chicago, IL 60606. Send protests to: Charles D. Little, District Supervisor, Interstate Commerce Commission, 414 Leland Office Building, 527 East Capitol Avenue, Springfield, IL 62704.

MC 135797 (Sub-177 TA), filed February 1, 1979. Applicant: J. B. HUNT TRANSPORT, INC., P.O. Box 200, Lowell, AR 72745. Representative: Paul R. Bergant (same as applicant). *Pallets* for Fayetteville, AR to points in IA, KS, MO, OK and TX, for 180 days, as a common carrier over irregular routes. Supporting shipper: Ozark Forrest Products, Inc., Fayetteville, AR 72701. Send protests to: William H. Land, Jr., District Supervisor, 3108 Federal Office Building, 700 West Capitol, Little Rock, AR 72201.

MC 135989 (Sub-3TA), filed February 8, 1979. Applicant: COAST EXPRESS, INC., P.O. Box 1215, Whittier, CA 90609. Representative: William J. Lippman, suite 330, Steele Park, 50 South Steele Street, Denver, CO 80209. *Contract:* irregular: *Such commodities as are used, distributed and dealt in by fabricators and distributors of canvas, webbing and industrial fabrics,* from points in AL, CT, FL, GA, NY, NJ, NC, OH, PA, RI, SC, TX and MO to points in CA, limited to a transportation service to be performed under a continuing contract or contracts with United Textile and Supply Company, division of Elizabeth Webbing Mills Co., Inc., for 180 days. An underlying ETA seeks up to 90 days operating authority. Supporting shipper: Elizabeth Webbing Mills Co., Inc., 1641 North Allesandro Street, Los Angeles, CA 90026. Send protests to: Irene Carlos, Transportation Assistant, Interstate Commerce Commission, Room 1321 Federal Building, 300 North Los Angeles Street, Los Angeles, CA 90012.

MC 136268 (Sub-19TA), filed February 12, 1979. Applicant: WHITEHEAD SPECIALTIES, INC., 1017 Third Avenue, Monroe, WI 53566. Representative: Michael Wyngaard, 150 E. Gilman Street, Madison, WI 53703. *Petroleum products, in containers,* from Roxana, IL to Milwaukee, Monroe, Brodhead and Waukesha, WI, for 180 days. An underlying ETA seeks 90 days Supporting shipper: McManus Oil Co., Inc., 1105 W. Fourth Ave., Brodhead, WI 53520. Send Protests to: Gail Daugherty, Transportation Asst., Interstate Commerce Commission, Bureau of Operations, U.S. Federal Building & Courthouse, 517 East Wisconsin Avenue, Room 619, Milwaukee, Wisconsin 53202.

MC 136407 (Sub-22TA), filed February 8, 1979. Applicant: COORS TRANSPORTATION CO., 5101 York Street, Denver, CO 80216. Representative: Leslie R. Kehl, 1600 Lincoln Center, 1660 Lincoln Street, Denver, CO 80264. *Contract* irregular, *articles dealt in by wholesale or retail drug, grocery and department stores,* from the facilities of Warner-Lambert Company, at Anaheim, CA to Portland and Medford, OR, and Spokane, Seattle and Tacoma, WA, restricted to transportation under contract with Warner-Lambert Company, for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): Warner-Lambert Company, 201 Tabor Road, Morris Plains, NJ 07950. Send protests to: District Supervisor Herbert C. Ruoff, 492 U.S. Customs House, 721 19th Street, Denver, CO 80202.

MC 136605 (Sub-90TA), filed February 13, 1979. Applicant: DAVIS BROS. DIST., INC., P.O. Box 8058, Missoula, MT 59807. Representative: Allen P. Felton (same address as applicant). *Aluminum ingots* from Columbia Falls, MT to Terre Haute, IN, for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): Robert F. Archer, Director of Transportation, The Anaconda Company, Aluminum Division, P.O. Box 32860, Louisville, KY 40232. Send protests to: Paul J. Labane, DS, ICC, 2602 First Avenue North, Billings, MT 59101.

MC 138643 (Sub-7TA), filed January 29, 1979. Applicant: MAKOVSKY BROTHERS, INC., 5202 Spring Mill Rd., Whitehall, PA 18052. Representative: Walter K. Swartzkofp, Jr., 407 N. Front St., Harrisburg, PA 17101. *Industrial rock salt,* in bulk, in dump vehicles, from the facilities of International Salt Co. in Lower Nazareth Township, Northampton County, PA to points in NY, NJ, DE and MD, for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): International Salt Co., Merritt Plaza, 30 Buxton Farm Rd., Stamford, CT. 06905. Send protests to: T. M. Esposito, Trans. Asst., 600 Arch St., Room 3238, Philadelphia, PA 06905.

MC 138686 (Sub-7TA), filed February 13, 1979. Applicant: L.C.W. TRUCKING, INC., 119 East Chavez St., Edinburg, TX 78539. Representative: L. C. Waller, P.O. Box 718, Edinburg, TX 78539. *Doors, door frames and mouldings* from the port of entry on the United States Mexican Border at or near El Paso, TX to Diboll and Harlingen, TX for 180 days. Restricted to traffic moving in foreign commerce. An underlying ETA seeks 90 days au-

thority. Supporting shipper(s): Ponderosa Products, Inc., P.O. Box 5231, El Paso, TX 79953. Send protests to: Richard H. Dawkins, District Supervisor, Interstate Commerce Commission, Room B-400 Federal Bldg., 727 E. Durango St., San Antonio, TX 78206.

MC 139006 (Sub-7TA), filed Feb. 2, 1979. Applicant: Rapier Smith, Rural Route 5, Loretto Road, Bardstown, KY 40004. Representative: Robert H. Kinker, Attorney, P.O. Box 464, Frankfort, KY 40602. Such commodities as are dealt in and used by producers and distributors of alcoholic beverages, liquors, and wines (except commodities in bulk in tank vehicles), between Bardstown, Ky., and its commercial zone, on the one hand, and, on the other, points in the United States in and East of IA, KS, MN, MO, OK, and TX. Supporting Shipper(s): Will F. Osborne, Traffic Manager, Barton Brands, LTD., P.O. Box 220, Bardstown, Ky. 40004; C. E. Mieras, Controller, General-Standard, Inc., 165 W. 9th Ave., North Kansas City, MO 64116. Send protests to: Mrs. Linda, H. Sypher, District Supervisor, Interstate Commerce Commission, 426 Post Office Building, Louisville, KY 40202.

MC 139112 (Sub-18TA), filed February 12, 1979. Applicant: CALEX EXPRESS, INC., 149 Warden Ave., Trucksville, PA 18708. Representative: Joseph F. Hoary, 121 S. Main St., Taylor, PA 18517. *Confectionery and cough drops,* from the facilities of Luden's, Inc., at Reading, PA, to WA, OR, CA, TX, OK, NM, UT, CO and AZ, for 150 days. An underlying ETA seeks 90 days authority. Supporting Shipper(s): Luden's, Inc., 200 N. Eighth St., Reading, PA 19601. Send protests to: P. J. Kenworthy, DS, ICC, 314 U.S. Post Office Bldg., Scranton, PA 18503.

MC 139171 (Sub-1TA), filed February 5, 1979. Applicant: CONTROLLED DELIVERY SERVICE, INC., P.O. Box 1299, City of Industry, CA 91749. Representative: Patricia M. Schnegg, Knapp, Stevens, Grossman & Marsh, 707 Wilshire Blvd., Los Angeles, CA 90017. *Contract:* irregular: *Hospital supplies,* between El Paso, TX, on the one hand, and, on the other, points in the United States, except Alaska and Hawaii, for 180 days. Supporting Shipper(s): Convertors, Division of American Hospital Supply Corporation, One Butterfield Trail, El Paso, Texas 79906. Send protests to: Irene Carlos, Transportation Assistant, Interstate Commerce Commission, Room 1321 Federal Building, 300 North Los Angeles Street, Los Angeles, California 90012.

MC 139495 (Sub-415TA), filed February 13, 1979. Applicant: NATIONAL CARRIERS, INC., P.O. Box 1358, Liberal, KS 67901. Representative: Herbert Alan Dubin, 1320 Fenwick Lane, Silver Spring, MD 20910. *Drugs, medicines, toilet preps* (except in bulk) in vehicles equipped with mechanical refrigeration; (1) Morris Plains, NJ to Allen Park, MI; (2) From facilities of Warner-Lambert Company at Allen Park, MI to Avon, CT, Cincinnati, OH, Doraville, GA, Dallas, TX, Denver, CO, Jessup, MD, Kansas City, MO, Pico Rivera, CA, and Seattle, WA. An underlying ETA seeks 90 days authority. Supporting Shipper(s): Warner Lambert Company, Pharmaceutical Division, 182 Tabor Rd., Morris Plains, NJ 07950. Send protests to: M. E. Taylor, Dist. Supv., Interstate Commerce Commission, 101 Litwin Bldg., Wichita, KS 67202.

MC 140086 (Sub-3TA), filed February 12, 1979. Applicant: DELAPIA TRANSPORT, INC., 327 8th Avenue, Northwest, New Brighton, MN 55112. Representative: James M. Christenson, 80 South 8th Street, 4444 IDS Center, Minneapolis, MN 55402. *Tallow, in bulk, in tank vehicles* from the facilities of Iowa Beef Processors, Inc. at Fort Dodge, IA and West Point and Dakota City, NE to points in IL and IN, for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): Iowa Beef Processors, Inc., Rate Analyst, Dakota City, NE 68731. Send protests to: Delores A. Poe, Transportation Assistant, Interstate Commerce Commission, 414 Federal Building & U.S. Court House, 110 South 4th Street, Minneapolis, MN 55401.

MC 140744 (Sub-7TA), filed February 5, 1979. Applicant: ARCTIC AIR TRANSPORT, INC., 103 North Eau Claire Street, Mondovi, WI 54755. Representative: Stanley C. Olsen, Jr., 4601 Excelsior Boulevard, Minneapolis, MN 55416. *Meat, meat products, meat by-products and articles distributed by meat packinghouses and frozen prepared foods* from (1) Fairmont, MN to Eau Claire, WI; and (2) Eau Claire, WI to points in MI, for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): Armour Food Company, P.O. Box 239, South St. Paul, MN 55075. Send protests to: Delores A. Poe, ICC, 414 Federal Building & U.S. Court House, 110 South South 4th Street, Minneapolis, MN 55401.

MC 141878 (Sub-9TA), filed January 30, 1979. Applicant: DIRECT COURIER, INC., 2780 S. Jefferson Davis Hwy., Arlington, VA 22202. Representative: Dean N. Wolfe, Suite 145, 4 Professional Dr., Gaithersburg, MD 20760. *Live laboratory animals,* between points in MI, on the one hand, and, on the other, points in MD, MA, NJ, NY, NC, PA, VA & DC, for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): Charles River Breeding Labs, Inc., 251 Ballardvale St., Wilmington, MA 01887. Send protests to: T. M. Esposito, Trans. Asst., 600 Arch St., Room 3238, Philadelphia, PA 19106.

MC 142368 (Sub-16TA), filed February 8, 1979. Applicant: DANNY HERMAN TRUCKING, INC., 1415 East Ninth Street, Pomona, CA 91766. Representative: William J. Monheim, P.O. Box 1756, Whittier, CA 90609. (1) *Doors and door frames,* from Los Angeles, CA to Waco, TX, and (2) *Mobile home or sectional building closets,* from San Jacinto, CA to Waco, TX, for 180 days. An underlying ETA seeks up to 90 days operating authority. Supporting shipper(s): Active Supply Company, 5433 San Fernando Road, Los Angeles, CA 90039; C & C Supply, 39441 7th Street, P.O. Box 651, San Jacinto, CA 92383. Send protests to: Irene Carlos, Transportation Assistant, Interstate Commerce Commission, Room 1321 Federal Building, 300 North Los Angeles Street, Los Angeles, California 90012.

MC 142508 (Sub-48TA), filed February 13, 1979. Applicant: NATIONAL TRANSPORTATION, INC., 10810 So. 144th St., P.O. Box 37465, Omaha, NE 68137. Representative: Lanny N. Fauss, P.O. Box 37096, Omaha, NE 68137. *Confectionery (except in bulk), in vehicles equipped with mechanical refrigeration,* from the facilities of E. J. Brach & Sons, Division of American Home Products Corporation, in the Chicago, IL commercial zone to points in MD, NJ, NY, and PA, for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): E. J. Brach & Sons, Division of American Home Products Corp., 4656 W. Kinzie St., Chicago, IL 60644. Send protests to: Carroll Russell, ICC, Suite 620, 110 No. 14th St., Omaha, NE 68102.

MC 144506 (Sub-1TA), filed February 9, 1979. Applicant: KOLLER PETROLEUM PRODUCTS, INC., 241 N. Baltimore St., Spring Green, WI 53588. Representative: Michael Wyngaard, 150 E. Gilman St., Madison, WI 53703. *Gasoline, diesel fuel and No. 1 and No. 2 fuel oil,* originating at the facilities of Amoco Oil Co. at Dubuque, IA and destined to points in Dane, Lafayette, Iowa, Crawford and Grant Counties, WI, for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): There are nine (9) shippers. Their statements may be examined at the office listed below and Headquarters. Send protests to: Gail Daugherty, Transportation Asst., Interstate Commerce Commission, Bureau of Operations, U.S. Federal Building and Courthouse, 517 East Wisconsin Avenue, Room 619, Milwaukee, Wisconsin 53202.

MC 144889 (Sub-2TA), filed February 8, 1979. Applicant: RONWAL

TRANSPORTATION, 2600 Calumet Ave., Hammond, IN 46320. Representative: Walter C. Rymarowicz (same address as applicant). *Iron and Steel articles,* from the facility of the Inland Steel Company at East Chicago, IN to pts in IL on and north of U.S. Rte. 36 for 180 days. An underlying ETA has been granted. Supporting shipper(s): Inland Steel Co., 30 W. Monroe St., Chicago, IL 60603. Send protests to: TA Annie Booker, 219 S. Dearborn St. Rm. 1386, Chicago, IL 60604.

MC 145779 (Sub-1TA), filed February 12, 1979. Applicant: OIL SERVICE COMPANY, INC., Route 3, Petty Lane, Columbia, TN 38401. Representative: Edward C. Blank II, P.O. Box 1004, Columbia, TN 38401. *Bailed waste corrugated paper stock and corrugated tubes* between the plantsites of Alton Box Board Co., Inc. in Nashville, TN and Cedartown, GA, for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): Alton Box Board Co., Inc., 401 Alton St., Alton, IL 62002. Send protests to: Glenda Kuss,, TA, ICC, Suite A-422, U.S. Court House, 801 Broadway, Nashville, TN 37203.

MC 146118 (Sub-1TA), filed February 9, 1979. Applicant: JAMES J. VAVALA, 428 Pennsylvania Avenue, West, Warren, PA 16365. Representative: Kenneth T. Johnson and Ronald W. Malin, Bankers Trust Building, Jamestown, NY 14701. *Flexible couplings and components and parts therefor,* moving in express, between the plantsite of Rexnord, Inc., located at or near Warren, PA on the one hand, and, on the other, points in the states of NY, NJ, MA, CT, PA, OH, MI, WV and VA, for 180 days. An underlying ETA seeks 90 days authority. RESTRICTION: No service shall be provided in the transportation of articles weighing more than five hundred pounds and in other than two-axle vehicles. Supporting shipper(s): Rexnord, Inc., Coupling Division, P.O. Box 543, Warren, PA 16365. Send protests to: John J. England, District Supervisor, Bureau of Operations, Interstate Commerce Commission, 2111 Federal Building, 1000 Liberty Avenue, Pittsburgh, PA 15222.

MC 146214 (Sub-1TA), filed February 8, 1979. Applicant: JAKE BAUMAN, d.b.a. JAKE BAUMAN TRUCKING, R.R. No. 1, Congerville, IL 61729. Representative: Robert T. Lawley, 300 Reisch Bldg., Springfield, IL 62701. *Contract Carrier:* irregular routes: (a) Farm wagons, farm tillage equipment, fertilizer spreading equipment, woodburning systems, truck bumper cushions from Goodfield, IL to points in the U.S. except AK and HI and (b) Materials and supplies used in the manufacture of farm wagons, farm tillage equipment, fertilizer spreading equipment and woodburning systems from Des Moines, Fairfield, Perry and Davenport, IA to Goodfield, IL all for the account of DMI, Inc. for 180 days. Supporting shipper(s): DMI, Inc., Route 150 E., Goodfield, IL 61742. Send protests to: TA Annie Booker, 219 S. Dearborn St., Rm. 1386, Chicago, IL 60604.

MC 146226 (Sub-1TA), filed February 7, 1979. Applicant: J&P TRUCKING, INC., 1035-A N. Flint St., Lincolnton, NC 28092. Representative: W. G. Reese III, P.O. Box 3005, Charlotte, NC 28203. *Textiles, textile products, textile machinery* between the facilities of Cortaulds North America Inc., at or near Lemoyne, AL, on the one hand and points and places in NC and SC on the other, for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): Courtaulds North America, Inc., P.O. Box 2648, Mobile, AL 36601. Send protests to: Terrell Price, District Supervisor, 800 Briar Creek Road, Rm. CC516, Mart Office Building, Charlotte, NC 28205.

MC 146244 (Sub-1TA), filed February 6, 1979. Applicant: C. & H. DISTRIBUTING CO., 2450 West 3rd, Craig, CO 81625. Representative: David E. Driggers, 1660 Lincoln St., Suite 1600, Denver, CO 80264. (1) *Malt beverages* from Jefferson County, CO to points in CA, and (2) *empty containers and materials for recycling* from points in CA to Jefferson County, CO for 180 days. Underlying ETA seeks 90 days authority. Supporting shipper(s): Adolph Coors Co., Golden, CO 80401. Send protests to: D/S Roger L. Buchanan, Interstate Commerce Commission, 721 19th St., 492 U.S. Customs House, Denver, CO 80202.

MC 146257 (Sub-1TA), filed February 13, 1979. Applicant: DAVID L. VOSS, d.b.a. VOSS TOWING, P.O. Box 301, Cuba, MO 65453. Representative: David L. Voss (address same as above). *Wrecked or disabled vehicles in initial and secondary movements, and replacement vehicles,* between points in Crawford, Gasconade, Franklin, Warren and St. Louis Counties, and St. Louis, MO, and points in its Commercial Zone, on the one hand, and, on the other, points in the U.S. except AK and HI, for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): Edward and Donald Richardson, 1220 W. Main, Union, MO 63084; M. R. Bruton, Inc., P.O. Box 547, Cuba, MO 65453; Leroy McGinnis, Route 1, Box 110A, Cuba, MO 65453; McClelland Lumber Transports, General Delivery, Cuba, MO 65453. Send protests to: P. E. Binder, ADS, ICC, Rm. 1465, 210 N. 12th St., St. Louis, MO 63101.

MC 146258 (Sub-1TA), filed February 12, 1979. Applicant: M. R. BRUTON, INC., P.O. Box 547, Cuba, MO 65453. Representative: Jack H. Blanshan, Suite 200, 205 W. Touhy Ave., Park Ridge, IL 60068. *Soybean flour, bacon bits, vital wheat gluten and vegetable oil shortening* (except commodities in bulk), from the facilities of Archer Daniels Midland Company, Decatur, IL, to Dallas, Garland, Houston and Palestine, TX; Honeyville and Ogden, UT; Anaheim, City of Commerce, Hayward, Los Angeles, Modesto, National City, Oakland, Riverside, Salinas, San Francisco, Terminal Island, Turlock and Vernon, CA; Tualatin and Portland, OR; Seattle, Spokane, Tacoma and Tukwila, WA; Oklahoma City, OK, and to points in the Commercial Zones of the respectivley named cities, for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): Archer-Daniels-Midland Company, 4666 Faries Parkway, Decatur, IL 62625. Send protests to: P. E. Binder, ADS, ICC, Rm. 1465, 210 N. 12th St., St. Louis, MO 63101.

MC 146267 (Sub-1TA), filed February 12, 1979. Applicant: LOUIS MATTEUCCI, d.b.a. MATTEUCCI TRUCKING, Rt. 3 Box 246-A (County Rd. 24), Orland, CA 95963. Representative: Louis Matteucci (same as applicant). *Shakes, Shingles or ridge, split either by hand or by machines* in 45 ft. Vans or Flatbed Trailers (1) between points in CA and points in WA; (2) between points in AZ and points in WA; (3) between points in CA and points in OR; (4) between points in AZ and points in OR; (5) between points in WA and points in OR, for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): Dier Lumber Co., Inc., 291 Roymar Road, Oceanside, CA 92054. Send protests to: District Supervisor A. J. Rodriguez, 211 Main Street, Suite, 500, San Francisco, CA 94105.

MC 146276 (Sub-1TA), filed February 13, 1979. Applicant: STEVE'S GAS SUPPLY, INC., 46 River Road, Essex Junction, VT 05452. Representative: Larry T. Stevens (same address as applicant). *Contract carrier,* irregular routes: *Fuel oil, gasoline and diesel fuel,* in bulk, in tank vehicles, from Rensselaer, NY to Bristol, Essex Junction and Richford, VT, for 180 days, under continuing contract or contracts with Robinson's Inc. An underlying ETA seeks 90 days authority. Supporting shipper(s): Robinson's, Inc., P.O. Box 405, Essex Junction, VT 05452. Send protests to: ICC, P.O. Box 548, Montpelier, VT 05602.

H. G. Homme, Jr.,
Secretary.

[FR Doc. 79-8049 Filed 3-15-79; 8:45 am]

[7035-01-M]

[Amendment No. 10]

SECTION 5a APPLICATION 45

Niagara Frontier Tariff Bureau, Inc.—Agreement

MARCH 1, 1979.

The Commission is in receipt of an application in the above proceeding for approval of amendments to the approved agreement.

Filed November 3, 1978 by: Robert G. Gawley, Attorney, P.O. Box 184, Buffalo, New York 14221.

The amendments involve: Changes to comply with 297, 349 I.C.C. 811 and 351 I.C.C. 437, and increasing the number of board members and quorum.

The complete application may be inspected at the Office of the Commission, in Washington, D.C.

Any interested person desiring to protest and participate in this proceeding shall notify the Commission in writing within 20 days from the date of publication of this notice in the FEDERAL REGISTER. As provided by the General Rules of Practice of the Commission, persons other than applicants should fully disclose their interest, and the position they intend to take with respect to the application. Otherwise, the Commission, in its discretion, may proceed to investigate and determine the matters involved without public hearing.

H. G. HOMME, Jr.,
Secretary.

[FR Doc. 79-8050 Filed 3-15-79; 8:45 am]

[1505-01-M]

[Notice No. 230]

MOTOR CARRIER TEMPORARY AUTHORITY APPLICATIONS

Correction

In FR Doc. 78-34651, published at page 58248, Wednesday, December 13, 1978, make the following corrections:

1. On page 58252, in the third column, the paragraph reading "MC 1447474TA" should be corrected to read "MC 144747 4TA";

2. On page 58253, in the third column, after the signature, the document number in the file line reading "[FR Doc. 78-34657 . . .]" should be corrected to read "[FR Doc. 78-34651 . . .]".

[6450-01-M]

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

ADVISORY COMMITTEE ON REVISION OF RULES OF PRACTICE AND PROCEDURE

Determination To Establish

Pursuant to the Federal Advisory Committee Act (Pub. L. 92-463), I hereby certify that the establishment of an Advisory Committee on Revision of Rules of Practice and Procedure is in the public interest in connection with the duties imposed upon the Federal Energy Regulatory Commission, Department of Energy, by the Department of Energy Organization Act of 1977 and other applicable law. This determination follows consultation with the Committee Management Secretariat, General Services Administration, pursuant to Section 9 (a)(2) of the Federal Advisory Committee Act and OMB Circular A-63 (Revised).

1. *Name of Advisory Committee.* Advisory Committee on Revision of Rules of Practice and Procedure.

2. *Purpose.* The Committee will provide the Commission and its staff with the benefit of suggestions from a broad range of public participants regarding additions, deletions, and other changes desirable in compiling revised Commission Rules of Practice and Procedure best suited to the needs of both the Commission and those who appear before it as parties to cases.

The current Rules of Practice and Procedure under which the Commission operates were formulated by the Interstate Commerce Commission and the Federal Power Commission. The latter ceased to exist on October 1, 1977, when the Federal Energy Regulatory Commission was established as part of the Department of Energy Organization Act (Pub. L. 95-91). The responsibilities of the FERC differ greatly from those of the FPC, and the Rules promulgated by the FPC and the ICC are no longer completely relevant to the regulatory responsibilities of the Commission.

Advice and recommendations from those outside the Commission staff who regularly appear as interested parties in proceedings before Commission Administrative Law Judges, or who communicate the status of Commission action on various issues to outside individuals and companies, as well as to the general public, will help to assure that the Rules are revised after consideration of the broadest possible range of comments.

The Commission will seek to include among the members of the Advisory Committee representatives of academic institutions, state governments, oil and gas producers, oil and gas pipelines, electric and gas utility companies, these categories, and organizations or associations representing any or all of these categories.

The Advisory Committee and its members will serve in an advisory capacity only. Final recommendations for revisions to be made in the Commission's Rules of Practice and Procedure will be made by the Commission's Office of the General Counsel, and final decisions regarding institution of any revisions will be made by the Commission itself.

3. *Effective Date of Establishment and Duration.* This Advisory Committee is established effective 15 days after publication of this notice and after filing of the charter with the standing committees of Congress having legislative jurisdiction over the Federal Energy Regulatory Commission and with the Library of Congress. The Committee will terminate two years from the date of its establishment, unless extended.

4. *Membership.* The membership of the Advisory Committee shall be fairly balanced in terms of the points of view and functions of the industry and functions of the industry and users affected, including those of wholesale and retail consumers. There will be no discrimination on the basis of race, color, national origin, religion, age or sex.

5. *Operations.* The Advisory Committee will operate in accordance with the provisions of the Federal Advisory Committee Act (Pub. L. 92-463), Commission policy and procedures, OMB Circular A-63 (Revised) and other directives and instructions issued in accordance with the implementation of the Act.

6. *Objectivity.* The advice and recommendations of the Advisory Committee will not be inappropriately influenced by the appointing authority or by any special interest, but will instead be the result of the Advisory Committee's independent judgment.

Issued at Washington, D.C. on March 13, 1979.

CHARLES B. CURTIS,
Chairman.

[FR Doc. 79-7916 Filed 3-15-79; 8:45 am]

[6450-01-M]

[Docket No. AR70-1]

AREA RATE PROCEEDING (PERMIAN BASIN AREA II)

Proposed Plan of Refund

MARCH 6, 1979.

Take notice that Transwestern Pipeline Company on February 15, 1979, filed a proposed plan of refund for the flow-through of monies received from suppliers pursuant to the Commission's order issued March 14, 1978 in Docket No. AR70-1.

Transwestern proposes to refund monies applicable to gas purchases for the period February 26, 1971 through June 30, 1972 to all of its CDQ customers in accordance with Article IV of the Stipulation and Agreement dated October 2, 1970, and approved by Commission order issued November 24, 1970, in Docket Nos. RP69-27, et al.; it proposes to flow-through to its jurisdictional customers the jurisdictional portion of refunds applicable to gas purchases made on or after July 1, 1972, in accordance with the Purchased Gas Cost Adjustment provision set forth in Section 19 of the General Terms and Conditions of its FERC Gas Tariff, Second Revised Volume No. 1.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, DC 20426, in accordance with §§ 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before March 15, 1979. 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 petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

KENNETH F. PLUMB,
Secretary.

[FR Doc. 79-8006 Filed 3-15-79; 8:45 am]

[6450-01-M]

[Docket No. ER77-278]

ARKANSAS POWER & LIGHT CO.

Filing

MARCH 6, 1979.

Take notice that Arkansas Power & Light on February 9, 1979, tendered for filing, pursuant to ordering Paragraph D of Commission Order Approving Settlement Agreement and Terminating Proceedings issued December 22, 1978, a compliance report which shows monthly billing determinants and revenues under prior, present and settlement rates.

Any person desiring to be heard or to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, in accordance with §§ 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8 and 1.10). All such protests should be filed on or before March 19, 1979. Protests will be considered by the Commission in determining the appropriate action to be taken. Copies of this filing are on file with the Commission and are available for public inspection.

KENNETH F. PLUMB,
Secretary.

[FR Doc. 79-8004 Filed 3-15-79; 8:45 am]

[6450-01-M]

[Docket No. ER77-535]

ARKANSAS POWER & LIGHT CO.

Filing

MARCH 6. 1979.

Take notice that Arkansas Power & Light Company on February 9, 1979, tendered for filing, pursuant to the Commission's letter order dated January 11, 1979, a revised rate schedule proposed to be effective September 21, 1979, reflecting the settlement rates approved by the Commission.

Any person desiring to be heard or to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, in accordance with §§ 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8 and 1.10). All such protests should be filed on or before March 19, 1979. Protests will be considered by the Commission in determining the appropriate action to be taken. Copies of this filing are on file with the Commission and are available for public inspection.

KENNETH F. PLUMB,
Secretary.

[FR Doc. 79-8005 Filed 3-15-79; 8:45 am]

[6450-01-M]

[Docket No. RP73-65 (PGA78-4) (AP78-1)]

COLUMBIA GAS TRANSMISSION CORP.

Certification of Proposed Settlement Agreement

MARCH 6, 1979.

Take notice that on February 14, 1979, Administrative Law Judge Benkin certified to the Commission a Stipulation and Agreement proposed in settlement of certain issues in the above-captioned rate proceeding. The certification states that all parties to the proceeding have reviewed the proposed settlement agreement and join in a motion that it be certified to the Commission. The certification also included five appendices to the proposed settlement agreement containing materials which serve as background to the settlement proposal. If approved, the proposed Stipulation and Agreement would resolve all but one of the issues in this proceeding; the reserved issue involves the prudence of certain peak shaving arrangements undertaken by Columbia.

Any person desiring to be heard or to protest said Stipulation and Agreement should file comments with the Federal Energy Regulatory Commisson, 825 North Capitol Street, N.E., Washington, D.C. 20426, on or before March 23, 1979. Comments will be considered by the Commission in determining the appropriate action to be taken. Copies of this agreement are on file with the Commission and are available for public inspection.

KENNETH F. PLUMB,
Secretary.

[FR Doc. 79-8007 Filed 3-15-79; 8:45 am]

[6450-01-M]

[Docket No. CP78-291]

EL PASO NATURAL GAS CO.

Findings and Order After Statutory Hearing Permitting and Approving Abandonment

MARCH 8, 1979.

On April 17, 1978, El Paso Natural Gas Company (El Paso)[1] filed in Docket No. CP78-291 an application pursuant to Section 7(b) of the Natural Gas Act for permission and approval to abandon facilities for deliveries of natural gas which are no longer required, all as more fully set forth in the application.

The facilities for which El Paso seeks permission and approval to abandon are as follows:

A. GAS PURCHASE FACILITIES TO BE ABANDONED

1. EPNG 10-¾-INCH O.D. FT. STOCKTON METER STATION

One 10-¾-inch O.D. standard orifice-type meter station, with appurtenances, located at the Pecos Company's Santa Rose Plant in Pecos County, Texas.

2. ROJO CABALLO PURCHASE METER STATION

One standard 8-⅝-inch O.D. orifice-type meter station, with appurtenances, located on Applicant's 8-⅝-inch O.D. Rojo Caballo pipeline in Pecos County, Texas.

3. PHILLIPS-ECTOR PLANT METER STATION AND PIPELINE

Approximately 0.73 mile of 10-¾-inch O.D. pipeline, with appurtenances, including one 10-¾-inch standard orifice-type meter station, located at the outlet of Phillips Petroleum

[1] El Paso, a Delaware corporation having its principal place of business in El Paso, Texas, is a "natural-gas company" within the meaning of the Natural Gas Act as heretofore found by order issued October 29, 1942, in Docket No. G-242 (3 FPC 851).

Company's Ector Plant in Ector County, Texas.

4. KEYSTONE EMPEROR PURCHASE NO. 2 METER STATION

Two 10-¾-inch O.D. orifice-type meter runs, with appurtenances, located at El Paso's Keystone Field Plant in Winkler County, Texas.

5. FOREST OIL CORPORATION WALKER NO. 1 WELLHEAD METER STATION

One standard 4-½-inch O.D. orifice-type meter station, with appurtenances, located at Forest Oil Corporation's Walker No. 1 well in Pecos County, Texas.

Gamble No. 1 Wellhead Meter Station. One standard 4-½-inch O.D. orifice-type meter station, with appurtenances, located at Forest Oil Corporation's Gamble No. 1 well in Pecos County, Texas.

Patterson No. 1 Wellhead Meter Station. One standard 4-½-inch O.D. orifice-type meter station, with appurtenances, located at Forest Oil Corporation's Patterson No. 1 well in Pecos County, Texas.

6. GOVERNMENT 134 NO. 1 METER STATION AND PIPELINE

Approximately 41.8 feet of 2-⅜-inch O.D. pipeline, with appurtenances, including one 2-⅜-inch O.D. standard orifice-type meter station, in Eddy County, New Mexico.

B. GAS SALES FACILITIES TO BE ABANDONED

1. W. A. DOBSON TAP

A 1-inch O.D. tap and valve assembly, with appurtenances, located at milepost 8.7 on El Paso's 4-½-inch O.D. Mesa pipeline in Maricopa County, Arizona.

2. WOODMAN OF THE WORLD HALL TAP

A 1-inch O.D. tap and valve assembly, with appurtenances, located on El Paso's 16-inch Blanco-Fruitland pipeline in San Juan County, New Mexico.

3. ROBERT DRAPER TAP

A 1-inch O.D. tap and valve assembly, with appurtenances, located at milepost 23.2 on El Paso's 24-inch O.D. Dumas Plant-to-Eunice Plant pipeline in Gaines County, Texas.

4. MAGNOLIA PIPELINE COMPANY TAP

A 1-inch O.D. tap and valve assembly, with appurtenances, located at milepost 1.1. on El Paso's 10-¾-inch O.D. Levelland pipeline in Hockley County, Texas.

5. SHELL PIPE LINE CORPORATION-MYERS LEASE PUMP PRODUCTION TAP

A 1-inch O.D. tap and valve assembly, with appurtenances, located on El Paso's 6-⅝-inch O.D. Jal high pressure gathering system pipeline in Lea County, New Mexico.

El Paso proposes to remove and place in stock, or scrap, the facilities as hereinbefore described.

Since Forest Oil has applied for but not received permission to abandon its Walker wells and appurtenances in Docket No. CI75-665, it appears that permission cannot be granted El Paso herein to abandon its related meter stations designated as A-5 pending the final determination in CI75-665.

It appears that El Paso may have violated Section 7 of the Natural Gas Act by abandoning without Commission approval the facilities designated A-1 and A-4 in this order and by installing the service tap described in designation B-1 of this order. The Commission will not take formal action at this time with respect to the apparent violations; however, the Commission expects that in the future timely authorization for such activities under either Section 7(b) or Section 7(c) of the Natural Gas Act will be sought.

The facilities proposed to be abandoned are used for the transportation of natural gas in interstate commerce subject to the jurisdiction of the Commission, and the abandonment of such facilities is subject to the requirements of Subsection (b) of Section 7 of the Natural Gas Act.

After due notice by publication in the FEDERAL REGISTER on May 10, 1978 (43 FR 20045), no petitions to intervene, notices of intervention, or protests to the granting of the application have been filed.

At a hearing held on February 28, 1979, the Commission on its own motion received and made a part of the record in this proceeding all evidence, including the application and the exhibits thereto, submitted in support of the authorization sought herein, and upon consideration of the record,

The Commission finds: The abandonments proposed by El Paso are permitted by the public convenience and necessity and should be approved as hereinafter ordered, except with respect to the facilities used to receive gas which is the subject of the proceeding in Docket No. CI75-665.

The Commission orders: (A) Permission for and approval of the abandonment of facilities and service as proposed are granted, with the exception of the Forest Oil Corporation wellhead meter stations used for the receipt of gas which is the subject of the proceeding in Docket No. CI75-665.

(B) El Paso shall notify the Commission of the date of abandonment of the service and facilities hereinbefore described within ten days thereof.

By the Commission.

KENNETH F. PLUMB,
Secretary.

[FR Doc. 79-8008 Filed 3-15-79; 8:45 am]

[6450-01-M]

[Docket No. RA79-11]

JACK HALBERT

Order Designating Presiding Officer and Appointing Commission Designee

MARCH 8, 1979.

On December 4, 1978 the Department of Energy (DOE) issued a final decision and order, denying Jack Halbert's application for an exception from the Mandatory Petroleum Price Regulations.[1]

On January 26, 1979, Jack Halbert filed a petition for review with this Commission. Section 1.40(d)(3) of the Commission's Rules of Practice and Procedure provides that upon receiving a petition for review, the Commission or its designee shall designate a presiding officer for the proceedings. The Commission, therefore, designates as a presiding officer in this proceeding, Dwight Alpern.

The Commission further appoints the Director or the Deputy Director of the Office of Opinions and Review as the Commission's designees for the purpose of designating, if necessary, another person to act temporarily as the presiding officer in this proceeding in Mr. Alpern's absence.

By the Commission.

KENNETH F. PLUMB,
Secretary.

[FR Doc. 79-8010 Filed 3-15-79; 8:45 am]

[6450-01-]

[Docket No. ES79-28]

IDAHO POWER CO.

Application

MARCH 6, 1979.

Take notice that on February 23, 1979, Idaho Power Company (Applicant) filed an application with the Commission, pursuant to Section 204 of the Federal Power Act and Part 34 of the Commission's Regulations, for authorization to negotiate the sale of up to 1,500,000 shares of Common Stock and of up to $62 million principal amount of First Mortgage Bonds. Applicant is incorporated under the laws of the State of Maine, with its principal business office in Boise, Idaho and is engaged primarily in the electric utility business in the States of Idaho, Oregon, Nevada, and Wyoming.

The net proceeds from the sale of the Common Stock and Bonds will be

[1] 10 CFR Part 212, Subpart D (1977).

used to repay short-term debt and for other corporate purposes.

Any person desiring to be heard or to make any protest with reference to the application should on or before March 20, 1979, file with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, petitions or protests in accordance with the Commission's Rules of Practice and Procedures (18 CFR 1.8 or 1.10). The application is on file and available for public inspection.

KENNETH F. PLUMB,
Secretary.

[FR Doc. 79-8009 Filed 3-15-79; 8:45 am]

[6450-01-M]

[Docket No. CP77-71, *et al.*]

NATURAL GAS PIPELINE CO. OF AMERICA, ET AL.

Petition to Amend

MARCH 7, 1979.

Take notice that on January 16, 1979, Natural Gas Pipeline Company of America (Petitioner), 122 South Michigan Avenue, Chicago, Illinois 60603, filed in Docket No. CP77-71 a petition to amend the certificate of public convenience and necessity issued to it pursuant to Section 7(c) of the Natural Gas Act on March 1, 1977, in said docket so as to extend the term of the transportation service authorized therein for General Electric Company (GE) for an additional two years, all as more fully set forth in the petition to amend which is on file with the Commission and open to public inspection.[1]

Petitioner indicates that the purpose of the original application in the subject docket and those of Columbia Gas Transmission Corporation and Columbia Gulf Transmission Company in Docket No. CP77-118 and Texas Gas Transmission Corporation in Docket No. CP77-125 was to arrange for the transportation of gas for a 10-year period from reserves purchased and placed in Cameron Parish, Louisiana, by GE to three of GE's plants located in Indiana, Kentucky and Maryland. Petitioner further states that on March 1, 1977, the Commission issued certificates authorizing the transportation service for a two-year term from initial delivery only, without prejudice to the filing for certificate authorization to continue the service beyond the two-year term on the condition that said filings be made at least 6 months prior to the expiration of the two-year term. Petitioner states that upon applications for rehearing on the grounds that the limitation of the term to two years, in the context, was not warranted, rehearing was granted and that formal hearings were held in these proceedings. Petitioner states that the proceeding is currently pending before the Presiding Administrative Law Judge. Petitioner requests the subject extension expressly without prejudice to the positions taken by any party to the subject proceedings with respect to the issues surrounding the long term (i.e., in excess of two years) transportation by an interstate pipeline of gas from reserves owned by an industrial consumer to the industrial consumer's plant facilities.

Any person desiring to be heard or to make any protest with reference to said petition to amend should on or before March 28, 1979, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10) 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 petition to intervene in accordance with the Commission's Rules.

LOIS D. CASHELL,
Acting Secretary.

[FR Doc. 79-8011 Filed 3-15-79; 8:45 am]

[6450-01-M]

[Project No. 2114, et al.]

PUBLIC UTILITY DISTRICT NO. 2, ET AL. OF GRANT COUNTY, WASHINGTON

Order Consolidating Proceedings, Establishing Hearing and Requiring Prehearing conference

MARCH 7, 1979.

In the matter of Public Utility District No. 2 of Grant County, Washington (Project No. 2114); Public Utility District No. 1 of Chelan County, Washington (Projects Nos. 943 and 2145); Public Utility District No. 1 of Douglas County, Washington (Project No. 2149); and State of Washington Department of Fisheries v. Public Utility District No. 2 of Grant County, Washington (Docket No. E-9569); Hearing: Temporary and Long-Term Flow Releases; Fisheries.

BACKGROUND

The recent petitions. The State of Washington Department of Fisheries and Department of Game, the Oregon Department of Fish and Wildlife, the U.S. National Marine Fisheries Service, and the Confederated Tribes and Bands of the Yakima Indian Nation (petitioners) have recently filed petitions asking the Commission to modify the operation of Priest Rapids Project No. 2114, Wells Project No. 2149, Rock Island Project No. 943 and Rocky Reach Project No. 2145, or, in the alternative, to institute a proceeding to consider their requests. The four projects are located on the Columbia River in the State of Washington.

The petitioners claim that commercial, Indian, and sport fisheries have suffered severe losses over the last twenty years due to the construction and operation of the four projects listed above. The are seeking certain minimum flows and spills at each project dam for the protection of the chinook, sockeye, and coho salmon and steelhead trout resources. The petitioners submitted provisional recommendations for instantaneous and daily average minimum flows, ranging from 10,000 cfs to 110,000 cfs, depending on the time of the year and the location of the project. They also request that during the period of spring juvenile downstream migration (April 26 through June 15), the equivalent of twenty percent of the average daily discharge at each project be spilled, rather than used to generate power.

The petitioners' requests are made pursuant to Article 39 of the license for Project No. 2114,[1] Article 41 of the license for Project No. 2149,[2] Article 21 of the license for Project No. 943,[3] and Article No. 31 of the license for Project No. 2145.[4] These articles generally require the licensees to comply with reasonable modifications to the operation of the project in the interest of fish and wildlife resources.

The petitioners assert that the licensees for these four mid-Columbia projects have been unable to obtain consent from their bulk power purchasers to accommodate the desired spring spilling. In addition, they state that the flows requested are also being negotiated with the Bonneville Power Administration, Bureau of Reclama-

[1] This proceeding was commenced before the Federal Power Commission (FPC). By the joint regulation of October 1, 1977 (10 CFR 1000.1), it was transferred to the Federal Energy Regulatory Commission (FERC). The term "Commission", when used in the context of action taken prior to October 1, 1977, refers to the FPC; when used otherwise, the reference is to the FERC.

[1] Public Utility District No. 2 of Grant County, Washington, Order Issuing License (Major), 14 F.P.C. 1067, 1073 (1955), *as amended*, 15 F.P.C. 1005, 1006 (1956).

[2] Public Utility District No. 1 of Douglas County, Washington, Order issuing License (Major), 28 F.P.C. 128 (1962), *as amended*, 28 F.P.C. 492 (1962).

[3] Public Utility District No. 1 of Chelan County, Washington, Order Amending License, 51 F.P.C. 1141, 1152 (1974).

[4] Public Utility District No. 1 of Chelan County, Washington, Opinion No. 304, 18 F.P.C. 25, 36 (1957).

tion, and the Corps of Engineers for the upstream federal dams those agencies operate.

In separate answers, the licensees for the four mid-Columbia projects opposed the requested modifications, but stated that they are willing to discuss these matters with the petitioners. Generally, the licensees argue that the available evidence does not support a modification in the current operations of the projects. They state that alternative, less costly means are available to facilitate downstream migration. The licensees also assert that the Commission lacks the authority to require modifications in the current minimum flows, and that any such requirement without their consent would contravene Section 6 of the Federal Power Act, 16 U.S.C. 799. In addition, the licensees contend that they cannot implement minimum flows until upstream federal projects—the Corps of Engineers' Chief Joseph and the Bureau of Reclamation's Grand Coulee Dams—modify their flow releases.

The Priest Rapids complaint. Before these recent petitions, the State of Washington Department of Fisheries (Department) had filed a complaint on September 22, 1976, respecting the operation of the Priest Rapids Project No. 2114 (Docket No. E-9569).[5] The Department alleged that the area downstream from the Priest Rapids Dam serves as an important spawning and rearing area for fall chinook salmon. The Department claims that the 36,000 cfs minimum flow established in the project license [6] causes many valuable spawning areas to dry up, resulting in the stranding and subsequent death of eggs and juvenile fish. The Department requested that the minimum flow requirement in the license be increased to 70,000 cfs during the period of October 15 to April 30 of each year. This period would allow for spawning, incubation of eggs, and rearing of juvenile fish. After notice of the complaint was issued, several petitions to intervene were filed and the Licensee, Public Utility District No. 2 of Grant County, filed its answer opposing the relief sought.

Between two conferences our staff held on March 3, 1977, and October 17, 1978,[7] the Department filed a motion on October 5, 1978, requesting that the minimum flows from the Priest Rapids Project be increased from 36,000 cfs to 50,000 cfs. This motion was supported by the Oregon Fish and Wildlife Commission, the Yakima Indian Nation, Idaho Fish and Game Commission, and the National Marine Fisheries Services. This motion was filed for the same reason the complaint was filed—to protect chinook salmon spawning and incubation areas—but subsequent to a joint study conducted by the Department and Public Utility District No. 2 of Grant County.[8]

PUD No. 2 of Grant County in its answer stated that the Department had failed to set forth facts in support of its request for a hearing. Grant County further stated that it believed that the measures taken during the 1977 spawning season were successful and should be continued for another year, with certain modifications. Under that 1977 scheme of regulation, minimum flows of 36,000 cfs were periodically released from the Priest Rapids Dam.

Consolidation

Because the matters and issues raised by the complaint are closely related to or subsumed within those raised by the more recent petitions, we will consolidate the complaint and petitions for consideration in a single proceeding. All of the parties earlier permitted to intervene with respect to Docket No. E-9569 will also be deemed intervenors with respect to the petitions in the consolidated proceeding.[9]

Hearing Issues

We find that it is appropriate and in the public interest that a hearing be held to investigate whether the operation of the projects listed above should be modified in the interest of protecting the fishery resources of the Columbia River. The following issues shall be considered during the hearing:

(1) the extent, if any, to which the current minimum flow at the Priest Rapids Project No. 2114 should be increased for the purpose of protecting the chinook salmon spawning and incubation areas downstream from the dam;

(2) the ways, if any, in which the operations of Projects Nos. 943, 2114, 2145, and 2149 should be modified in the interest of protecting chinook, sockeye, and coho salmon, and steelhead trout which must pass these mid-Columbia projects (including determinations of any appropriate instantaneous and daily average minimum flows and spilling percentages); and

(3) all other associated issued raised by the Washington Department of Fisheries' complaint in Docket No. E-9567, the Department's motion filed October 5, 1978, and the petitioners' motions filed on December 4, and 15, 1978.

As we noted earlier, the licensees argue that the Commission lacks the authority to require changes in minimum flows without their consent. For example, P.U.D. No. 2 of Grant County argues that Article 39 of its Project No. 2114 license does not grant the Commission the authority to amend Article 45, which specifies a minimum flow of 36,000 cfs.[10] The licensees' arguments, however, are without merit.

Article 39 of the license for Project No. 2114 provides:

The licensee shall construct, operate and maintain or shall arrange for the construction, operation and maintenance of such fish ladders, fish traps, fish hatcheries, or other fish facilities or fish protective devices for the purpose of conserving the fishery resources, and *comply with such reasonable modifications in project* structures and *operations* in the interest of fish life in connection with the project as may be prescribed hereafter by the Commission upon recommendations of the Secretary of the Interior, the Washington State Departments of Fisheries and game and the licensee. [15 F.P.C. 1005, 1006 (1956). Emphasis added.]

Flow releases are unquestionably an element of "project operations", which we may reasonably modify in the interest of fish life.[11]

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[5] The Priest Rapids project consists of two dams, Priest Rapids and Wanapum.

[6] Article 45, F.P.C. at 1074.

[7] In addition to the two conferences our staff has held concerning the complaint, a number of other conferences and meetings have been held among the parties under the auspices of the Columbia Committee on Fishery Operations. These meetings led to agreements under which certain steps, including spilling, were taken to insure the safe passage of juvenile fish during past annual spring migration runs.

[8] That study culminated in Technical Report No. 38 entitled "The Effect of Daily Flow Fluctuations on Spawining Fall Chinook in the Columbia River." According to the Department's October 5, 1978, motion, the licensee has refused to modify the operation of the project in the manner recommended in the study.

[9] In addition to the three licensees, the Department, and the petitioners, these intervenors in Docket No. E-9569 are parties to the consolidated proceeding:

The Washington Water Power Company; Puget Sound Power & Light Company; Portland General Electric Company; Pacific Power & Light Company; the Cities of Eugene, McMinnville, Milton-Freewater, and Forest Grove, Oregon; State of Oregon Fish and Wildlife Commission; City of Seattle, Washington; City of Tacoma, Washington; Cowlitz County Public Utility District; State of Idaho Fish and Game Commission; and the Confederated Tribes of the Umatilla Indian Reservation.

[10] Article 45 provides:

The licensee shall so regulate the flow from Project No. 2114 that it will not result in flows of less than 36,000 cubic feet per second of water at the Hanford Works of the Atomic Energy Commission except when conditions are beyond the licensee's control.

Grant County P.U.D. also argues that an agreement it entered with the Department on September 16, 1963, bars the Department from seeking any relief. That agreement, however, has never been approved by the Commission and in no way binds us. In any event, we may investigate the matters at issue here on our own motion, under Article 18 of the Project No. 2114 license. See p. 7 *infra*.

[11] Article 45 of the Project No. 2114 license is irrelevant to the issue of flow releases for

Footnotes continued on next page

In any event, the licensees also overlook the standard article contained in each of the four licenses which provides:

> . . . the operations of the licensee, so far as they affect the use, storage and discharge from storage of waters affected by the license, shall at all times be controlled by such reasonable rules and regulations . . . as the Commission may prescribe for the protection of life, health, and property, and in the interest of the fullest practicable conservation and utilization of such waters for power purposes and for *other beneficial public uses, including recreational purposes,* and *the licensee shall release water* from the project reservoir *at such rate* in cubic feet per second, *or such volume* in acre-feet per specified period of time, . . . *as the Commission may prescribe for the . . . purposes* [other than navigation] *hereinbefore mentioned.* [Emphasis added.] [12]

The words "other beneficial public uses, including recreational purposes" are taken directly from Section 10(a) of the Federal Power Act. In *Udall* v. *FPC*, 387 U.S. 428 (1967), the Supreme Court ruled beyond cavil that this language includes the purpose of protecting anadromous fishery resources (specifically including salmon and steelhead trout).

In light of these open-ended license articles, we find that we have ample authority to require modifications to the projects' operations to provide the relief the complainant and petitioners seek, or other relief that may prove necessary or desirable. The licensees' contentions that such modifications would alter their licenses without their consent, in violation of Section 6 of the Federal Power Act, are not well taken.

The issuance of a license does not relieve the Commission from ensuring throughout the term of the license that fishery resources are protected and enhanced. During the term of a license, changes in circumstances or available information may well demand reappraisal of the ways in which the project as originally conceived may be kept best adapted to a comprehensive plan of development. This is precisely why we include open-ended conditions in the project licenses. A modification under such an open-ended license article is not an alteration within the meaning of Section 6 of the Act requiring a licensee's agreement. Both the courts and Congress have recognized the Commission's authority to impose open-ended license conditions, which reserve our right to *impose* changes in project works or operations despite Section 6.[13] By accepting a license with open-ended conditions, a licensee agrees to make modifications the Commission might order under those conditions. If the licensee could later avoid the imposition of modifications ordered under an open-ended license condition simply by refusing to agree to them, the Commission's recognized reservation of rights would be vitiated.

NEED FOR EXPEDITED HEARING—PHASE I

In providing for a hearing, we recognize that there have been extensive and continuing efforts to resolve the anadromous fish problems related to the construction and operation of the four mid-Columbia projects. The final solution to these problems may require a substantial amount of time for discovery, further studies, discussions among the parties, and hearings.

The immediate problem, however, concerns the impending Spring 1979 downstream migration of smolts during their journey seaward. According to the pleadings, the migration would begin around the middle of April and continue to the middle of June. With so little time available before migration begins, we find that due and timely execution of our responsibilities in this matter imperatively and unavoidably requires departures from our usual practice and procedure. Because the parties have been unable to resolve their differences over what measures should be required for this coming spring, we are directing the presiding administrative law judge to convene a prehearing conference in Portland, Oregon, on March 20, 1979, for the exclusive purpose of considering the issue of what interim measures, if any, should be imposed to protect the Spring 1979 downstream fish migration. If it appears to the presiding judge that the parties have been unable to resolve their differences over the proper operating regime during the Spring 1979 downstream fish migration by the end of the prehearing conference, he shall convene the hearing immediately and continue it until he has compiled a sufficient record to reach a decision on what measures should be required for this spring.[14] All parties should come to the hearing prepared to present oral evidence and to cross-examine any oral testimony by sworn witnesses.

We are delegating authority to establish the Spring 1979 interim operating measures to the presiding judge, who must render a decision on this phase of the hearing by April 13, 1979. The licensees must follow the presiding judge's decision on the interim measures. Those measures will go into effect immediately and will be stayed only by Commission action. Any party wishing to appeal or support the presiding judge's decision on interim measures must do so by filing its briefs, comments, or statements of position within fifteen days of issuance of the decision.

HEARING—PHASE II

Further scheduling of hearings in the remainder of this proceeding will be the responsibility of the presiding judge. Moreover, as noted above, additional studies may be required before a long-term solution can be reached, and may even be needed before effective hearings can commence to consider what fish measures should be required for the remainder of the license terms. Moreover, interim operating measures may be necessary beyond the Spring 1979 downstream fish migration, to facilitate studies or to govern during the period prior to final Commission action in this proceeding. These matters, as well as the development of a complete record, will be left to the judgment of the presiding administrative law judge as part of the exercise of his delegated authority under § 1.27 of our regulations.

The Commission orders: (A) The complaint proceeding designated Docket No. E-9569, and the petitions discussed above and filed by petitioners in Projects Nos. 943, 2114, 2145, and 2149, are consolidated.

(B) Pursuant to the Federal Power Act, particularly Sections 4(g), 10(a), 10(g), 306, 307, 308, and 309, the licenses for Projects Nos. 943, 2114, 2145, and 2149, and the Commission's Rules of Practice and Procedure, a hearing shall be held in this proceeding respecting the issues discussed above, in accordance with the provisions of this order.

(C) The Commission's Rules of Practice and Procedure shall apply in this proceeding except to the extent they are modified and supplemented below.

(D) A prehearing conference shall be held commencing at 9:30 a.m. local time on March 20, 1979, in Judge Soloman's court room of the U.S. Courthouse, 620 S.W. Main, Portland, Oregon, to initiate the first phase of the hearing in this proceeding. The first phase will consider the interim

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Footnotes continued from last page

protecting fish life. That article sets a *minimum* flow for the purpose of ensuring the safe operation of the downstream Hanford Nuclear Plant. It does not establish a ceiling on minimum flows for other purposes, nor was it designed to provide sufficient protection for fish life.

[12] Project No. 2114, Art. 18 [14 F.P.C. 1067, 1072 (1955)]; Project No. 2145, Art. 18 [18 F.P.C. at 35]; Project No. 2149, Art. 18 [28 F.P.C. 128, 132 (1962)]; see generally 16 F.P.C. 1121, 1125 (1956). Project No. 943, Art. 14 [51 F.P.C. at 1151-52].

[13] *See* State of California V. FPC, 345 F.2d 917, 924-25 (9th Cir. 1965), *cert. denied*, 382 U.S. 941 (1965); H.R. Rep. No. 1643, 90th Cong., 2 Sess. 2 (1968); 114 Cong. Rec. 21440-41 (1968).

[14] The presiding judge and the parties should consider the extent to which those interim measures might best be adapted to any additional studies that may be desirable to develop information sufficient to reach a long-term solution to the mid-Columbia anadromous fish problems.

operating measures necessary or desirable for Projects Nos. 943, 2114, 2145, and 2149 during the Spring 1979 downstream fish migration on the Columbia River.

(E) Under Section 309 of the Federal Power Act, 16 U.S.C. 825h, the Commission delegates to the designated presiding administrative law judge authority to order the licensees for Projects Nos. 943, 2114, 2145, and 2149, to modify the operations of those projects during the Spring 1979 downstream fish migration. The presiding judge's order on interim operating measures shall be issued no later than April 13, 1979. The effect of the presiding judge's order shall be stayed only by Commission action. Any party wishing to appeal or support the presiding judge's order shall file its brief, comments, or statement of position no later than 15 days from the issuance of that order.

(F) Any order of the presiding administrative law judge on modifications to the operations of Projects Nos. 943, 2114, 2145, and 2149, beyond the Spring 1979 downstream fish migration shall be effective immediately and be stayed only be Commission action. Any appeal from such an order must conform to § 1.7(d) of the Commission's regulations.

(G) The licensees for Projects Nos. 943, 2114, 2145, and 2149, the complainant and intervenors in Docket No. E-9569, and the petitioners identified above shall all be permitted to participate in this consolidated proceeding.

(H) The Secretary shall cause prompt publication in the FEDERAL REGISTER of notice of the prehearing conference ordered in paragraph (D) above.

By the Commission.

KENNETH F. PLUMB,
Secretary.

[FR Doc. 79-8012 Filed 3-15-79; 8:45 am]

[6450-01-M]

[Project No. 2861]

ROBERT W. SHAW

Notice Granting Intervention

MARCH 6, 1979.

On July 28, 1978, Robert W. Shaw, of 4 Parsons Street, Colebrook, New Hampshire 03576, filed an application for a preliminary permit for the Pontook Hydroelectric Project No. 2861 to be located on the Androscoggin River in the Town of Drummer, Coos County, New Hampshire.

Public notice of that application was given on November 21, 1978. Three parties have petitioned to intervene in this matter: The Attorney General's Office, State of New Hampshire, Environmental Protection Division (Attorney General), January 2, 1979; Appalachian Mountain Club (AMC), January 26, 1979; and the Society for the Protection of New Hampshire Forests (SPNHF), January 29, 1979.

The Attorney General's Office has statutory power to act as Attorney for the State of New Hampshire and to exercise common law powers in protecting the environment for the benefit of the public. Further, the Attorney General acts as Counsel for those New Hampshire administrative agencies regulating terms and conditions for the location and construction of energy facilities.

AMC, a non-profit New Hampshire Corporation, is actively concerned with the preservation of the recreational resources of the State's rivers and lakes. It has an active membership of 22,000 residing throughout New England and the Mid-Atlantic States. Over 2,000 members reside in New Hampshire. AMC has been involved in programs of natural resource preservation and conservation for over 101 years. Its petition lists a number of concerns regarding the potential impact of the proposed project.

SPNHF, a membership organization founded in 1901, is the oldest and largest statewide conservation organization in New Hampshire. The SPNHF promotes sound management practices for the state's natural resources and cooperates with government agencies at all levels to ensure implementation of policies consistent with legislative mandates designed to protect and enhance the environment. SPNHF's specific interest in the application derives from the location of the proposed project's Pontook site. The site borders an environmentally sensitive area, "Thirteen Mile Woods", which enjoys a scenic easement as a result of prior organizational effort by SPNHF.

Intervention by each of the three parties noted above appears to be in the public interest. As to each of the three petitions to intervene no answer has been filed with the Commission (18 CFR 1.8(e)).

Pursuant to § 3.5(a) of the Commission's Rules of Practice and Procedure (Rules), 18 CFR 3.5(a) (1978), as promulgated by Federal Energy Regulatory Commission Rulemaking RM78-19 (issued August 14, 1978), the above named parties are permitted to intervene in this proceeding subject to the Commission's Rules and Regulations under the Federal Power Act. Participation of the Intervenors shall be limited to matters affecting asserted rights and interests specifically set forth in their petitions to intervene. The admission of the Intervenors shall not be construed as recognition by the Commission that they might be aggrieved by any order entered in this proceeding.

KENNETH F. PLUMB,
Secretary.

[FR Doc. 79-8013 Filed 3-15-79; 8:45 am]

[6450-01-M]

[Docket No. ER78-522]

VIRGINIA ELECTRIC AND POWER CO.

Proposed Settlement Agreement

MARCH 6, 1979.

Take notice that on February 21, 1979, Virginia Electric and Power Company (VEPCO) filed a partial settlement agreement between VEPCO and certain municipal intervenors (ElectriCities). The partial settlement agreement would provide for a rate reduction to the ElectriCities under Schedule RS and, in turn, permit the ElectriCities to withdraw their price squeeze allegations. The reasonableness of the reduced rates to the ElectriCities pursuant to the settlement agreement will be left for resolution in hearing. On February 27, 1979, Judge Benkin certified the partial settlement agreement to the Commission.

Any person desiring to be heard or to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, D.C. 20426, in accordance with the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such protests should be filed on or before March 19, 1979. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection.

KENNETH F. PLUMB,
Secretary.

[FR Doc. 79-8014 Filed 3-15-79; 8:45 am]

[6450-01-M]

Office of Hearings and Appeals

ISSUANCE OF PROPOSED DECISIONS AND ORDERS

February 12 Through February 16, 1979

Notice is hereby given that during the period February 12 through February 16, 1979, the Proposed Decisions and Orders which are summarized below were issued by the Office of Hearings and Appeals of the Department of Energy with regard to Applications for Exception which had been filed with that Office.

Amendments to the DOE's procedural regulations, 10 CFR, Part 205, were issued in proposed form on September 14, 1977 (42 FR 47210 (September 20,

1977)), and are currently being implemented on an interim basis. Under the new procedures any person who will be aggrieved by the issuance of the Proposed Decision and Order in final form may file a written Notice of Objection within ten days of service. For purposes of the new procedures, the date of service of notice shall be deemed to be the date of publication of this Notice or the date of receipt by an aggrieved person of actual notice, whichever occurs first. The new procedures also specify that if a Notice of Objection is not received from any aggrieved party within the time period specified in the regulations, the party will be deemed to consent to the issuance of the Proposed Decision and Order in final form. Any aggrieved party that wishes to contest any finding or conclusion contained in a Proposed Decision and Order must also file a detailed Statement of Objections within 30 days of the date of service of the Proposed Decision and Order. In that Statement of Objections an aggrieved party must specify each issue of fact or law contained in the Proposed Decision and Order which it intends to contest in any further proceeding involving the exception matter.

Copies of the full text of these Proposed Decisions and Orders are available in the Public Docket Room of the Office of Hearings and Appeals, Room B-120, 2000 M Street, N.W., Washington, D.C. 20461, Monday through Friday, between the hours of 1:00 p.m. and 5:00 p.m., e.s.t., except federal holidays.

MELVIN GOLDSTEIN,
Director, Office of Hearings and Appeals.

MARCH 8, 1979.

PROPOSED DECISIONS AND ORDERS

Arizona Fuels Corporation, Salt Lake City, Utah; DXE-1988, crude oil

Arizona Fuels Corporation (Arizona Fuels) filed an Application for Exception from the provisions of 10 CFR 211.67 (the Entitlements Program). The request, if granted, would relieve Arizona Fuels of its obligation to purchase entitlements during the period January through June 1979 to account for its crude oil runs to stills and receipts of old oil during the period November 1978 through April 1979. On February 16, the Department of Energy issued a Proposed Decision and Order which denied the firm's request.

Chevron U.S.A., Inc., San Francisco, California; DEE-2004, crude oil

Chevron U.S.A. Inc. filed an Application for Exception from the provisions of 10 CFR, Part 212, Subpart D. The exception request, if granted, would permit Chevron to sell the crude oil which it will produce from the Vickers 1-Aggregated Vickers Rindge, located in Los Angeles County, California, at prices which exceed the applicable lower tier ceiling prices. On February 12, 1979, the DOE issued a Proposed Decision and Order which determined that Chevron should be permitted to sell 25.18 percent of the crude oil produced from the Vickers 1-Aggregated Vickers Rindge at upper tier ceiling prices.

Rickelson Oil & Gas Company, Tulsa, Oklahoma; DXE-2002, crude oil

Rickelson Oil & Gas Company filed an Application for Exception from the provisions of 10 CFR, Part 212, Subpart D, which, if granted, would result in the extension and increase of exception relief granted to Rickelson in two previous Decisions and Orders. On February 16, 1979, the DOE issued a Proposed Decision and Order which determined that the Rickelson request should be granted.

Dome Petroleum Corporation, Washington, D.C.; DPI-0018, crude oil

Dome Petroleum Corporation (Dome) file an Application for Exception from the provisions of 10 CFR 213.35. The exception request, if granted, would result in the refund of certain license fees which the firm paid on imports of natural gas liquid products from Canada during the 1974-75 and 1975-76 allocation periods. On February 12, 1979 the DOE issued a Proposed Decision and Order in which it determined that the exception request should be granted in part.

Hydrotherm, Inc., Northvale, New Jersey; DEE-2091, furnaces

Hydrotherm, Incorporated filed an Application for Exception in which it requested that it be permitted to advertise the fuel efficiency of its new pulse combustion boiler without regard to the provisions of Section 430.24(n) of the DOE Regulations. On February 12, 1979, the Department of Energy issued a Proposed Decision and Order which determined that the Hydrotherm exception request be granted.

Reading & Bates Petroleum Company, Tulsa, Oklahoma; DXE-2125

Reading & Bates Petroleum Company filed an Application for Exception from the provisions of 10 CFR, Part 212, Subpart D. The exception request, if granted, would result in an extension of exception relief previously granted and would permit the firm to sell 50.14 percent of the crude oil which it produces from the Dempsey Mantooth 2-A Lease at upper tier ceiling prices. On February 13, 1979, the DOE issued a Proposed Decision and Order and tentatively determined that an extension of exception relief should be granted with respect to Reading & Bates' Dempsey Mantooth 2-A Lease.

Laketon Asphalt Refining, Inc., Evansville, Indiana; DXE-2113, crude oil

Laketon Asphalt Refining, Inc. filed an Application for Exception from the provisions of 10 CFR 211.67 (the Entitlements Program). The exception request, if granted, would relieve Laketon of its entitlement purchase obligations under the provisions of 10 CFR 211.67 to account for the firm's crude oil receipts and runs to stills during its fiscal year ending December 31, 1979. On February 16, 1979 the DOE issued a Proposed Decision and Order which determined that Laketon's entitlement purchase obligations should be reduced by $124,311 per month during the period March 1 through August 31, 1979 to account for the firm's crude oil receipts and runs to stills during the period January 1 through June 30, 1979.

Tosco Corporation, Los Angeles, California; DXE-1910, motor gasoline

Tosco Corporation filed an Application for Exception from the provisions of the refiner price rule, Section 212.83. The exception request, if granted, would result in an extension of the exception relief which the DOE previously granted to the firm on February 1, 1978. *See Tyson Corporation* 1 DOE Par. 80,193 (1978). In the February 1 Decision, the DOE found that Tosco had relied to its detriment on Agency advice regarding the firm's pricing policies. Consequently, the DOE approved exception relief from the provisions of Section 212.83 and permitted Tosco to treat its execution of two variable price contracts as relevant transactions in determining its May 15, 1973 selling prices for motor gasoline to certain classes of purchaser. On February 13, 1979 the DOE issued a Proposed Decision and Order in which it determined that the exception relief granted in the February 1 Decision should be extended through December 31, 1979.

Coastal States Gas Corporation/LoVaca Gathering Company, Houston, Texas; DEE-1479, NGL/NGLP

Coastal States Gas Corporation and LoVaca Gathering Company jointly filed an Application for Exception which, if granted, would assign a portion of their base period supply obligations for NGLs and NGLPs to a new firm, Valero Energy Corporation, and would affect the manner in which Valero will calculate its maximum prices for those covered products. On February 16, 1979, the DOE issued a Proposed Decision and Order which determined that the exception request should be granted in part.

Econ-O-Gas, Inc., Temple, Texas; DEE-1416, DSG-0031

Econ-O-Gas filed an Application for Exception and a Petition for Special Redress. The Application, if granted, would result in the issuance of an order assigning the Atlantic Richfield Corporation (ARCO) or another firm to replace Foremost Petroleum Corporation Inc. (Foremost) as EOG's base period supplier of motorgasoline. The Petition, if granted, would result in (i) the rescission of two orders issued by the Director of Operations of Region VI of the Federal Energy Administration which had the effect of terminating ARCO's base period supply relationship with EOG and assigning Foremost as EOG's base period supplier of motor gasoline and (ii) the invalidation of a three-party agreement executed by ARCO, Foremost and EOG on November 22, 1976. On February 12, 1979, the DOE issued a Proposed Decision and Order which determined that both requests be denied.

[FR Doc. 79-8043 Filed 3-15-79; 8:45 am]

[6450-01-M]

ISSUANCE OF PROPOSED DECISIONS AND ORDERS

February 19 through February 23, 1979

Notice is hereby given that during the period February 19 through February 23, 1979, the Proposed Decisions and Orders which are summarized

below were issued by the Office of Hearings and Appeals of the Department of Energy with regard to Applications for Exception which had been filed with that Office.

Amendments to the DOE's procedural regulations, 10 CFR, Part 205, were issued in proposed form on September 14, 1977 (42 FR 47210 (September 20, 1977)), and are currently being implemented on an interim basis. Under the new procedures any person who will be aggrieved by the issuance of the Proposed Decision and Order in final form may file a written Notice of Objection within ten days of service. For purposes of the new procedures, the date of service of notice shall be deemed to be the date of publication of this Notice or the date of receipt by an aggrieved person of actual notice, whichever occurs first. The new procedures also specify that if a Notice of Objection is not received from any aggrieved party within the time period specified in the regulations, the party will be deemed to consent to the issuance of the Proposed Decision and Order in final form. Any aggrieved party that wishes to contest any finding or conclusion contained in a Proposed Decision and Order must also file a detailed Statement of Objections within 30 days of the date of service of the Proposed Decision and Order. In that Statement of Objections an aggrieved party must specify each issue of fact or law contained in the Proposed Decision and Order which it intends to contest in any further proceeding involving the exception matter.

Copies of the full text of these Proposed Decisions and Orders are available in the Public Docket Room of the Office of Hearings and Appeals, Room B-120, 2000 M Street NW., Washington, D.C. 20461, Monday through Friday, between the hours of 1:00 p.m. and 5:00 p.m., e.s.t., except federal holidays.

MELVIN GOLDSTEIN,
Director, Office of Hearings and Appeals.

MARCH 12, 1979.

PROPOSED DECISIONS AND ORDERS

Callon Petroleum Company, Natchez, Miss.; DEE-0659 through DEE-0662, Crude oil

The Callon Petroleum company filed four Applications for Exception from the provisions of 10 CFR, Part 212, Subpart D. The exception requests, if granted, would permit Callon to charge prices for crude oil in excess of the otherwise applicable ceiling prices on February 22, 1979, the Department of Energy issued a Proposed Decision and Order which determined that the Callon requests should be denied.

Texaco, Inc., Denver, Colo.; DXE-2089, DXE-2090, crude oil

Texaco, Inc. filed two Applications for Exception from the provisions of 10 CFR, Part 212, Subpart D. The exception requests, if granted, would permit Texaco to sell the crude oil produced for the benefit of the working interest owners from the State of Wyoming "G" and John Sweeney Leases at upper tier ceiling prices. On February 22, 1979 the DOE issued a Proposed Decision and Order which determined that the exception request be granted.

Shell Oil Company, Houston, Texas; DEE-1955, crude oil

Shell Oil Company filed an Application for Exception from the provisions of 10 CFR, Part 212, Subpart D. The exception request, if granted, would permit Shell to sell, at upper tier ceiling prices, a portion of the crude oil that the firm expects to produce for the benefit of the working interest owners at the Gas City Unit, after it undertakes a capital investment program there. On February 23, 1979, the DOE issued a Proposed Decision and Order which determined that the exception request be granted.

R. W. Tyson Producing Company, Jackson, Mississippi; DXE-2005, crude oil

R. W. Tyson Producing Company filed an Application for Exception from the provisions of 10 CFR, Part 212, Subpart D, in which the firm requested that it be permitted to continue to sell certain of the crude oil produced from the Stevens Lease, located on the Glazier Field, in Perry County, Mississippi at market prices to enable the firm to realize a sufficient rate of return on a proposed investment to restore the #4 and #5 Wells to production. On February 23, 1979, the DOE issued a Proposed Decision and Order which determined that the Tyson exception request be granted.

[FR Doc. 79-8044 Filed 3-15-79; 8:45 am]

[6450-01-M]

NOTICE OF CASES FILED

Week of February 23 Through March 2, 1979

Notice is hereby given that during the week of February 23 through March 2, 1979, the appeals and applications for exception or other relief listed in the Appendix to this Notice were filed with the Office of Hearings and Appeals of the Department of Energy.

Under the DOE's procedural regulations, 10 CFR, Part 205, any person who will be aggrieved by the DOE action sought in this case may file with the DOE written comments on the application within ten days of service of notice, as prescribed in the procedural regulations. For purposes of those regulations, the date of service of notice shall be deemed to be the date of publication of this Notice or the date of receipt by an aggrieved and Appeals, Department of Energy, Washington, D.C. 20461.

MELVIN GOLDSTEIN,
Director, Office of Hearings and Appeals.

MARCH 12, 1979.

LIST OF CASES RECEIVED BY THE OFFICE OF HEARINGS AND APPEALS

[Week of February 23 through March 2, 1979]

Date	Name and location of applicant	Case No.	Type of submission
Feb. 23, 1979	Champlin Petroleum Co., Fort Worth, Tex	DXE-2212	Extension of relief granted in *Champlin Petroleum Co.*, 2 DOE Par.——— (January 8, 1979). If granted: Champlin Petroleum Co. would be permitted to continue to sell the crude oil produced from the State of New Mexico 18 lease located in Lea County, N. Mex., at upper tier ceiling prices.
Do	City of Los Angeles, Department of Water and Power, Washington, D.C.	DRD-0018	Motion for discovery. If granted: Discovery would be granted with respect to the Proposed Remedial Order issued to Coastal States Gas Corp. (Case No. DRO-0113).
Do	Clark Oil & Refining Corp. Washington, D.C.	DFA-0324	Appeal of information request denial. If granted: The DOE's Feb. 16, 1979, Information Request Denial would be rescinded and Clark Oil & Refining Corp. would receive access to documents regarding the acquisition of American Petrofina's refinery in Mt. Pleasant, Tex., by Dorchester Gas Corp.

LIST OF CASES RECEIVED BY THE OFFICE OF HEARINGS AND APPEALS—Continued

[Week of February 23 through March 2, 1979]

Date	Name and location of applicant	Case No.	Type of submission
Feb. 23, 1979	Coastal States Gas Corp. Houston, Tex	DES-158, DSG-0045.	Request for Special Redress; Request for Stay. If granted: The Office of Hearings and Appeals would review the denial by DOE Special counsel for Compliance of the Application to Quash a Subpoena submitted by Coastal States Gas Corporation. A Stay of the Subpoena would be approved pending a determination of Coastal States Gas Corporation's Petition for Special Redress Relief.
Do	Glickman, Inc., McPherson County, Kans	DEE-2211	Price exception (Section 212.73). If granted: Glickman, Inc. would be permitted to sell the crude oil produced from the Burch Lease located in McPherson County, Kans. at stripper well prices.
Do	Hewit & Dougherty Austin, Tex	DEE-2222	Price Exception. If granted: Hewit & Dougherty would be permitted to calculate its base period costs for its Roche plant based on its base quarter for the months of October, November and December 1973.
Do	Jerome P. McHugh, Denver, Colo	DEE-2217	Exception to reporting requirements. If granted: Jerome P. McHugh would not be required to file EIA Form 23.
Do	Mid-Continent, Inc., Little Rock, Ark	DRD-0179	Motion for Discovery. If granted: Discovery would be granted in connection with Mid-Continent's Statement of Objections to a Supplemental Remedial Order (Case No. DRA-0179).
Do	Mobil Oil Corp., Ventura County, Calif	DEE-2210	Price Exception (Section 212.73). If granted: Mobil Oil Corp. would be permitted to sell the crude oil produced from the Ferguson Lease, Rincon Field, located in Ventura County, Calif., at upper tier ceiling prices.
Do	Pacific Gas & Electric Co., San Francisco, Calif.	DRD-0019	Motion for Discovery. If granted: Discovery would be granted with respect to a Proposed Remedial Order issued to Coastal States Gas Corp. (Case No. DRO-0113).
Do	Charles Schwartz, Berkeley, Calif	DFA-0325	Appeal of Information Request Denial. If granted: Charles Schwartz would receive access to documents regarding the DOE's Energy Research Advisory Board.
Do	Southland Royalty Co., Forth Worth, Tex	DXE-2213	Extension of relief granted in *Southland Royalty Co.*, 2 DOE Par. —— (October 3, 1978). If granted: Southland Royalty Co. would be permitted to continue to sell the crude oil produced from the Axtec Totah Unit at upper tier ceiling prices.
Do	Sunman Tire & Service Center, Sunman, Ind.	DEE-2215	Exception to change supplier. If granted: Sunman Tire & Service Center would be assigned a new base period supplier of motor gasoline to replace Bruce Miller Oil Co.
Do	Texaco, Inc., Denver, Colo	DXE-2214	Extension of relief granted in *Texaco, Inc.*, DOE Par. —— (December 21, 1978). If granted: Texaco, Inc. would be permitted to continue to sell the crude oil produced from the Graves lease located in Campbell County, Wyo., at upper tier ceiling prices.
Do	Texas Pacific Oil Co., Inc., Houston, Tex	DRH-0165, DRD-0165.	Motion for Discovery; Motion for Evidentiary Hearing. If granted: An evidentiary hearing would be convened and discovery would be granted with respect to Texas Pacific Oil Co. Inc.'s objections to the Proposed Remedial Order (Case No. DRO-0165).
Do	TransOcean Oil, Inc., Houston, Tex	DEE-2216	Exception to reporting requirements. If granted: TransOcean Oil, Inc. would receive an extension of time in which to file EIA Form 23.
Feb. 26, 1979	Ashland Oil Inc., Washington, D.C.	DEA-0326	Appeal of October 1978 Entitlements Notice. If granted: The October 1978 Entitlements Notice would be amended with respect to Ashland Oil Inc.'s entitlements purchase obligations.
Do	E. B. Brooks, Jr., Dallas, Tex	DEE-2223	Price Exception (Section 212.73). If granted: E. B. Brooks, Jr. would be permitted to sell the crude oil produced from the Baptist Foundation Lease located in Stonewall County, Tex., at stripper well prices.
Do	Dean Dart, Oblong, Ill	DEE-2220	Exception to change supplier. If granted: Dean Dart would be assigned a new base period supplier of motor gasoline to replace Marathon Oil Co.
Do	Electricity Consumers Resources Council, Washington, D.C.	DFA-0331	Appeal of Information Request Denial. If granted: The DOE's January 24, 1979 Information Request Denial would be rescinded and Electicity Consumers Resources Council would receive access to certain FEA rates documents.
Do	Energy Cooperatives, Inc. Washington, D.C.	DEA-0327	Appeal of October 1978 Entitlements Notice. If granted: The October 1978 Entitlements Notice would be amended with respect to Energy Cooperatives, Inc.'s entitlements purchase obligations.
Do	General Motors Corp., Washington, D.C	DEH-0299	Motion for Evidentiary Hearing. If granted: An evidentiary hearing would be convened with respect to the firm's Appeal of a Decision and Order issued by the Economic Regulatory Administration (Case No. DEA-0299).
Do	George F. Gerard, Inglewood, Calif	DEE-2232	Allocation Exception. If granted: George F. Gerard would receive an increase in his base period use of motor gasoline.
Do	Hobbs Trucking Co., Anaheim, Calif	DEE-2219	Exception to change suppliers. If granted: Hobbs Trucking Co. would be assigned a new base period supplier to replace Gulf Oil Corp.
Do	Mobil Oil Corp., New York, N.Y	DES-2163	Request for Stay. If granted: Mobil Oil Corp. would receive a stay of the provisions of 10 CFR 211.9 and 211.10, pending a final determination on an Application for Exception (Case No. DEE-2163).
Do	Pacific Resources, Inc., Honolulu, Hawaii	DEA-0328	Appeal of November 1978 Entitlements Notice. If granted: The November 1978 Entitlements Notice would be amended with respect to Pacific Resources, Inc.'s entitlements purchase obligations.
Do	Tenneco Oil Co., Houston, Tex	DXE-2218	Extension of the relief granted in *Tenneco Oil Co.*, 2 DOE Par. —— (October 13, 1978). If granted: Tenneco Oil Co. would be permitted to continue to sell the crude oil produced from the South Coast Unit located in St. Mary Parish, La., at upper tier ceiling prices.
Feb. 27, 1979	Bennington Power Equipment Co., North Bennington, Vt.	DEE-2227	Exception to change suppliers. If granted: Bennington Power Equipment Co. would be assigned a new base period supplier to replace distributor Paul J. Martin, Inc.
Do	Bonham, Carrington & Fox, Houston, Tex	DFA-0334	Appeal of an Information Request Denial. If granted: Bonham, Carrington & Fox would receive access to certain DOE data.
Do	Cibro Petroleum Products, Inc., Washington, D.C.	DEA-0329	Appeal of November 1978 Entitlements Notice. If granted: The November 1978 Entitlements Notice would be amended with respect to Cibro Petroleum Products, Inc.'s entitlements purchase obligation.

LIST OF CASES RECEIVED BY THE OFFICE OF HEARINGS AND APPEALS—Continued

[Week of February 23 through March 2, 1979]

Date	Name and location of applicant	Case No.	Type of submission
Feb. 27, 1979	Commonwealth Oil Refining Co., Inc., San Antonio, Tex.	DEN-1022	Request for Interim Order. If granted: Commonwealth Oil Refining Co., Inc. would be permitted to utilize the partial exception relief which the DOE proposed to grant in a November 7, 1978 Proposed Decision and Order issued to the firm.
Do	Crown Central Petroleum Corp., Bellaire, Tex.	DXE-2230	Extension of relief granted in *Crown Central Petroleum Corp.*, 2 DOE Par. —— (February 1, 1979). If granted: Crown Central Petroleum Corp. would be permitted to continue to sell the crude oil produced from the Santa Ana & Fresno Land Lease located in Fresno County, Calif., at upper tier ceiling prices.
Do	Despot Exploration, Inc., Beauregard Parish, La.	DEE-2231	Price Exception (Section 212.73). If granted: Despot Exploration, Inc. would be permitted to sell the crude oil produced from the North Singer Field located in Beauregard Parish, La. at upper tier ceiling prices.
Do	Gulf Oil Corp., Houston, Tex	DEA-0330, DES-0330.	Appeal of ERA Decision; Request for Stay. If granted: The ERA's February 7, 1979 Decision and Order issued to Gulf Oil Corp. directing it to sell crude oil to Marion Corp. would be modified. Gulf Oil Corp. also requests a stay of this directive.
Do	M. J. Mitchell, Dallas, Tex	DXE-2229	Extension of relief granted in *M. J. Mitchell*, 2 DOE Par. —— (February 5, 1979). If granted: M. J. Mitchell would be permitted to sell the crude oil produced from the Pickrel Ranch Minnelusa Sand Unit, located in Campbell County, Wyo. at stripper well prices.
Do	Office of Enforcement, Washington, D.C	DRX-0144	Supplemental Order. If granted: The DOE's January 23, 1979, Decision and Order issued to Glenn Martin Heller (Case No. DRS-0167) would be modified.
Do	Shank, Irwin, Conant, Williamson and Grevelle, Dallas, Tex.	DFA-0333	Appeal of an Information Request Denial. If granted: Shank, Irwin, Conant, Williamson & Grevelle would receive access to certain DOE data regarding complaints filed against Murphy Oil Corp.
Do	Swafford & Stucki, Idaho Falls, Idaho	DFA-0332	Appeal of an Information Request Denial. If granted: The January 19, 1979 Information Request Denial would be rescinded and Swafford & Stucki would receive access to certain DOE data.
Do	Tutcher Magic Gas Co., Inc., Kansas City, Mo.	DSG-0046, DES-0159	Request for Special Redress; Request for Stay. If granted: The Office of Hearings and Appeals would review the denial by DOE Region VII of the Application to Quash a Subpoena submitted by Tutcher Magic Gas Co., Inc. A stay of the subpoena would be approved pending a determination on Tutcher's Petition for Special Redress.
Do	United Refining Co., Warren, Pa	DEE-2224	Allocation Exception (Section 211.10 and 211.102). If granted: United Refining Co. would be permitted to allocate gasoline to its customers on the basis of their actual purchases in the corresponding month of the prior year instead of the 1972 base period.
Do	Bert Waller, Hammett, Ind	DEE-2225	Allocation Exception. If granted: Bert Waller would receive an increase in his base period used of motor gasoline.
Do	Williams Furnace Co., Buena Park, Calif	DEE-2228	Exception from provisions of 10 CFR 405. If granted: Williams Furnace Co. would receive an exception to the provisions of 10 CFR 405, Section 430.33(n)(1) regarding test procedures.
Feb. 28, 1978	Acomi Petroleum, Marblehead, Mass	DST-0014	Request for a Temporary Stay. If granted: Cities Service would be assigned to replace Union Petroleum as the base period supplier of motor gasoline to Acomi Petroleum.
Do	Atlantic Richfield Co., Dallas, Tex	DXE-2235	Extension of relief granted in *Atlantic Richfield Company*, 2 DOE Par. —— (January 12, 1979). If granted: Atlantic Richfield Co. would be permitted to continue to sell the crude oil produced from the California State Lease PRC-1466, located in Rincon Island Offshore Lease, at upper tier ceiling prices.
Do	Cities Service Co., Tulsa, Okla	DEA-0335	Appeal of ERA Order. If granted: The Economic Regulatory Administration's January 31, 1979 Decision and Order issued to Cities Service Co. directing it to sell crude oil to Sigmor Refining Co. would be modified.
Do	Coastal States Gas Corp., Washington, D.C	DEE-2236	Allocation Exception. If granted: Coastal States Gas Corp. would receive an exception from the provisions of 10 CFR 211.67 in regard to the California Entitlements rule.
Do	Dixilyn-field Drilling Co., Houston, Tex	DEE-2233	Exception to the reporting requirements. If granted: Dixilyn-Field Drilling Co. would not be required to file Form EIA-23.
Do	Earth Resources Co., Fairbanks, Alaska	DEE-2237	Exception to the Entitlements Program. If granted: Earth Resources Co. would receive Small Refiner Bias entitlements for the period September 1977 through August 1978.
Do	Johnson Oil Co., Inc., Washington, D.C	DEH-0043	Motion for Evidentiary Hearing. If granted: An evidentiary hearing would be convened with respect to the Statement of Objections submitted by Johnson Oil Co., Inc. to the Proposed Decision and Order issued to Southwestern Refining Co. (Case No. DEE-0483).
Do	Keller-Piasa Terminal, Inc., Hartford, Ill	DST-2234, DEE-2234	Exception to change supplier; Request for Temporary Stay. If granted: A new base period supplier would be assigned to Keller-Piasa Terminal, Inc.
Do	Lower Broadway Exxon Service, Nanticoke, Pa.	DEE-2221	Allocation Exception. If granted: Lower Broadway Exxon Service would be assigned motor gasoline directly by Exxon Company, U.S.A. rather than by the distributor, Swithers Heating Oil Service, Inc.
Do	McCulloch Gas Processing Corp., Los Angeles, Calif.	DRH-0177, DRD-0177	Motion for Evidentiary Hearing and Discovery. If granted: Discovery would be granted and an evidentiary hearing would be convened with respect to McCulloch Gas Processing Corp. Statement of Objections to a Proposed Remedial Order (DRO-0177).
Do	Quincy Oil, Inc. Boston, Mass	DRA-0336	Appeal of Remedial Order. If granted: The DOE's January 1, 1979 Decision and Order (Case No. FRA-1428) issued to Quincy Oil, Inc. would be modified.
Do	Tesoro Petroleum Corp., San Antonio, Tex	DSG-0047, DES-0161	Petition for Special Redress; Request for Stay. If granted: The Office of Hearings and Appeals would review the denial by the Office of Special Counsel of the Application to Quash a Subpoena. A stay of the subpoena woud be approved pending a determination on the firm's Petition for Special Redress.

LIST OF CASES RECEIVED BY THE OFFICE OF HEARINGS AND APPEALS—Continued

[Week of February 23 through March 2, 1979]

Date	Name and location of applicant	Case No.	Type of submission
Mar. 1, 1979	Blarney Castle Oil Co., Bear Lake, Mich	DEE-2239	Allocation Exception (Sections 211.10 and 211.102). If granted: Blarney Castle Oil Co., would be permitted to allocate motor gasoline to its customers on the basis of their actual purchases in the corresponding month of the prior year instead of the 1972 base period.
Do	Newport News Shipbuilding and Dry Dock Co., Washington, D.C..	DFA-0337	Appeal of an Information Request Denial. If granted: Newport News Shipbuilding and Dry Dock Co., would receive access to documents relating to an investigation which is being conducted by the Department of Justice in connection with the Department of the Navy.
Do	State of Nebraska, Lincoln, Nebr	DEE-2238	Price Exception (Part 211). If granted: The State of Nebraska would be granted an exception to the provisions of 10 CFR 212 regarding the sale of petroleum products.

Notices of Objection Received

[Week of February 23 through March 2, 1979]

Date	Name and location of applicant	Case No.
Feb. 23, 1979	Southland Royalty Co., Casper, Wyo	DEE-1964
		DEE-1965
Feb. 26, 1979	Coastal States Gas Corp., Washington, D.C.	DEE-1479
Feb. 27, 1979	Cities Service Co., Tulsa, Okla	DEE-1822
Do	Husky Oil Co., Denver, Colo	DEE-1436
		DEE-1444
Do	Econ-O-Gas, Inc., Temple, Tex	DEE-1416
		DSG-0031
Do	Arizona Fuels Corp., Washington, D.C.	DXE-1988

Proposed Remedial Orders, Notices of Objection Received

Feb. 27, 1979	Cosby Oil Co., Whittier, Calif	DRO-0179

[FR Doc. 79-8045 Filed 3-15-79; 8:45 am]

sunshine act meetings

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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[6570-06-M]

1

EQUAL EMPLOYMENT OPPORTUNITY COMMISSION.

TIME AND DATE: 9:30 a.m. (eastern time), Tuesday, March 20, 1979.

PLACE: Commission Conference Room, No. 5240, on the fifth floor of the Columbia Plaza Office Building, 2401 E Street NW., Washington, D.C. 20506.

STATUS: Part will be open to the public and part will be closed to the public.

MATTERS TO BE CONSIDERED:

Open to the public:

1. Internal procedures for handling matters brought before EEOC for coordination under Executive Order 12067.
2. Proposed internal uniform procedures for treatment of Commission decisions made at Headquarters.
3. Freedom of Information Act Appeal No. 78-12-FOIA-290, concerning a request for materials in an investigative file.
4. Freedom of Information Act Appeal No. 78-8-FOIA-176, concerning a request for compliance data in connection with a consent decree.
5. Report on Commission operations by the Executive Director.

Closed to the public:

Litigation Authorization; General Counsel Recommendations.

Matters closed to the public under the Commission's regulations at 29 CFR 1612.13.

NOTE.—Any matter not discussed or concluded may be carried over to a later meeting.

CONTACT PERSON FOR MORE INFORMATION:

Marie D. Wilson, Executive Officer, Executive Secretariat, at 202-634-6748.

This notice issued March 13, 1979.

[S-517-79 Filed 3-14-79; 12:33 pm]

[6712-01-M]

2

FEDERAL COMMUNICATIONS COMMISSION.

TIME AND DATE: 9:30 a.m., Thursday, March 15, 1979.

PLACE: Room 856, 1919 M Street NW., Washington, D.C.

STATUS: Additional item to be considered at closed Commission meeting which is scheduled to follow the open meeting.

MATTER TO BE CONSIDERED:

Agenda, Item NO., and Subject

General—1—WARC Research Funding for fiscal year 79.

Additional information concerning this meeting may be obtained from the FCC Public Affairs Office , telephone number (202) 632-7360.

Issued: March 14, 1979.

[S-519-79 Filed 3-14-79; 2:16 pm]

[6730-01-M]

3

FEDERAL MARITIME COMMISSION.

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT: 44 FR 15565, March 14, 1979.

PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING: 10 a.m., March 20, 1979.

CHANGE IN THE MEETING: Addition of the following items to the open session:

8. Special Docket No. 602: Application of Trans Freight Lines, Inc. for the benefit of International Transportation Corp.—Consideration of exceptions to Initial Decision.
9. Docket No. 78-30: Time Limit on the Filing of Overcharge Claims—Petitions for reconsideration and stay.
10. Special permission application of Matson Navigation Co. to advance effective date of proposed bunker surcharge.

[S-520-79 Filed 3-14-79; 2:16 pm]

[6735-01-M]

4

FEDERAL MINE SAFETY AND HEALTH REVIEW COMMISSION.

TIME AND DATE: 10 a.m., March 20, 1979.

PLACE: Room 600, 1730 K Street NW., Washington, D.C.

STATUS: This meeting may be closed.

MATTER TO BE CONSIDERED: The Commission will consider and act upon the following:

3. *Secretary of Labor and UMWA* v. *Canterbury Coal Co.*, PITT 78-127, 78-128, 78-301-P, 78-302-P. (Motion of Administrative Law Judge to intervene; Secretary of Labor's motion to strike; UMWA's motion to strike).

It was determined by unanimous vote of the Commissioners that Commission business required that this item be added to the March 20, 1979 agenda and that no earlier announcement of the change was possible.

CONTACT PERSON FOR MORE INFORMATION:

Joanne Kelley, 202-653-5632.

[S-524-79 Filed 3-14-79; 3:11 pm]

[6210-01-M]

5

BOARD OF GOVERNORS OF THE FEDERAL RESERVE SYSTEM.

TIME AND DATE: 10 a.m., Wednesday, March 21, 1979.

PLACE: 20th Street and Constitution Avenue NW., Washington, D.C. 20551.

STATUS: Open.

MATTERS TO BE CONSIDERED:

SUMMARY AGENDA

Because of its routine nature, no substantive discussion of the following item is anticipated. This matter will be voted on without discussion unless a member of the Board requests that the item be moved to the discussion agenda.

1. Request by the American Telephone and Telegraph Company for a Board interpretation regarding exemption from Regulation Z (Truth in Lending) of certain public utilities transactions.

DISCUSSION AGENDA

1. Proposed action regarding the handling of non-interest bearing negotiable orders of

withdrawal of mutual savings banks in Pennsylvania.

2. Proposed delegation of authority with respect to Federal Reserve Bank matters.

3. Report to the Federal Deposit Insurance Corporation regarding the competitive factors involved in the proposed merger of The Colonial Bank, Providence Forge, Virginia, with Citizens and Farmers Bank, West Point, Virginia.

4. Any agenda items carried forward from a previously announced meeting.

NOTE.—This meeting will be recorded for the benefit of those unable to attend. Cassettes will be available for listening in the Board's Freedom of Information Office, and copies may be ordered for $5 per cassette by calling (202) 452-3684 or by writing to: Freedom of Information Office, Board of Governors of the Federal Reserve System, Washington, D.C. 20551.

[S-516-79 Filed 3-14-79; 10:30 am]

[6820-35-M]

6

LEGAL SERVICES CORPORATION (Committee on Provision of Legal Services).

TIME AND DATE: 8:15 p.m., Wednesday, March 21, 1979.

PLACE: Copley Plaza, State Suite, Copley Square, Boston, Mass.

STATUS: Open meeting.

MATTERS TO BE CONSIDERED:

1. Adoption of Agenda.
2. Approval of Minutes.
3. Client Training.
4. 1007(h) Study Report.
5. Other Business.

CONTACT PERSON FOR FURTHER INFORMATION:

Dellanor Young, Office of the President, telephone 202-376-5100.

Issued: March 13, 1979.

THOMAS EHRLICH,
President.

[S-518-79 Filed 3-14-79; 1:53 pm]

[7590-01-M]

7

NUCLEAR REGULATORY COMMISSION.

TIME AND DATE: Week of March 12, 1979 (changes).

PLACE: Commissioners' Conference Room, 1717 H Street NW., Washington, D.C.

STATUS: Open and closed.

MATTERS TO BE CONSIDERED:

MONDAY, MARCH 12, 2 P.M.

Discussion of personnel matter (approximately 1½ hours) (rescheduled from March 13) (closed—exemption 6).

THURSDAY, MARCH 15 11:30 A.M. (APPROXIMATELY)

3. Meeting on Bailly to consider handling of petitions on short pilings (approximately 1 hour) (closed—exemption 10) (additional item—rescheduled from March 13, 1979).

THURSDAY, MARCH 15, 2 P.M.

1. Discussion of NRC legislative proposals (approximately 3 hours) (start time delayed ½ hour—public meeting).

CONTACT PERSON FOR MORE INFORMATION:

Walter Magee, 202-634-1410.

ADDITIONAL INFORMATION: The item "Discussion of Staff Communications with the Commission" previously announced for Thursday, March 15, should be identified as "Open, Portions May be Closed."

WALTER MAGEE,
Office of the Secretary.

[S-521-79 Filed 3-14-79; 2:50 pm]

[7590-01-M]

8

NUCLEAR REGULATORY COMMISSION.

TIME AND DATE: March 13, 1979.

PLACE: Commissioners' Conference Room, 1717 H Street NW., Washington, D.C.

STATUS: Closed (additional item).

MATTERS TO BE CONSIDERED:

TUESDAY, MARCH 13, 8:45 A.M.

Discussion of Seismic Design Problems in Certain Plants (approximately 1 hour) (closed—tentative).

CONTACT PERSON FOR MORE INFORMATION:

Walter Magee 202-634-1410.

WALTER MAGEE,
Office of the Secretary.

[S-522-79 Filed 3-16-79; 2:50 pm]

[7590-01-M]

9

NUCLEAR REGULATORY COMMISSION.

TIME AND DATE: Wednesday, March 14 (changes) and Tuesday, March 20.

PLACE: Commissioners' Conference Room, 1717 H Street, NW., Washington, D.C.

STATUS: Open and closed.

MATTERS TO BE CONSIDERED:

WEDNESDAY, MARCH 14, 2:30 P.M.

Continuation of Discussion of Report to Congress: Means for Improving State Participation in the Federal Nuclear Waste Management Program (Approximately 1½ hours) (public meeting) (continued from March 13).

TUESDAY, MARCH 20, 9:30 A.M.

1. Briefing on Reactor Licensing Schedules (Approximately 1 hour) (public meeting).

2. Discussion of Proposed Executive Branch Format for Analyses of Export Applications (Approximate 1 hour) (open—portions may be closed—exemption 1).

TUESDAY MARCH 20, 1:30 P.M.

1. Discussion of NRC Legislative Proposals (Approximately 1½ hours) (public meeting).

2. Discussion of Personnel Matter (Approximately 1½ hours) (closed—exemption 6).

CONTACT PERSON FOR MORE INFORMATION:

Walter Magee, 202-634-1410.

WALTER MAGEE,
Office of the Secretary.

[S-523-79 Filed 3-14-79; 2:50 pm]

[8120-01-M]

10

TENNESSEE VALLEY AUTHORITY (MEETING NO. 1212).

TIME AND DATE: 10:30 a.m., Tuesday, March 20, 1979.

PLACE: Conference Room B-32, West Tower, 400 Commerce Avenue, Knoxville, Tennessee.

STATUS: Open.

MATTERS FOP ACTION:

OLD BUSINESS

1. Supplemental agreement between TVA and the Tennessee Department of Public Health providing for cooperation in an environmental and public health services program for the Phipps Bend Nuclear Plant area.

NEW BUSINESS

PERSONNEL ACTIONS

1. Revised organizational bulletin—Tennessee Valley Authority.

2. Status changes and appointments relating to reorganization.

3. Change of status of John S. Bynon from Assistant Director, Division of Personnel, to assistant to the General Manager.

CONSULTING AND PERSONAL SERVICE CONTRACTS

1. Renewal of consulting contract with Nuclear Water and Waste Technology, Inc., San Jose, California, for advice and assistance in the field of nuclear chemistry, requested by Office of Power.

2. Renewal of consulting contract with NUS Corporation, Rockville, Maryland, for advice and assistance in connection with power system planning, requested by the Office of Power.

3. Renewal of consulting contract with the S. M. Stoller Corporation, New York, New York, for advice and assistance on power resource planning matters, requested by the Office of Power.

PURCHASE AWARDS

1. Req. No. 577589: Indefinite quantity term contract for Linde welding and cutting equipment repair parts and repair services for any TVA project or warehouse.

2. Req. No. 581148: Gantry crane for construction pool equipment.

3. Req. No. 561140: Railroad tank cars for Chemical Development.

4. Req. No. 108208: Galvanized structural tower steel for Union-Cordova 500-kV transmission line.

5. Req. No. 19219: Uranium concentrates.

6. Req. No. 590466: Procurement of word processing system for Computing Services Branch.

7. Req. No. 823875: Gas ducts and hoppers for electrostatic precipitators for Cumberland Steam Plant.

8. Rejection of bids received in response to Invitation No. 824281 for louver and guillotine dampers for electrostatic precipitators for Cumberland Steam Plant.

9. Amendment to Requirement Contracts 76K72-769403-1 and 77K72-822199 with Chaparral Steel Company for deformed steel reinforcing bars for Hartsville Nuclear Plants.

10. Req. No. 825029—High density spent fuel storage racks for Sequoyah Nuclear Plant.

11. Proposal for enrichment services for Browns Ferry Nuclear Plant.

PROJECT AUTHORIZATIONS

1. No 3372: Purchase approximately 65 acres of land for the Cumberland Steam Plant for use as a buffer zone and storage area.

2. No. 3413: Rehabilitation of boilers for Johnsonville Steam Plant Units 7-10.

FERTILIZER ITEM

1. Memorandum of understanding between TVA and the International Fertilizer Development Center for program to promote fertilizer research, development, education, training, and introduction in less developed countries.

POWER ITEMS

1. New power contract with Upper Cumberland Electric Membership Corporation.

2. New power contract with Sand Mountain Electric Cooperative.

3. Lease and amendatory agreement with Tri-State Electric Membership Corporation covering arrangements for 69-kV delivery at TVA's Basin 161-kV Substation.

4. Deed conveying to Southwest Tennessee Electric Membership Corporation a 0.34-acre portion of TVA's Mason Substation site located in Tipton County, Tennessee.

5. Letter agreement with 4-County Electric Power Association covering arrangements for service to Cooperative's proposed South Macon, Brooksville, and New Hope, Mississippi, 161-kV Substations; and deed and bill of sale conveying TVA's Shuqualak 46-kV Substation to Cooperative.

6. Agreement with Georgia Power Company covering arrangements for connection of its proposed Crawfish Creek 230-46-kV Substation to TVA's Widows Creek-Rock Springs 230-kV line in dade County, Georgia.

7. Interconnection agreement with Appalachian Power Company.

8. Agreement with State of Alabama Highway Department covering adjustment of transmission line necessitated by construction of a section of new interstate highway near Bessemer, in Jefferson County, Alabama.

9. Agreement between the Department of Energy and TVA covering arrangements for cooperation in a TVA/DOE/ORNL low-temperature thermal energy storage program.

10. Letter agreement between Electric Power Research Institute and TVA covering arrangements for a joint test program concerning the evaluation of TVA's demonstration scale high-intensity ionizer at the Shawnee Steam Plant.

11. Agreement with Electric Power Research Institute covering arrangements for superheater tube material testing in connection with atmospheric fluidized bed combustion program.

12. Amendment to agreement with Electric Power Research Institute covering arrangements for construction and operation of absorption steam stripping pilot plant at Colbert Steam Plant.

13. Proposed nuclear fuel lease.

REAL PROPERTY TRANSACTIONS

1. Filing of condemnation suites.

2. Abandonment of flowage easement rights affecting 0.05-acre portion of land located on Fort Loudoun Reservoir—Tract FL-67F.

3. Sale at public auction of approximately 14.65 acres of Muscle Shoals Reservation Land in Colbert County, Alabama—Tract X2NPT-8.

CONTACT PERSON FOR MORE INFORMATION:

James L. Bentley, Director of Information, or a member of his staff can respond to requests for information about this meeting. Call 615-632-3257, Knoxville, Tennessee. Information is also available at TVA's Washington Office, 202-566-1401.

Dated: March 13, 1979.

[S-515-79 Filed 3-14-79; 10:30 am]

federal register

FRIDAY, MARCH 16, 1979

PART II



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

VITAMIN AND MINERAL DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

Establishment of a Monograph, Proposed Rule

[4110-03-M]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Part 345]

[Docket No. 78N-0024]

VITAMIN AND MINERAL DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

Establishment of a Monograph; Notice of Proposed Rulemaking

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: This proposed rule would establish conditions under which over-the-counter (OTC) vitamin and mineral drug products are generally recognized as safe and effective and not misbranded. The proposed rule, based on the recommendations of the Advisory Review Panel on OTC Vitamin, Mineral, and Hematinic Drug Products, is part of the Food and Drug Administration's ongoing review of OTC drug products.

DATES: Comments by June 14, 1979, and reply comments by July 16, 1979.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

William E. Gilbertson, Bureau of Drugs (HFD-510), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4960.

SUPPLEMENTARY INFORMATION: Pursuant to Part 330 (21 CFR Part 330), the Commissioner of Food and Drugs received on November 1, 1977, a report of the Advisory Review Panel on OTC Vitamin, Mineral, and Hematinic Drug Products. Additional technical changes were made by the Panel during a telephone conference on December 8, 1977. In accordance with § 330.10(a)(6) (21 CFR 330.10(a)(6)), the Commissioner is issuing (1) a proposed regulation containing the monograph recommended by the Panel, which establishes conditions under which OTC vitamin and mineral drugs are generally recognized as safe and effective and not misbranded; (2) a statement of the conditions excluded from the monograph on the basis of a determination by the Panel that they would result in the drugs not being generally recognized as safe and effective or would result in misbranding; (3) a statement of the conditions excluded from the monograph on the basis of a determination by the Panel that the available data are insufficient to classify such conditions under either (1) or (2) above; and (4) the conclusions and recommendations of the Panel to the Commissioner. The minutes of the Panel meetings are on public display in the office of the Hearing Clerk (HFA-305), Food and Drug Administration (address given above).

The purpose of issuing the unaltered conclusions and recommendations of the Panel is to stimulate discussion, evaluation, and comment on the full sweep of the Panel's deliberations. The Commissioner has not yet fully evaluated the report; the Panel's findings are being issued as a formal proposal to obtain public comment before the agency reaches any decision on the Panel's recommendations. The report has been prepared independently of the Food and Drug Administration (FDA).

It represents the best scientific judgment of the Panel members but does not necessarily reflect the agency position on any particular matter contained in it. After careful review of all comments submitted in response to this proposal, the Commissioner will issue a tentative final regulation in the FEDERAL REGISTER to establish a monograph for OTC vitamin and mineral drug products.

In accordance with § 330.10(a)(2) (21 CFR 330.10(a)(2)), all data and information concerning OTC vitamin and mineral drug products submitted for consideration by the Advisory Review Panel have been handled as confidential by the Panel and FDA. All such data and information will be put on public display at the office of the Hearing Clerk, Food and Drug Administration, after April 16, 1979, except to the extent that the person submitting it demonstrates that it still falls within the confidentiality provisions of 18 U.S.C. 1905 or section 301(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(j)). Requests for confidentiality should be submitted to William E. Gilbertson, Bureau of Drugs (HFD-510) (address given above).

Based upon the conclusions and recommendations of the Panel, the Commissioner proposes the following:

1. That the conditions included in the monograph, under which the drug products would be generally recognized as safe and effective and not misbranded (Category I), be effective 30 days after the date of publication of the final monograph in the FEDERAL REGISTER.

2. That the conditions excluded from the monograph because they would cause the drug to be not generally recognized as safe and effective or to be misbranded (Category II), be eliminated from OTC drug products effective 6 months after the date of publication of the final monograph in the FEDERAL REGISTER, regardless of whether further testing is undertaken to justify their future use.

3. That the conditions excluded from the monograph because the available data are insufficient (Category III) to classify such conditions either as Category I or Category II be permitted to remain on the market, or to be introduced into the market after the date of publication of the final monograph in the FEDERAL REGISTER: *Provided*, That FDA receives notification of testing in accordance with § 330.10(a)(13) (21 CFR 330.10(a)(13)).

The Panel recommended that a period of 2 years be permitted for the completion of studies to support the movement of Category III conditions to Category I. The Commissioner will review that recommendation as well as all comments on this document, and will determine what time period to permit for Category III testing after that review is completed.

In the FEDERAL REGISTER of January 5, 1972 (37 FR 85), the Commissioner announced a proposed review of the safety, effectiveness, and labeling of all OTC drugs by independent advisory review panels. In the FEDERAL REGISTER of May 11, 1972 (37 FR 9464), the Commissioner published the final regulations providing for the OTC drug review under § 330.10 which made effective immediately. Pursuant to these regulations, the Commissioner issued in the FEDERAL REGISTER. of October 15, 1973 (38 FR 28581) a request for data and information on all active ingredients utilized in OTC vitamin, mineral, and hematinic drug products.

The Commissioner appointed the following Panel to review the data and information submitted and to prepare a report pursuant to § 330.10(a)(1) on the safety, effectiveness, and labeling of those products:

Irwin H. Rosenberg, M.D., Chairman
Louis V. Avioli, M.D.
George M. Briggs, Ph.D.
Robert S. Goodhart, M.D., D.Med.Sc.
Mary Anne Kimble, Pharm.D.
Carroll M. Leevy, M.D.
Mary Susanne Roscoe, M.D.

The Panel was first convened on December 11, 1973 in an organizational meeting. Working meetings were held on February 17 and 18, April 8 and 9, May 18 and 19, June 16 and 17, July 30 and 31, September 29 and 30, and November 15 and 16, 1974; January 6 and 7, February 16 and 17, April 27 and 28, June 24 and 25, and November 14 and 15, 1975; January 13 and 14, March 22 and 23, July 22 and 23, August 25, 26, and 27, October 17 and 18, and December 14 and 15, 1976; February 14 and 15, June 23 (telephone conference), October 31, November 1, and December 8, 1977 (telephone conference).

Seven nonvoting liaison representatives served on the Panel. Ms. Sandra Zimmerman, nominated by an ad hoc group of consumer organizations, served as the consumer liaison; Joseph M. Pisani, M.D., nominated by the Proprietary Association, served as the industry liaison until August 25, 1976, followed by William W. Bradley; William E. Marshall, Ph.D., nominated by the Council for Responsible Nutrition, also served as an industry liaison until July 1974, followed by Harry Wax, Ph.D. until November 1975, followed by Annette Dickinson. Paul A. Buck, Ph.D., nominated by the National Nutritional Foods Association, also served as an industry liaison.

The following FDA employees served: J. William Boehne served as Executive Secretary. Thomas D. DeCillis, R.Ph., served as Panel Administrator. Lloyd G. Scott, R.Ph., served as Drug Information Analyst until April 1974, followed by Gary P. Trosclair, R.Ph., until October 1974, followed by Thomas H. Gingrich, R.Ph., until June 1975, followed by T. Thomas Clark, R.Ph., until June 1976, followed by Gary P. Trosclair, R.Ph., John T. McElroy, J. D., served as Consumer Safety Officer from June 24, 1975 until March 23, 1976.

The following individuals were given an opportunity to appear before the Panel to express their views:

Ernest Beutler, M.D.
Myron Brin, Ph.D.
Paul A. Buck, Ph.D.
Robert B. Choate
Leon Ellenbogen, Ph.D.
David Herting, Ph.D.
C. J. Jansen, Jr., M.D.
Daniel Marcus, Esq.
L. G. Marviney
Daniel B. Menzel, M.D.
Lowell D. Miller, Ph.D.
Harold Newmark
Billy J. Softly, Ph.D.
William Driscoll

The following individuals were given an opportunity to present their views at the Panel's request:

Leslie Z. Benet, Ph.D.
Gilbert Forbes, M.D.
Linus Pauling, Ph.D.
Daphne A. Roe, M.D.
Leon Rosenberg, M.D.
Harold H. Sandstead, M.D.
H. P. Sarett, Ph.D.

No person who so requested was denied an opportunity to appear before the Panel.

The Panel has thoroughly reviewed the literature and data submissions, has listened to additional testimony from interested persons, and has considered all pertinent data and information submitted through December 8, 1977, in arriving at its conclusions and recommendations. The charge to the Panel required the review of three classes of OTC drugs, i.e., vitamins, minerals, and hematinics. However, the Panel concluded early in its deliberations that the review of hematinic drugs as a separate class was in appropriate since this class of drugs could not be considered apart from vitamins and minerals. Hematinics are substances which increase the hemoglobin of the blood and/or increase the number of red blood cells. These effects are discussed by the Panel under the appropriate vitamin or mineral ingredient elsewhere in this document and not as effects of a separate class of drugs. Therefore, the Panel has presented its conclusions and recommendations in only two parts. (See part III. below—VITAMINS, and part IV. below—MINERALS.) Each part covers the submission of data and information discussed below. (See part I. below—SUBMISSION OF DATA AND INFORMATION.)

In accordance with the OTC drug review regulations (21 CFR 330.10), the Panel's findings with respect to OTC vitamin and mineral drug products are set out in three categories:

Category I. Conditions under which OTC vitamin and mineral drug products are generally recognized as safe and effective and are not misbranded.

Category II. conditions under which OTC vitamin and mineral drug products are not generally recognized as safe and effective or are misbranded.

Category III. Conditions for which the available data are insufficient to permit final classification at this time.

I. Submission of Data and Information

Pursuant to the notice published in the Federal Register of October 15, 1973 (38 FR 28581) requesting the submission of data and information on OTC vitamin, mineral, and hematinic drugs, the following firms made submissions relating to the indicated products:

A. Submissions by Firms

Firm and Marketed Products

A. H. Robins Co., Richmond, VA 23220—Adabee Multivitamins, Adabee with Minerals Tablets, Allbee Capsules, Allbee-T Multivitamins.

Abbott Laboratories, North Chicago, IL 60064—Daylong Tablets, Fero-Gradumet Filmtab, Fero-Grad-500 Filmtabs, Iberet-500 Liquid, Iberet Filmtab Tablets, Iberet Liquid, Iberol-F Filmtab Tablets, Iberol Filmtab Tablets, Iberet-500 Filmtab Tablets, Optilets-500 Filmtab Tablets, Optilets-M-500 Filmtab Tablets, Surbex Filmtab Tablets, Surbex w/C Filmtab Tablets, Surbex-T Filmtab Tablets.

Ayerst Laboratories, New York, NY 10017—Beminal 500 Tablets, Beminal Forte with Vitamin C Capsules, Beminal Vitamin B Complex with Iron and Liver Capsules, Clusivets Tablets, Clusivol Chew Tablets, Clusivol Syrup, Cyoteferin Tablets.

Central Pharmacal Co., Seymour, IN 47274—Niferex-150, Niferex Elixir, Niferex Tablets.

Cooper Laboratories, Inc., Bedford Hills, NY 10507—Ferronord Tablets, Vitron-C Hematinic Tablets.

Dorsey Laboratories, Lincoln, NE 68501—Neo-Calglucon Syrup.

E. R. Squibb & Sons, Inc., Princeton, NJ 08540—B Complex with Vitamin C Capsules, Iron with Vitamin C Tablets, Natural Vitamin E Capsules 100 I.U., Natural Vitamin E Capsules 400 I. U., Niacin Tablets 50 mg, Niacin Tablets 100 mg, Niacin Tablets 500 mg, Vitamin C Tablets 125 mg, Stress Formula B Complex with Vitamin C Tablets, Theragran Liquid, Theragran-M Tablets, Theragran Tablets, Vitamin A Capsules 10,000 U., Vitamin A from Natural Sources Capsules 10,000 U., Vitamin B-1 50 mg Tablets, Vitamin B-1 100 mg Tablets, Vitamin B-12 Capsules 25 mcg, Vitamin Cmg, Vitamin C Tablets 250 mg, Vitamin C Tablets 500 mg, Vitamin C Orange-Flavored Tablets 250 mg, Vitamin E Capsules 100 I.U., Vitamin E Walnut Flavored Tablets 200 I.U.

ICI America Inc., Wilmington, DE 19899—Ferancee-HP Hematinic Tablets, Ferancee Hematinic Tablets, Mucoplex Tablets, Orexin Therapeutic Vitamin Supplement Tablets, Probec-T Tablets, Probec Tablets, Stuart Hematinic Liquid, Stuart Hematinic Tablets, Stuart Therapeutic Multi-vitamin Tablets, Stuartinic Hematinic Tablets, Theron Tablets.

International Pharmaceutical Corp., Warrington, PA 18976—Calcident Tablets.

J. B. Williams Co., Inc., New York, NY 10022—Geritol Liquid, Geritol Tablets.

Lederle Laboratories, Pearl River, NY 10965—Ferro-Mandets Tablets, Ferro-Sequels Capsules, Filibon OT Prenatal Tablets, Filibon Prenatal Capsule, Gevrabon Vitamin Mineral Supplement, Gevral Capsules, Gevral Protein, Gevral T Capsules, Gevrite Tablets, Incremin with Iron Syrup, Lederplex Capsules, Lederplex Liquid, Lederplex Tablets, Peritinic Tablets, Recoup Tablets, Stresscaps, Stresstabs 600, Vi-magna Capsules.

Mallinckrodt Chemical Works, St. Louis, MO 63160—Toleron Suspension, Toleron Tablets.

Marion Laboratories, Inc., Kansas City, MO 64137—Os-Cal Tablets.

Mead Johnson Laboratories, Evansville, IN 47721—Feminins Tablets.

Merrell-National Laboratories, Cincinnati, OH 45215—Simron Capsules, Simron Plus Capsules.

Pfizer Pharmaceuticals, New York, NY 10017—Crystalets, Stablets, Vitamin A Palmilets.

Plus Products, Los Angeles, CA 90058—Plus Formula 10 Multimineral Tablets, Plus Formula 14 Multi-mins Tablets, Plus Formula 15 Multi-Mins Tablets, Plus Formula 22 Magnesium Oxide Powder, Plus Formula 23 Manganese Tablets, Plus Formula 50 Liver, Iron & B Vitamins Tablets, Plus Formula 49 Vitamin B Complex Tablets, Plus Formula 49A Vitamin B Complex Tablets, Plus Formula 70 Vitamin B complex Tablets, Plus Furmula 71 High Potency Vitamin B Complex with Vitamin C Tablets, Plus Formula 72 Stress Supplement Tablets, Plus Formula 74 Vitamin and Mineral Supplement Perles, Plus Formula 75 B Complex 75 Tablets, Plus Formula 77 Vitamin B complex Syrup with Iron, Plus Formula 78 Vitamin Syrup for

Children, Plus Formula 80A Bone Meal Powder, Plus Formula 85 Natural Bone Meal with Magnesium, Manganese and Zinc Tablets, Plus Formula 86 Zinc 30 mg Tablets (proposed), Plus Formula 87 Zinc Tablets 50 mg (proposed), Plus Formula 92 Granular Soya Lecithin, Plus Formula 93A Lecithin Perles, Plus Formula 98 Vita-Fems tablets (proposed), Plus Formula 100 DFS Perles, Plus Formula 101A Vitamin A Perles, Plus Formula 104A Emulsified A Perles, Plus Formula 122 PABA Tablets 100 mg (proposed), Plus Formula 123 Para-Aminobenzoic Acid (PABA) Tablets 30 mg, Plus Formula 124 Choline Tablets 250 mg, Plus Formula 125A Inositol Tablets 250 mg, Plus Formula 126 Inositol Powder, Plus Formula 127 Choline Tablets 500 mg (proposed), Plus Formula 128 Inositol tablets 500 mg (proposed), Plus Formula 152 Emulsified Vitamin E Complex Perles, Plus Formula 153 Vitamin E Complex Perles, Plus Formula 154A Emulsified Vitamin E Complex Perles, Plus Formula 155 Vitamin E Complex Perles, Plus Formula 156 Vitamin E Complex Perles, Plus Formula 157 Vitamin E Capsules 400 I.U. (proposed), Plus Formula 158 Vitamin E tablets 100 I.U., Plus Formula 159 Vitamin E Perles 100 Units, Plus Formula 160 Vitamin E Capsules 600 I.U. (proposed), Plus Formula 162 Vitamin E Perles 200 I.U., Plus Formula 163 Vitamin E Perles 300 I.U., Plus Formula 164 Vitamin E Perles 400 Units, Plus Formula 165 Vitamin E Perles 500 Units, Plus Formula 166 Vitamin E Capsules 600 I.U. (proposed), Plus Formula 175 Dietary Food Supplement Perles, Plus Formula 180 Potassium & Iodine Tablets, Plus Formula 184 Calcium and Magnesium Tablets, Plus Formula 202A Vitamins A & D Perles, Plus Formula 203A Vitamins A & D Dry Form Tablets, Plus Formula 205A Vitamins A, D & E Perles, Plus Formula 206 A, D & E Drops, Plus Formula 207 Vitamins A & E Perles, Plus Formula 222 High Potency Cod Liver Oil, Plus Formula 234 Vitamin B-1 Tablets 100 mg, Plus Formula 242 Vitamin B-2 Tablets 10 mg, Plus Formula 243 Vitamin B-2 50 mg Tablets (proposed), Plus Formula 244 Vitamin B-2 Tablets 100 mg (proposed), Plus Formula 249 Dried Yeast Tablets, Plus Formula 250 Yeast Plus, Plus Formula 251 Vitamin B-6 Tablets 10 mg, Plus Formula 252 Vitamin B-6 Tablets 25 mg, Plus Formula 253 Vitamin B-6 Tablets 50 mg, Plus Formula 259 Pantothenic Acid Tablets 250 mg (proposed), Plus Formula 260 Niacin Tablets 100 mg, Plus Formula 261 Niacin Tablets 250 mg (proposed), Plus Formula 262 Niacinamide Tablets 250 mg (proposed), Plus Formula 264A Pantothenic Acid Tablets 100 mg, Plus Formula 263 Niacinamide Tablets 200 mg, Plus Formula 265A Acerola Chews Tablets, Plus Formula 266A Chewable Vitamin C Tablets 200 mg, Plus Formula 267A Chewable Vitamin C Tablets 100 mg, Plus Formula 268 Liquid Vitamin C, Plus Formula 272A Vitamin C Tablets 250 mg, Plus Formula 273A Vitamin C Tablets 500 mg, Plus Formula 275 Vitamin C Complex 200 mg, Plus Formula 277 Vitamin C Complex 100 mg, Plus Formula 278 Vitamin C Powder, Plus Formula 279 Vitamin C Powder, Plus Formula 280A Vitamin C Tablets 600 mg, Plus Formula 282 Vitamin C Complex Tablets 200 mg, Plus Formula 290 granular Kelp, Plus Formula 303 Vitamin B-12 Tablets 100 mcg (proposed), Plus Formula 304 Vitamin B-12 Tablets 25 mcg, Plus Formula 333 Dried Yeast and Iron Tablets, Plus Formula 380 Mint-A-Mins Chewable Vitamin Wafers, Plus Formula 450 Instant Brewer's Yeast, Plus Formula 445 Iron Supplement Tablets, Plus Formula 740 Tiger's Milk Cookies, Plus Formula 745 Tiger's Milk Carob Coated Bar, Plus Formula 746 Tiger's Milk Real Peanut Butter Bar, Plus Formula 747 Tiger's Milk Peanut Butter and Honey Bar, Plus Formula 748 Tiger's Milk Peanut Butter and Jelly Bar, Plus Formula 749 Tiger's Milk Calorie Watcher's Snack, Plus Formula 800 Tiger's Milk Nutrition Booster Plain, Plus Formula 825 Tiger's Milk Nutriton Booster Natural Carob Flavor, Plus Formula 850 Tiger's Milk Nutrition Booster Natural Vanilla Flavor, Plus Formula 875 Tiger's Milk Nutrition Booster Natural Cocoa Flavor.

R. L. Gaddy Co., Tallahassee, FL 32302—Vita-Pep Tablets.

Radiance Products Co., Alhambra, CA 91802—Bone Meal Plus Vitamin D and Iron Tablets, Chewable Tasti C with Bioflavanoid Wafers, Dry Aqua-E 200 Int'l Units Tablets, Norwegian Cod Liver Oil with Vegetable Oils Capsules, Proportioned Magnesium 500 mg Tablets, Super B-Complex Plus C Capsules, Super Potency Multiple Vitamins and Minerals Tablets, Vitamin B-6 100 mg Tablets, Vitamin B-12 250 mcgs in a Special Base Tablets.

S. S. S. Co., Atlanta, GA 30302—S. S. S. Tonic Liquid, S. S. S. Tonic Tablets.

Schering Corp., Kenilworth, NJ 07033—Mol-Iron Chronosule Capsules, Mol-Iron Liquid, Mol-Iron Tablets.

Signet Laboratories, Inc., Burbank, CA 91502—Anti-X Tablets, B-12 Tablets 250 Micrograms, Citrex Plus Tablets, Double Absorption B-12 Tablets 500 mcg, Double Absorption B-12 Tablets 25 mcg, Intensive Care B with C Tablets, Mag-Cal Balanced, Neo-Tone Asimicaps Iron with Vitamins and Minerals tablets, Omni Nutrition Plan Tablets, One Plan Multivitamin-Mineral Supplement Tablets, Pantothenic Acid Tablets 100 mg, Premium Nutrition Plan tablets, POWER-B with Paba Tablets, Super Citrex Tablets, Taste-E-Tab 100 I.U., Taste-E-Tab 200 I.U., Taste-E-Tab 400 I.U., Toco E Sol Tablets 100 I.U., Toco E Sol Tablets 200 I.U., Ultra-Vite Multivitamin-Mineral Supplement Tablets, Vitamin B-1 Tablets 50 mg, Vitamin B-1 Tablets 100 mg, Vitamin B-2 Tablets 25 mg, Vitamin B-6 Tablets 25 mg, Vitamin B-6 Tablets 100 mg.

Smith, Kline and French Laboratories, Philadelphia, PA 19101—Feosol Spansule Capsules.

Sterling Drug, Inc., New York, NY 10016—Afaxin Capsules, Betaxin Tablets, Drisdol, Fergon Capsules, Fergon Compound Elixir, Fergon Elixir, Fergon Tablets, Fergon With C Caplets, Ironized Yeast Tablets, Pluravit Capsules, Pluraxin.

TPR Pharmaceuticals, Inc., Indianapolis, IN 46222—B-Tinic Plus Iron.

William H. Rorer, Inc., Fort Washington, PA 19034—Fermalox Tablets.

Wm. T. Thompson Co., Carson, CA 90745—Acerola C Chewable Tablets, B Complex "50" Capsules, B Complex "50" Tablets, B Complex Capsules (proposed), B Complex Plus C Tablets, C-Flavoids "500" Tablets, C Rose Hips Tablets, E & C with A Capsules, Ex-Po 36 Capsules, Ex-Po 36 Capsules (proposed), Flavoid Complex Tablets (proposed), Fluoride 1 mg Tablets, Folic Acid 0.5 mg Tablets (proposed), Iron Hematinic Tablets, Iron Hematinic Tablets (proposed), Multiminerals with Sea Minerals Tablets, Neo-Globin Tablets, Niacin 100 mg Tablets, Niacinamide 250 mg Tablets, Nuplex Tablets, One Gram C Capsules, Pantothenic Acid 100 mg Tablets, Rose Hips C-Flavoids "650" Tablets, Trace Elements Tablets (proposed), Vitamin A 10,000 I.U. Capsules, Vitamin A 10,000 I.U. Tablets, Vitamin A 10,000 I.U. & Vitamin D 400 I.U. Capsules (proposed), Vitamin A 10,000 Unit Tablets, Vitamin A 25,000 I.U. Tablets, Vitamin A & D Capsules, Vitamin B-1 100 mg Tablets, Vitamin B-1 Tablets 100 mg (proposed), Vitamin B-2 100 mg Tablets, Vitamin B-2 100 mg Tablets (proposed), Vitamin B-6 100 mg Tablets, Vitamin B-6 100 mg Tablets (proposed), Vitamin B-12 "250" mg Tablets, Vitamin B-12 250 mcg Tablets (proposed), Vitamin C Tablets 500 mg, Vitamin D 1200 I.U. Tablets (proposed), Vitamin E 400 Capsules (proposed), Vitamin E 400 I.U. Tablets (proposed), Vitamin E 400 Tablets, Vitamin E & C with A Capsules, Vitamin K-1 mg Tablets (proposed), Zinc 30 mg Tablets (proposed).

In addition, the following firms or groups made related data submissions:

Firm and Data Submitted

Abbott Laboratories, North Chicago, IL 60064—Additional Studies on the usefulness of vitamin C in promoting iron absorption, data to demonstrate the clinical efficacy of controlled-release iron preparations.

A. E. Staley Manufacturing Co., Decatur, IL 62525—Inositol (bulk).

Council for Responsible Nutrition, Washington, DC 20036—Reference bibliographies for ascorbic acid, fat-soluble vitamins, niacin and niacinamide, vitamin A and E; proposed labeling of OTC vitamin and mineral products to be used for the prevention of deficiencies.

Eastman Chemical Products, Inc., Kingsport, TN 37662—Supplemental submission of data and views of vitamin E.

General Mills Chemicals, Inc., Minneapolis, MN 55435—Information and abstracts of significant literature on vitamin E.

Hoffman-LaRoche, Inc., Nutley, NJ 07110—Absorption of vitamins, ascorbic acid, biotin, niacin, pantothenic acid, riboflavin, thiamine, vitamin A, vitamin B-6, vitamin E; supplemental submissions on "High Vitamin Dose Levels in man"; summary data on multivitamins; critical review of OTC Panel addendum to vitamin C review; critical review of vitamin C sodium ascorbate: Sodium warning recommended by the OTC VMH Panel; manufacturing overages of vitamins in pharmaceutical products; supplemental submissions on biotin and vitamin E; comments on ascorbyl plamitate and vitamin A.

ICI America, Inc., Wlmington, DE 19899—Calcium sulfate as a source of calcium.

J. B. Williams Co., Inc., New York, NY 10022—Statement regarding safety of self-administered iron preparations.

Marion-Laboratories, Inc., Kansas City, MO 64137—Data supporting the safety of oyster shell (OS-CAL); presentation to the FDA Advisory Review Panel on OTC Vitamin, Mineral, and Hematinic drug products on OS-CAL (oyster shell).

Merrell-National Laboratories, Cincinnati, OH 45215—Comments on polysorbate 20.

Paul A. Buck, Ph.D., Ithaca, NY 14850—Presentation to Panel of previously nonreviewed literature.
Philadelphia Dry Yeast Co., Philadelphia, PA 19122—Debittered Brewers Dry Yeast.
Ross Laboratories, Columbus, OH 43216—Alpha tocopheryl polyethylene glycol 1,000 succinate; proposed product for women on oral contraceptives; animal data on water-soluble vitamin E.
Vitaminerals Inc., Glendale, CA 91201—Bioflavonoids; data and views on vitamin A, vitamin D and iron indications, lipotropic substances, magnesium, vitamins, minerals, and hematinics.

B. LABELED INGREDIENTS CONTAINED IN MARKETED PRODUCTS SUBMITTED TO THE PANEL.

Acerola
Activated ergosterol
Alanine
Alcohol
Alfalfa
Algin
p-Aminobenzoic acid
Apricot
Arginine
Ascorbic acid (vitamin C)
Aspartic acid
Beet greens
Betaine
Biotin
Black currants
Bone meal
Brewer's yeast
Buckwheat
Butyl paraben
Cabbage
Calcium
Calcium ascorbate
Calcium carbonate
Calcium caseinate
Calcium citrate
Calcium fluoride
Calcium glubionate
Calcium iodate
Calcium lactate
Calcium pantothenate
Calcium phosphate dibasic anhydrous
Calcium phytate
Calcium sulfate
Carrot powder
Chaparral
Chlorophyll
Chlorophyllins
Cholecalciferol (vitamin D-3)
Choline
Choline bitartrate
Choline citrate
Citrus bioflavonoids
Cobalamin concentrate
Cod liver oil
Comfrey root
Copper
Copper gluconate
Copper oxide
Copper sulfate
Corn oil
Cyanocobalamin (vitamin B-12)
Cystine
Dandelion greens
Date powder
Desiccated liver
Dexpanthenol
Dioctyl sodium sulfosuccinate
Dolomite
Dulse
Duodenal substance
Edible bone phosphate
Egg albumin
Egg shell
Egg yolk
Ergocalciferol (vitamin D-2)
Extract of ox bile
Ferric ammonium citrate
Ferric phosphate
Ferric pyrophosphate
Ferroglycine sulfate complex
Ferrous carbonate stabilized
Ferrous fumarate
Ferrous gluconate
Ferrous sulfate, dried
Fish liver oil
Folic acid
Formic acid
Gelatin
Glutamic acid
Glycine
Green buckwheat
Green pepper powder
Heprofrax (liver fractions A and 2)
Hesperidin
Hesperidin complex
Histidine
Inositol
Iodine
Iron
Irradiated ergosterol
Isoleucine
Kelp
Lactose
Lecithin
Lemon bioflavonoid complex
Lemon grass oil
Lettuce
Leucine
Linoleic acid
Linolenic acid
Liver fraction 1
Liver fraction, insoluble
Liver preparations
Liver substance
Liver substance concentrate
l-Lysine monohydrochloride
Lysine
Magnesium
Magnesium-aluminum hydroxide
Magnesium carbonate
Magnesium chloride
Magnesium hydroxide
Magnesium oxide
Magnesium silicate
Magnesium sulfate
Magnesium trisilicate
Malt extract
Manganese
Manganese chloride
Manganese gluconate
Manganese oxide
Methionine
Mixed bioflavonoids
Molasses
Niacin
Niacinamide
Niacinamide ascorbate
Nicotinic acid
Oyster shell
Pancreatin
Panthenol
Pantothenic acid
d-Pantothenyl alcohol
Papain
Papaya
Parsley
Peas
Pectin
Pepsin
Phenylalanine
Phosphorus
Phytonadione
Polysorbate
Polysorbate 20
Potassium
Potassium gluconate
Potassium iodide
Potassium sulfate
Proline
Protein hydrolysate
Prune concentrate
Pyridoxine hydrochloride (vitamin B-6)
Red bone marrow
Riboflavin
Riboflavin-5-phosphate sodium
Rice bran
Rice oil, cold pressed
Rice polishings
Rose hips powder
Rutin
Safflower oil
Serine
Silica
Silicon
Sodium ascorbate
Sodium benzoate
Sodium saccharin
Sorbitol
Soya lecithin
Soy flower
Soy oil, cold pressed
Spinach powder
Sucrose
Sulfur
Thiamine
Thiamine hydrochloride
Thiamine mononitrate
Threonine
Tillandsia
dl-alpha-Tocopheryl acetate
dl-alpha-Tocopheryl acid succinate
alpha-Tocopheryl polyethylene glycol 1000 succinate
Torula food yeast
Torula yeast
Tricholine citrate
Tryptophan
Turnip greens
Tyrosine
Unsaturated fatty acids (vitamin F)
Valine
Vanilla
Vitamin A
Vitamin A acetate
Vitamin A palmitate
Vitamin B-6
Vitamin B-12
Vitamin C
Vitamin D
Vitamin E
Vitamin K
Watercress
Wheat germ
Wheat germ oil
Wild cherry concentrate
Yeast
Zinc
Zinc gluconate
Zinc lactate
Zinc oxide
Zinc sulfate

The following ingredients have been reviewed in addition to the submitted data:

Ascorbyl palmitate
Calcium gluconate
Choline chloride
Ferric ammonium phosphate
Ferric citrate
Ferric sulfate
Ferric versenate
Ferrocholinate (ferric choline isocitrate)
Ferrous citrate
Ferrous glutamate
Ferrous lactate
Ferrous succinate
Ferrous tartrate

Fluoride (sodium fluoride)
Folacin
Magnesium gluconate
Phylloquinone
Potassium chloride
Retinol
Silicon dioxide (silica, silicon)
alpha-Tocopherol
alpha-Tocopheryl acetate
alpha-Tocopheryl acid succinate
Vitamin K-1
Zinc carbonate
Zinc chloride
Zinc hydroxide
Zinc oxalate
Zinc phytate
Zinc sulfide

C. CLASSIFICATION OF INGREDIENTS.

1. *Active ingredients.* The following ingredients were submitted for Panel review and have been classified into groups identified below according to the vitamin or mineral which these ingredients are intended to provide.

VITAMINS

Vitamin C
  Ascorbic acid
  Ascorbyl palmitate
  Calcium ascorbate
  Niacinamide ascorbate
  Sodium ascorbate
Biotin
  Biotin
Choline
  Choline bitartrate
  Choline chloride
  Choline citrate (tricholine citrate)
Vitamin B-12
  Cyanocobalamin
Folacin
  Folic acid
Niacin
  Niacin (nicotinic acid)
  Niacinamide
  Niacinamide ascorbate
Pantothenic acid
  Calcium pantothenate
  Dexpanthenol (*d*-pantothenyl alcohol, panthenol)
  Pantothenic acid
Vitamin B-6
  Pyridoxine hydrochloride
Riboflavin
  Riboflavin
  Riboflavin-5-phosphate sodium
Thiamine
  Thiamine hydrochloride
  Thiamine mononitrate
Vitamin A
  Vitamin A (retinol)
  Vitamin A acetate
  Vitamin A palmitate
Vitamin D
  Cholecalciferol (vitamin D-3)
  Ergocalciferol (activated ergosterol, irradiated ergosterol, and vitamin D-2)
Vitamin E
  Tocophersolan (alpha-tocopheryl polyethylene glycol 1,000 succinate)
  apha-Tocopheryl acetate (*dl*-alpha-tocopheryl acetate)
  alpha-Tocopheryl acid succinate (*dl*-alpha-tocopheryl acid succinate)
  Vitamin E (alpha-tocopherol)
Vitamin K
  Phytonadione (phylloquinone, vitamin K-1)

MINERALS

Calcium
  Calcium caseinate
  Calcium citrate
  Calcium glubionate
  Calcium gluconate
  Calcium lactate
  Calcium phosphate dibasic (calcium phosphate dibasic anhydrous)
  Calcium sulfate
  Precipitated calcium carbonate (calcium carbonate)
Copper
  Cupric gluconate (copper gluconate)
  Cupric oxide (copper oxide)
  Cupric sulfate (copper sulfate)
Fluoride
  Calcium fluoride
  Sodium fluoride
Iodine
  Calcium iodate
  Potassium iodide
Iron
  Ferric ammonium citrate
  Ferric ammonium phosphate
  Ferric citrate
  Ferric phosphate
  Ferric pyrophosphate
  Ferric sulfate
  Ferric versenate
  Ferrocholinate (ferric choline isocitrate)
  Ferrohlycine sulfate (ferroglycine sulfate complex)
  Ferrous carbonate (ferrous carbonate stabilized)
  Ferrous citrate
  Ferrous fumarate
  Ferrous glutamate
  Ferrous gluconate
  Ferrous lactate
  Ferrous succinate
  Ferrous sulfate, dried
  Ferrous tartrate
Magnesium
  Magnesium carbonate
  Magnesium chloride
  Magnesium gluconate
  Magnesium hydroxide
  Magnesium oxide
  Magnesium silicate
  Magnesium sulfate
  Magnesium trisilicate
Manganese
  Manganese chloride
  Manganese gluconate
  Manganous oxide (manganese oxide)
Phosphorus
  Calcium phosphate dibasic (calcium phosphate dibasic anhydrous)
Potassium
  Potassium chloride
  Potassium gluconate
  Potassium sulfate
Zinc
  Zinc carbonate
  Zinc chloride
  Zinc gluconate
  Zinc hydroxide
  Zinc lactate
  Zinc oxalate
  Zinc oxide
  Zinc phytate
  Zinc sulfate
  Zinc sulfide

2. *Inactive ingredients.* The Panel has classified the following submitted ingredients as pharmaceutical necessities only.

Alcohol
Butyl paraben
Corn oil
Formic acid
Gelatin
Lactose
Lecithin
Pectin
Polysorbate
Polysorbate 20
Safflower oil
Silicon dioxide (silica, silicon)
Sodium benzoate
Sodium saccharin
Sorbitol
Soya lecithin
Soy oil, cold pressed
Sucrose
Vanilla
Wild cherry concentrate

3. *Miscellaneous ingredients.* The following list of ingredients includes natural sources of vitamins and minerals. Some of these ingredients may have other therapeutic effects (e.g., antacids, enzymes, amino acids) which do not contribute to the effectiveness of vitamins and minerals in treating vitamin or mineral deficiencies. These ingredients have been used in the past as sources for the vitamins and minerals discussed in this document; however, the Panel concludes that these ingredients and/or sources are not appropriate for OTC drug use. It is irrational that any of the following ingredients be included in OTC vitamin and mineral drug products as sources of vitamin or mineral drugs because they are not known to add to the effectiveness or safety of the preparation. For example, magnesium-aluminum hydroxide has been used as an antacid. Betaine hydrochloride and glutamic acid hydrochloride are claimed to be acidifying agents. However, dioctyl sodium sulfosuccinate has been reviewed by another OTC Advisory Review Panel elsewhere as a fecal softener and mild laxative but may be rational when in combination with iron, if testing recommended elsehwere in this document confirms claims of decreased side effects. The use of the above ingredients as separate drugs properly belongs to the review of other FDA Advisory Review Panels. The same restriction applies to the addition of what are supposed to be digestive aids, e.g., duodenal substance, extract of ox bile, pancreating, papain, papaya, and pepsin, to OTC vitamin-mineral preparations. There is no justification for the addition of amino acids or peptides such as histidine, lysine, methionine, or protein hydrolysates in OTC vitamin and mineral preparations, as these compounds make no significant contribution to the vitamin or mineral content or utilization of these products.

Finally, the submissions to the Panel include ingredients of no established nutritional or therapeutic value which are not sources of the vitamins or minerals approved for these combinations. The Panel recognizes no additional nutritional or other benefits from the ad-

dition of these compounds to vitamin and mineral preparations and therefore recommends that their addition not be allowed. Included in this group are such compounds as buckwheat, hesperidin, inositol, lecithin, bioflavonoids, *p*-aminobenzoic acid, rutin, and sulfur.

Acerola
Alanine
Alfalfa
Algin
p-Aminobenzoic acid
Apricot
Arginine
Aspartic acid
Beet greens
Betaine
Black currants
Bone meal
Brewers' yeast
Buckwheat
Cabbage
Calcium phytate
Carrot powder
Chaparral
Chlorophyll
Chlorophyllins
Citrus bioflavonoids
Cobalamin concentrate
Cod liver oil
Comfrey root
Cystine
Dandelion greens
Date powder
Desiccated liver
Dioctyl sodium sulfosuccinate
Dolomite
Dulse
Duodenal substance
Edible bone phosphate
Egg albumin
Egg shell
Egg yolk
Extract of ox bile
Fish liver oil
Glutamic acid
Glycine
Green buckwheat
Green pepper powder
Hesperidin
Hesperidin complex
Histidine
Inositol
Isoleucine
Kelp
Lecithin
Lemon bioflavonoid complex
Lemon grass oil
Lettuce
Leucine
Linoleic acid
Linolenic acid
Liver fraction
Liver fraction, insoluble
Liver fractions A and 2
Liver preparations
Liver substance
Liver substance concentrate
l-Lysine monohydrochloride
Lysine
Magnesium-aluminum hydroxide
Malt extract
Methionine
Mixed bioflavonoids
Molasses
Oyster shell
Pancreatin
Papain
Papaya
Parsley
Peas
Pepsin
Phenylalanine
Proline
Protein hydrolysate
Prune concentrate
Red bone marrow
Rice bran
Rice oil, cold pressed
Rice polishings
Rose hips powder
Rutin
Serine
Soy flower
Spinach powder
Sulfur
Threonine
Tillandsia
Torula food yeast
Torula yeast
Tryptophan
Turnip greens
Tyrosine
Unsaturated fatty acids (vitamin F)
Valine
Watercress
Wheat germ
Wheat germ oil
Yeast

D. REFERENCED OTC VOLUME SUBMISSIONS

All "OTC Volumes" cited throughout this document refer to the submissions made by interested persons pursuant to the call for data notice published in the FEDERAL REGISTER of October 15, 1973 (38 FR 28581). The volumes will be put on public display after April 16, 1979, in the office of the Hearing Clerk, Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

II. GENERAL STATEMENTS AND RECOMMENDATIONS

A. HISTORICAL FRAMEWORK AND RATIONALE

1. *Background.* No comprehensive review of OTC drugs has previously been carried out by FDA and no detailed review of OTC vitamin and mineral drug products has been undertaken. Vitamin and mineral products first came under the provisions of the Food and Drugs Act of 1906, with subsequent major modifications of the act by Congress in 1912, 1938, 1951, and 1962.

The initial effort by Congress to exert some control over the marketing of foods and drugs was embodied in the Food and Drugs Act of 1906. Under this law, drugs marketed in interstate commerce were required to meet their professed minimal standards of strength, quality, and purity. This act was largely designed to prevent adulteration of foods and drugs and was not directed at the effectiveness or safety of the ingredients themselves.

In 1912 Congress passed the Sherley Amendment to the 1906 Act which defined a drug as misbranded if it included false and fraudulent claims.

In 1938 a comprehensive Federal Food, Drug, and Cosmetic Act was passed with "new drug" provisions which required premarket clearance, i.e., new drugs which were not generally recognized as safe had to be shown to be safe through an approved new drug application (NDA) prior to marketing. "Old" drugs, including vitamins, which were considered safe prior to 1938, were permitted to continue on the market without further review. However, FDA maintained the authority to review these old drugs if possible safety concerns became apparent. In 1951, the Durham-Humphrey Amendment to the Federal Food, Drug, and Cosmetic Act was passed. This act formally differentiated between prescription and OTC drugs. It provided that a drug be sold OTC if it is safe and if adequate directions for use can be written which are readily discernible by a layman so that a professional's advice is not required for administration or use of the drug.

In 1962 Congress passed the Kefauver-Harris Bill requiring that all "new drugs," both prescription and OTC, be proven effective as well as safe before marketing. The amendment required an effectiveness review for all new drug products which had been approved for safety between the 1938 Act and the 1962 Amendment. In 1966 FDA contracted with the National Academy of Sciences, National Research Council (NAS/NRC) for an extensive review of 4,000 drugs which had NDA's approved between 1938 and 1962. Some 500 of these drugs were OTC products, and several of them were vitamin and/or mineral preparations. Most OTC vitamins and minerals, however, were marketed without the submission of proof of safety or effectiveness to FDA. Thus, the current OTC drug review of vitamins and minerals is really the first time that FDA has systematically reviewed, in relation to the drug provisions of the Federal Food, Drug, and Cosmetic Act, vitamins and minerals for safety and effectiveness and for the appropriateness of labeled claims for OTC drug use.

2. *Dietary supplement use of vitamins and minerals as compared to OTC drug use of vitamins and minerals.* The Panel accepted the terms of the Federal Food, Drug, and Cosmetic Act in which products are considered drugs if intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease (21 U.S.C. 321). The Panel therefore concludes that representation of a vitamine or mineral preparation for use in the "prevention" or for the "treatment" of a vitamin or mineral deficiency is clearly a representation for therapeutic usage, and that such a preparation should be subject to this document and regulat-

ed as a drug, not as a dietary supplement.

A dietary supplement of a vitamin or mineral is a food intended (i.e., purported or represented) to supplement a diet by increasing the total dietary intake of one or more essential vitamins or minerals. The Panel established the philosophy that a vitamin or mineral active ingredient becomes an OTC drug when that vitamin or mineral is used to overcome a probable deficit in the diet (i.e., to prevent the imminent development of a disease condition or for treatment of a vitamin- or mineral-deficiency disease). The Panel concluded that the need for such prevention or treatment should be determined by a physician.

Although a balanced diet provides adequate amounts of essential nutrients, some individuals may not be receiving a balanced diet for various reasons and may wish to supplement their diet. Dietary supplements of vitamins and minerals are marketed for this purpose and are regulated as "foods for special dietary use," as distinguished from OTC drug use. Dietary supplements are regulated by a separate set of regulations which were originally promulgated in 1941 and are clearly outside the purview of this Panel. Efforts to amend the regulations have been ongoing since 1962 and were the subject of hearings from 1968 to 1970, and finally culminated in the publication of final regulations in 1973—the same year this Panel held its first meeting. The 1973 dietary supplement regulations were pertinent to the activities of this Panel in that an "upper limit" on the quantity of vitamins and minerals in a dietary supplement was established (150 percent of the U.S. RDA, in most instances). Products containing vitamins and minerals in excess of the upper limit, as well as those making drug claims, were to be regulated as drugs and therefore were subject to this Panel's review. Due to judicial and legislative developments, the 1973 dietary supplement regulations were never enforced. New regulations were published in the FEDERAL REGISTER of October 19, 1976 (41 FR 46156), and were to take effect in January 1978. Subsequently, the effective date was extended to July 1, 1979. These regulations established "lower limits" (50 percent of the U.S. RDA, in most instances) for the quantity of vitamins and minerals included in dietary supplements. Products intended for use by children or by pregnant or lactating women had to conform to a "standard of identify" specifying which nutrients must be included and the quantity of each that must be present. Products intended for adults other than pregnant or lactating women were not covered by the October 19, 1976 standard of identity, and there were no upper limits on the quantity of vitamins and minerals in such products except when safety limits are established by regulation, e.g., as in the case of food additive regulations limiting the permissible quantities of folic acid and iodine which may be included in any food product, including special dietary foods such as dietary supplements. On February 16, 1978, these regulations were vacated by the United States Court of Appeals for the Second Circuit (*National Nutritional Foods Assn.* v. *Kennedy*, 472 F. 2d 377 (2d Cir. 1978)). They must be re-proposed in conformity with the Court's instructions.

Products subject to the dietary supplement regulations are not subject to the labeling and compositional requirements recommended in this document, which is addressed to OTC vitamin and mineral drug preparations intended for therapeutic use. However, the Panel emphasizes that observations in this document with respect to the safety, effectiveness, and appropriate labeling of vitamins and minerals may be relevant to dietary supplements as well as to drug usage.

3. *Present status.* The Panel viewed its charge according to the OTC drug regulations (21 CFR 330.10) to review all submitted data and the relevant scientific literature in order to make recommendations for the conditions under which vitamins and minerals could be marketed for safe and effective OTC use with appropriate labeling. Thus, for each ingredient reviewed, a determination was made of the conditions under which a vitamin or mineral could be used in the prevention or treatment of a disease or the mitigation of symptoms. In addition, it was necessary to identify those situations under which vitamins, minerals, or combinations of vitamins and minerals could be safely and effectively used as OTC drugs. Thus, for a vitamin or mineral ingredient or combination of vitamins and minerals to be considered Category I, that is safe, effective, and appropriately labeled for OTC drug use, two requisite conditions had to be satisfied: (1) Identification of a disease or condition in a significant target population which could be safely treated or prevented by the OTC ingredient, and (2) instructions to the consumer which are clear, true, and not misleading.

B. LABELING FOR OTC VITAMINS AND MINERALS

After review of all submitted claims and after evaluating pertinent literature, the Panel concluded that the appropriate use for vitamins and minerals as OTC drug products was for the prevention or treatment of vitamin and mineral deficiencies. Since the identification of many conditions which predispose to nutritional deficiency of vitamins and minerals and the identification of the deficiencies require the professional capabilities of a physician, effective instructions to the consumer for the use of vitamins and minerals for the prevention or treatment of vitamin and mineral deficiency can only be given when the need for such prevention and treatment is identified by a physician. Therefore, the formula which has been adopted for labeling use, in the case of each vitamin, mineral, or combination, refers to the use of vitamins and minerals for prevention or treatment "when the need for such therapy has been determined by a physician." This OTC use of vitamins and minerals is to be distinguished clearly from the use of vitamins and minerals by prescription. When vitamins and minerals are being used in doses and combinations which require the persistent and continuing supervision of a physician in order to monitor the therapy for its safety or effectiveness, such therapy must be controlled by prescription. On the other hand, the recommendation of a physician for OTC purchase of vitamins and minerals implies that the patient is not required to see the physician before each purchase of vitamins and minerals. Once the need for prevention or treatment is identified, it is expected that such therapy could be carried out safely and effectively on the basis of labeled directions.

After reviewing all the claims and the date submitted and in keeping with other similar restrictions in the OTC drug review, the indications for use which the Panel recommends will constitute an exclusive list of labeling claims. Claims of special effectiveness or potency (e.g., stress, high or super potency) will not be permitted. In addition, symptoms that may suggest the presence of a specific vitamin or mineral deficiency may not be listed, except as specifically provided in these recommendations. For example, weakness or tiredness may under certain rare circumstances be symptoms indicative of vitamin or mineral deficiency. However, it is not safe or appropriate that vitamins or minerals be taken for weakness or tiredness unless the cause of these symptoms is vitamin or mineral deficiency. The Panel recognizes no symptoms of vitamin or mineral deficiency as so characteristic that they might be recognized by consumers and safely treated under customary conditions of labeling, purchase, and use.

The Panel recommends that FDA consider labeling in its totality. Terms such as "stress," "super potency," and "geriatric" in the brand name are implied claims and do not comply with the labeling recommendations stated within this document.

To avoid confusion, a vitamin present in a product must be identified by its established name as used within this document and the amount present stated in terms of a designated reference form (equivalent). Frequently, more than one source may appropriately supply the active principle of a particular vitamin or mineral, but equal weights of different sources of vitamins or minerals will not always supply equal amounts of biologic activity. For example, 100 milligrams (mg) of vitamin C biologic activity is supplied by 100 mg of *L*-ascorbic acid, but requires 112.5 mg of sodium ascorbate for the same effects. Therefore, a consumer who compares products may be confused if the vitamin content is listed only in terms of the amount of the contributing ingredient and not in terms of the amount required to produce the desired biologic response. When appropriate, the name, formula, and molecular weight of the reference form (equivalent) are given, for each vitamin.

For products containing minerals, each mineral is best described in the labeling by the name of the element, the amount present, and the name and amount of the source of the mineral, e.g., 150 mg ferrous sulfate provides 30 mg elemental iron.

The Panel does object to the designation of a product as "natural" on a label since this may imply an advantage which the Panel rejects as unsupported by evidence.

The Panel also recommends that all ingredients used for formulation be listed in the labeling so that the consumer may be aware of all ingredients, active or inactive. This is particularly important in view of those occasional instances of an allergic or idiosyncratic response of some individuals to ingredients present in a preparation.

Some vitamin-mineral preparations contain as much as, or more than, 17 percent alcohol. This amount of alcohol may be enough to encourage abusive consumption by some persons. In persons using drugs such as disulfiram, acute reactions can be precipated.

C. EVALUATION OF EFFECTIVENESS

In the view of the Panel, the definition of effectiveness of vitamins and minerals as drugs has three major elements: (1) A disease entity or condition which the ingredient is capable of preventing or treating; (2) a dose or dosage range which can be expected to achieve the desired effect on the basis of instructions on the labeling; and (3) assurance that the form and the dose in which the vitamin or mineral is ingested will permit absorption and, therefore, achieve the predicted effect. This latter phenomenon is referred to as bioavailability. (See part II. paragraph D.1. below—Bioavailability.)

In considering the effectiveness of OTC vitamins and minerals, the Panel had to clarify several important issues: (1) The identification of target populations having a need for OTC vitamins and minerals, (2) the questionable added benefit or potential hazard to health by taking higher doses of a vitamin or mineral when lower doses are recognized as adequate, (3) the determination of when dosages of vitamins and minerals sold OTC are appropriate, and (4) the determination of when these drugs should be reserved for use by prescription.

The Panel recognizes that the greatest need for prevention and treatment of vitamin and mineral deficiency will be found largely within certain groups in the population with special nutritional and metabolic needs. A listing of such target groups includes, for example, persons on a restricted diet; persons with intestinal disease which impairs normal dietary intake or absorption; those individuals with known increased requirements for vitamins and minerals, such as pregnant and lactating women; those individuals at increased risk because of increased blood loss, e.g., iron deficiency in women of child-bearing age; and individuals who tend to neglect the adequate intake of vitamins and minerals and in addition have impaired metabolic function, e.g., alcoholics, and individuals who are taking certain drugs which either impair the absorption of vitamins and minerals from the diet or interfere with their normal utilization by the body. Individuals in the above target groups are at greater risk of vitamin and mineral depletion than the general population, which ordinarily can maintain adequate vitamin and mineral status by the regular use of a balanced diet. It is important that the needs of these individuals for prevention or treatment be identified by a physician. In addition, the physician's review of the problem will ensure that a vitamin or mineral deficiency which is attributable to abnormality in diet, intestinal disease, alcoholism, or increased requirements will not be treated without appropriate diagnosis and attention to the underlying cause.

D. ESTABLISHMENT OF ADEQUATE DOSAGE UNITS AND SCHEDULES

For vitamins and minerals, as for other therapeutic agents, effectiveness is not an abstract concept but is operational only in the context of a certain dosage or dosage schedule. A vitamin or mineral ingredient might be judged to be appropriate for Category I when recommended for the prevention of a vitamin or mineral deficiency or recommended for prevention and treatment of vitamin or mineral deficiency. Only when a vitamin or mineral deficiency or a predisposing condition occurs in man in significant numbers and the deficiency is identified by a physician, and then safely treated by OTC medication, are Category I requirements fulfilled. When treatment of deficiency can be safely and effectively carried out only under the specific direction and monitoring of a physician, then such therapy requires the use of prescription vitamins and minerals, and only prevention is recognized as an appropriate Category I definition of effectiveness for OTC use. Such is the case, for example, in vitamin B-12 deficiency, where oral vitamin B-12 may safely prevent the depletion seen in the presence of a completely vegetarian diet. On the other hand, vitamin B-12 deficiency as a manifest clinical syndrome is so commonly associated with absorption abnormalities as to require parenteral therapy or, at least, direct monitoring of oral therapy. Therefore, the Panel concludes that the use of vitamin B-12 sources for the prevention of extrinsic or dietary deficiency is rational but has also concluded that the treatment of vitamin B-12 deficiency is not appropriate for OTC drug use. (See part III. paragraph A.4. below—Vitamin B-12.)

Sometimes an essential vitamin or mineral will have no Category I use because the deficiency state only occurs in the presence of severe disease or with other drug use. In these instances, total medical management is required. Such is the case with potassium deficiency, for example. At times the margin between an effective dose and a toxic dose is so small as to require specific supervision of a physician. Such is also the case for the mineral iodine. In these instances, vitamin or mineral therapy must be prescribed specifically for the unique problem of the individual patient and safety and effectiveness monitored by a physician.

When a vitamin or mineral is recommended for prevention or treatment, the dose requirements are different for these two purposes. In general, a dose range is recommended for each situation. This range encompasses a variety of doses currently in safe use, and extends from a minimum effective dose to an upper dose beyond which no greater benefit is achieved and the benefit-to-risk ratio diminishes. The minimum effective dose for prevention is arrived at on the basis of studies in human subjects of all ages and sexes. The minimum effective dose for treatment is based, when possible, upon successful quantitative therapeutic studies on patients with vitamin and/or mineral deficiencies.

At times, this upper rational limit is based upon known limitations in intes-

tinal absorption, or it is based upon known dangers of higher doses, and at other times upon the concept of implied toxicity. Studies on treating deficiencies have often arbitrarily used doses of vitamins or minerals 5 to 10 times the doses required to prevent deficiency. The rationale for higher doses of vitamins and minerals to treat, as compared to doses needed to prevent, vitamin and mineral deficiency is based on the observations which show that the higher doses more quickly saturate depleted body stores and, therefore, may be expected to initiate a faster reversal of the abnormal metabolic processes which are associated with vitamin and mineral deficiency disease.

The Panel has sought to recommend dosage levels so that a daily dosage unit can generally be taken to achieve the desired effect. The Panel does not object to the mechanism of using multiple dosage units to achieve a fully daily dose. It is understood, however, that a single dosage unit might be recommended for prevention when taken once daily, and for treatment when taken several times daily. However, in view of the advertising campaigns aimed at reinforcing the tendency of consumers to take a single dosage unit of a vitamin or mineral daily and the difficulty encountered in adhering to multidose daily schedules, the Panel does not consider it appropriate for a daily preventive dose to be achieved by multiple dosage units, each of which is below the minimum recommended dose for prevention of vitamin or mineral deficiency. Instead, the Panel recommends that preventive doses whenever possible be given in single daily doeses such that the total quantity of a vitamin and/or mineral will be within the dosage range recommended by the Panel.

Bioavailability. For a vitamin or mineral preparation to be effective, it must be bioavailable, i.e., it must be able to be transported through the intestinal wall in order to enter the blood stream for circulation to the tissues where the biologically active form of the vitamin or mineral will achieve the desired effect of alleviating a deficiency or preventing a deficiency. Bioavailability depends not only on the basic chemical characteristics of the vitamin or mineral and its salts or counterions, but also on the dosage form in which it is administered, e.g., tablet or liquid. It is the requirement of this Panel that all products which are marketed OTC, whether as single ingredients or combination products, be in a form so that all active ingredients are bioavailable to the user. However, to assure that this will be so, the current level of technology in determining the absorption of vitamins and minerals, singly or in combination, must be expanded. We consider it an important responsibility of FDA to ensure that the necessary research is done to form the basis for establishing specific testing requirements for an appropriate degree of bioavailability of all active ingredients in vitamin and mineral products. In the interim, where bioavailability data indicate that a problem exists, requirements for special testing have been included in the appropriate ingredient statements in this document.

E. EVALUATION OF SAFETY

The considerations of paramount importance in the safety of OTC vitamin and mineral preparations are the intrinsic safety of the ingredient or combination, the safety of OTC use of the vitamin and mineral and, most important, the concept of a safe dose range.

Since all the vitamins and minerals considered by the Panel, with the exception of choline, are nutrients which are essential to man, the Panel readily accepts the intrinsic safety of these compounds at the recommended dosages. Therefore, safety was judged largely in the context of the circumstances and dosage under which the vitamin or mineral is taken. As noted above, large amounts of some vitamins and minerals cannot be taken safely as OTC drug preparations even though their use under the direct and continuous care of a physician can be effective. The decision regarding the quantity of a vitamin or mineral which is unsafe at doses above the maximum recommended dose may be based upon unwanted side effects or implied toxicity, i.e., an unsatisfactory ratio of risk to benefit at a given dose, in addition to known or documented toxic effects. The Panel agrees that there is no ingested substance, including water, which is altogether safe at any dose. It is therefore rational to set upper limits of a recommended dose at the point where there is known effectiveness and minimal relative risk of toxicity. A well-established concept in pharmacology is that medication should not be taken in doses beyond those needed to achieve the desired effect, and that to do so increases the risk of unwanted or toxic effects. Each increment of the dose which does not at the same time increase the therapeutic effect of the medication, decreases the therapeutic ratio (benefit to risk) and therefore increases the risk of toxicity. The therapeutic effects of vitamins and minerals are dose-related only to the extent that they replete and saturate the body tissues to prevent or treat deficiency disease. Beyond these saturating doses, which have been taken, in general, as the upper limits of the recommended dosage, some vitamins and minerals may be stored in such a way as to produce abnormal tissue effects, e.g., vitamin A; or they may produce undesirable metabolic effects, e.g., vitamin D; or they may interfere with the physician's ability to diagnose other medical conditions, e.g., high doses of folic acid which mask the diagnosis of pernicious anemia and vitamin B-12 deficiency, and excessive doses of ascorbic acid which may interfere with a commonly use method of testing for urinary sugar in diabetics.

To the concept of a worsening benefit-to-risk ratio caused by doses beyond those of known therapeutic benefit must be added the danger of delayed appearance of toxic symptoms. The toxic effects of excessive doses of vitamins and minerals can be divided roughly into two different types of syndromes. One is the acute toxic reaction which usually occurs in the presence of an excessive vitamin or mineral intake over a short period of time. Such acute intoxication is well described for vitamin A and for most of the known minerals taken in great excess. Second, there is a more chronic or delayed toxic reaction which occurs due to excessive intake over a long period of time. Thus, in the case of vitamin A toxicity, it is possible that the patient may continue to ingest excessive doses of vitamin A without untoward symptoms or recognized side effects until such time as the vitamin has been stored in the liver to such excess that the liver is damaged and scarring and cirrhosis occur. A similar effect of excessive doses of nicotinic acid and even nicotinamide with the delayed development of liver toxicity has been reported and emphasis the contention of the Panel that even water-soluble vitamins such as nicotinic acid or nicotinamide may produce toxic effects which may be recognized only after significant tissue damage has occurred. Although far less well documented as a toxic agent, vitamin C, or ascorbic acid, is known to produce increments in the urinary excretion of oxalate when taken in 1,000 mg or greater daily doses (Ref. 1). Such increases have not been shown clearly to result in an increased incidence of oxalate kidney stones. However, when the theoretical benefits of increasing vitmain C dosage beyond known nutritional benefit are matched against the theoretical dangers of enhancing this metabolic side reaction, the Panel has chosen a safe position of identifying a maximum dose at which all scientifically recognized therapeutic effects can be achieved with a minimum risk of unwanted effects.

There are claims that some individuals in the population require doses of vitamins for maximal health which are 10, 50, or even 100 times the doses which are recognized as needed for nu-

tritional reasons. The Food and Nutrition Board of the National Academy of Sciences (Ref. 2) has stated, "We are aware of no convincing evidence of unique health benefits accruing from consumption of a large excess of any one nutrient." Claims for the effectiveness of high doses of vitamins for the treatment of psychiatric and other medical disorders have been justified by some on the basis of uncontrolled studies of a few practitioners and a theoretical concept called orthomolecular psychiatry. When such claims have been scientifically tested by controlled studies which avoid placebo bias, they have regularly been disproved; these claims have not been reproducible in the hands of other than the original proponents. The claims made for mega-dose therapy are understandably attractive to individuals seeking symptomatic relief or recovery from conditions with no known cure. At the present time, however, there is no scientific documentation for the rational use of mega-quantities of vitamins except for those rare individuals with a specific genetic defect. Until we have obtained adequate evidence of the safety of large doses of vitamins taken for long periods of time or the documentation that high doses of vitamins do have a special health benefit which justifies a worse risk-to-benefit ratio, the Panel has chosen not to venture beyond a recommended dose range which accomplishes the therapeutic goals set out on the label.

Another factor which enters into the decisions to establish an upper dose limit for vitamins or minerals is the theoretical principle of systemic conditioning. This is based on observations which indicate that in the presence of large doses of a vitamin or mineral, certain metabolic responses occur which condition or adapt the body to such large doses. If these large doses are stopped abruptly for one reason or another, the body, conditioned to such large doses, may for a short period of time react as if the tissue is depleted even though the intake is adequate for normal requirements at that point. Shortly thereafter the metabolic machinery of the body adjusts to the new dose of vitamin or mineral and normal functioning is restored. The evidence that such systemic conditioning occurs is still very preliminary. Scurvy has been observed in an individual ingesting 10 to 15 grams (g) ascorbic acid daily when the vitamin was abruptly discontinued. Symptoms abated after vitamin C therapy (Ref. 3). Such a readjustment in metabolic responsiveness may be particularly important in the case of pregnancy. Excessive doses of a vitamin taken by the pregnant woman may pass the placenta and adapt the fetal tissues to a high and excessive vitamin environment. When the infant is delivered and must adjust to normal intakes of a vitamin, a temporary deficiency syndrome may theoretically ensue. A syndrome of vitamin B-6 deficiency in a newborn infant has been reported in one instance when a pregnant woman was taking large doses of vitamin B-6 during the third trimester of pregnancy. No cause-and-effect relationship has been proven. Also in the case of vitamin B-6, there have been cases reported in which the cessation of high-dose vitamin B-6 therapy to pregnant women or women on birth control pills has been followed by sharp exacerbation of symptoms of depression which necessitated reinstitution of high-dose vitamin B-6 therapy (Ref. 4).

The Panel recognizes that there is controversy regarding the applicability of a recommended dose or even a recommended dosage range to a heterogeneous population. Therefore, the Panel has selected an upper dose limit which would satisfy the requirements of the target populations for which the treatment is recommended. The Panel is aware of arguments which suggest that vitamin and mineral requirements may be highly variable on a genetic basis. There are, in fact, rare genetically determined conditions which may be ameliorated with high doses of a specific vitamin. These specific genetic abnormalities tend to appear early in life and produce dramatic clinical presentations. Their diagnosis and management requires intensive and continued involvement of specially skilled clinicians, and management of these conditions with large doses of the special vitamin needed cannot be safety carried out by OTC medication. The presence of such rare genetically determined disorders cannot, however, be extrapolated to suggest that there are wide ranges of genetically determined requirements for vitamins and minerals in the otherwise normal population. There is such a large reserve or safety factor in the normal human system which regulates the utilization of vitamins that small variability in genetic potential is not reflected in substantial variability in individual requirements in the normal population. Thus, a genetic basis for expression of marked individual variability in nutrient requirement is not a tenable concept and constitutes such a small number of consumers with unique requirements as to fall outside the target populations for OTC drug products.

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(3) Dykes, M. H. M., and P. Meier, "Ascorbic Acid and the Common Cold. Evaluation of its Efficacy and Toxicity," *Journal of the American Medical Association*, 231:1073-1079, 1975.

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F. COMBINATION POLICY

1. *General statements.* In order to clarify the place of cominations in the marketplace, the Panel applied the OTC drug review regulation (21 CFR 330.10(a)(4) (iv)) which states:

> An OTC drug may combine two or more safe and effective active ingredients and may be generally recognized as safe and effective when each active ingredient makes a contribution to the claimed effect(s); when combining of the active ingredients does not decrease the safety or effectiveness of any of the individual active ingredients; and when the combination, when used under adequate direction for use and warnings against unsafe use, provides rational concurrent therapy for a significant proportion of the target population.

A special reationale for multiple vitamin and vitamin-mineral preparations is derived from the fact that circumstances of restricted dietary intake, increased requirements, or defective absorption as in pregnancy rarely affect a single nutrient. Thus, combinations of vitamins and minerals may often be the rational means of preventing or treating vitamin and mineral deficiencies in those at special risk.

The Panel concludes, therefore, that multiple vitamin preparations and preparations containing both vitamins and minerals which claim effectiveness for prevention or treatment of vitamin and mineral deficiencies should be formulated on the basis of supplying all those vitamins and minerals whose combined deficiencies may be expected in a significant target population. Preparations of multiple minerals alone, however, are not recommended. (See part II. paragraph F.12.f. below—Preparations of multiple minerals.) When multiple deficiencies are present, or are at increased risk of occurring, it would not be rational or safe to use preparations containing only two or three vitamins and minerals for the observed symptoms or deficiencies and thus unwitingly neglect therapy of other deficiencies. Therefore, a product containing only the fat-soluble vitamins A, D, E, and K is not allowed since the conditions of diet and intestinal disease which may predispose to depletion of some of these vitamins are more rationally treated with preparations which contain all Category I vitamins. Because the water-soluble vitamins (the B-vitamins and vitamin C) are less well stored in the body than the fat-soluble vitamins and may be depleted more

rapidly in the presence of altered intake or disease, and because the several B-vitamins often occur together in the same foods, a preparation containing all B-vitamins with or without vitamin C to prevent or reverse disease in man is recommended.

Minerals pose a different problem. There are few minerals for which a deficiency state in man is recognized which can be safely managed by OTC medication. The conditions leading to deficiency of these few Category I minerals in contrast to the vitamins are not common ones, and thus there is no basis for a multimineral preparation for OTC use. For example, the conditions leading to iron deficiency in women of childbearing age and in pregnant women are distinct from conditions which may result in depletion of either zinc or calcium, the other Category I minerals.

2. *Safety.* In its consideration of active ingredients, the Panel reviewed the safety and effectiveness of all combinations submitted. All combinations that meet the criteria of Category I as set forth below are considered safe. (See part II. paragraph F.7. below—Category I combinations.) In addition, the Panel considered it rational to include both vitamin E and pantothenic acid in multivitamin or vitamin and mineral preparations despite the fact that these two vitamins have no Category I use as single ingredients. (See part III. paragraph A.7. below—Pantothenic acid and part III. paragraph A.13. below—Vitamin E.)

3. *Effectiveness.* Combination products are regarded as effective if each active ingredient is present in the product within the dose range set by the Panel for each Category I active vitamin or mineral ingredient, as discussed within the individual ingredient statements within this document. The Panel deemed unnecessary any attempt to establish the percent of contribution that an active ingredient must make to effectiveness of the product in order for that contribution to be considered significant; the Panel concludes that, where a combination product is permitted, it is sufficient to demonstrate that each active ingredient is present and available in the recommended dosage quantity which would be effective in obtaining the pertinent vitamin or mineral therapeutic result unless interference between two or more vitamins and/or minerals occurs which alters safety or effectiveness as discussed in the individual vitamin and mineral statements within this document.

Combinations claiming effectiveness for prevention of deficiencies should contain doses of the individual vitamins and minerals as recommended for single ingredients for prevention while preparations claiming effectiveness for treatment must use recommended treatment doses for individual ingredients. The Panel recognizes that there may be combinations claiming effectiveness for treatment of deficiency which contain vitamins and/or minerals for which only a preventive dose has been recommended as a single nutrient. Under such circumstances, the maximal permitted preventive dose shall be used in the combination product claiming effectiveness for treatment.

When there is evidence that the combination of ingredients at certain levels may influence bioavailability of any ingredient, testing is required. For example, in solution, zinc may precipitate folic acid; therefore, bioavailability of folic acid must be documented in combinations containing folic acid and zinc.

4. *Active ingredients.* Each claimed active ingredient must be an ingredient that has been reviewed and approved by the Panel. If a product contains ingredients that are in Category II or have not been reviewed and approved by the Panel and consequently not found in this document, such a product is automatically classified as Category II, i.e., not safe and/or not effective.

5. *Panel policy regarding other ingredients in combination preparations.* Inactive ingredients may be present as a vehicle for formulation of biologically active ingredients. Other inactive ingredients may be present in preparations as pharmaceutic aids, as described in the proposed regulations for conditions for use and labeling of inactive ingredients published in the FEDERAL REGISTER of April 12, 1977 (42 FR 19156). The vitamin or mineral preparation must be prepared so that none of its inactive ingredients is present in an amount that exceeds the amount reasonably required to accomplish its intended physical or technical effect, or that impairs the biological availability of the vitamins or minerals.

6. *Review of submitted combination products.* The Panel considered only those combination products submitted pursuant to the notice published in the FEDERAL REGISTER of October 15, 1973 (38 FR 28581). The Panel recognizes that other combination products may be in the marketplace but has no knowledge of such products, or insufficient data with respect to such products, to make a judgment of safety and/or effectiveness.

7. *Category I combinations.* Combinations are recommended to meet needs for multiple-vitamin preparations and preparations containing both vitamins and minerals for prevention and therapy for the following special groups when such need has been identified and recommended by a physician: (1) Individuals of all ages on highly restricted diets for whatever reason; (2) pregnant women who have increased nutritional requirements for a variety of vitamins and minerals; and (3) individuals who use alcohol to excess. This latter group is well known to be at increased risk of multiple vitamin and mineral deficiencies and a preparation which addresses itself to the specific needs of this population is strongly recommended. Thus, the Panel recommends that allowable combinations should include and be limited to the following:

a. *Combination for prevention of deficiency.* (1) All Category I vitamins may be combined within the recommended dosage ranges identified within this document for the prevention of deficiency. Although the Panel does not recommend Category I use for either pantothenic acid or vitamin E as single ingredients, either or both of these vitamins may be added to the above combination. (See part III. paragraph A.7. below—Pantothenic acid and part III. paragraph A.13 below—Vitamin E.)

(2) All Category I B-vitamin ingredients (thiamine, riboflavin, pyridoxine, niacin, folic acid, and vitamin B-12) may be combined within the recommended dosage ranges identified within this document for the prevention of deficiency. Although the Panel does not recommend Category I use for pantothenic acid as a single ingredient, this vitamin may be added to the above combination. (See part III. paragraph A.7. below—Pantothenic acid.)

(3) All Category I B-vitamin ingredients (thiamine, riboflavin, pyridoxine, niacin, folic acid, and vitamin B-12) may be combined with vitamin C, all within the recommended dosage ranges identified in this document for the prevention of deficiency. Although the Panel does not recommend Category I use for pantothenic acid as a single ingredient, this vitamin may be added to the above combination. (See part III. paragraph A.7. below—Pantothenic acid.)

(4) Any combination of vitamin ingredients identified in (1) through (3) above may be combined with iron.

(5) Any combination of vitamin ingredients identified in (1) above may be combined with zinc with or without iron and/or calcium.

(6) Any combination of vitamin ingredients identified in (1) above may be combined with calcium with or without iron and zinc.

(7) All Category I vitamins may be combined with zinc for the prevention of deficiency in persons who use alcohol to excess, provided all the ingredients are present at levels provided for treatment of deficiency identified in this document or are at the maximum

dosage level for prevention of deficiency when treatment levels have not been specified. Although the Panel does not recommend Category I use for either pantothenic acid or vitamin E as single ingredients, either or both of these vitamins may be added to the above combination. (See part III. paragraph A.7. below—Pantothenic acid and part III. paragraph A.13. below—Vitamin E.)

(8) Any combination is acceptable for prevention of deficiency in pregnant women provided that dosages of all Category I vitamins that may be combined with iron (zinc and calcium optional) are present and that all ingredients present are within the dosage ranges recommended for pregnancy, or within the prevention dosage ranges if no pregnancy dosage range has been specified.

b. *Combinations for the treatment of deficiency.* (1) All Category I vitamin ingredients within the recommended dosage ranges identified in this document for the treatment of deficiency (niacin, vitamin C, pyridoxine, riboflavin, thiamine, and vitamin A) may be combined with all Category I vitamin ingredients which have no established dosage range for the treatment of deficiency, provided that these ingredients are present at the maximum dosage level identified in this document for the prevention of deficiency (vitamin B-12, folic acid, and vitamin D). Although the Panel does not recommend Category I use for either pantothenic acid or vitamin E as single ingredients, either or both of these vitamins may be added to the above combination. (See part III. paragraph A.7. below—Pantothenic acid and part III. paragraph A.13. below—Vitamin E.)

(2) All Category I B-vitamin ingredients within the recommended dosage ranges identified in this document for the treatment of deficiency (niacin, thiamine, riboflavin, and pyridoxine) may be combined with all Category I B-vitamin ingredients which have no established dosage range for the treatment of deficiency, provided that these ingredients (folic acid and vitamin B-12) are present at the maximum dosage level identified in this document for the prevention of deficiency. Although the Panel does not recommend Category I use for pantothenic acid as a single ingredient, this vitamin may be added to the above combination. (See part III. paragraph A.7. below—Pantothenic acid.)

(3) All Category I B-vitamin ingredients within the recommended dosage ranges identified in this document for the treatment of deficiency (thiamine, riboflavin, pyridoxine, and niacin) may be combined with vitamin C and with all Category I B-vitamin ingredients which have no established dosage range for the treatment of deficiency provided that these ingredients are present at the maximum dosage level identified in this document for the prevention of deficiency (folic acid and vitamin B-12). Although the Panel does not recommend Category I use for pantothenic acid as a single ingredient, this vitamin may be added to the above combination. (See part III. paragraph A.7. below—Pantothenic acid.)

8. *Criteria for determining Category I combinations.* To qualify as a Category I combination, i.e., one that is generally recognized as safe and effective, each of the following conditions must be met: (1) A specific combination of active ingredients as set forth above (See part II. paragraph F.7. above—Category I combinations.), and (2) each ingredient in a combination must be present within the dosage range for a Category I active ingredient as set forth elsewhere in this document within the individual ingredient statements.

9. *Category I combination labeling claims.* The Panel recommends that labeling consist of two parts: (1) A major part in bold type which includes the labeling statements below as they correspond to specific combinations identified above as well as a listing of all the vitamins and minerals and the total quantity of each vitamin and/or mineral contained in the product; and (2) a secondary part of the labeling in smaller type must reflect the name of all inactive ingredients used as pharmaceutic necessities.

The following claims will be acceptable for specific combinations of vitamins and minerals as identified in part II. paragraph F.7.a. above—Combinations for prevention of deficiency and part II. paragraph F.7.b. above—Combinations for the treatment of deficiency:

a. *For prevention*—(1) *For combinations containing only vitamins.* "For the prevention of deficiencies of vitamins named on the label when the need for such therapy has been determined by a physician."

(2) *For combinations containing vitamins and mineral(s).* "For the prevention of deficiencies of vitamins and mineral(s) named on the label when the need for such therapy has been determined by a physician."

(3) *For products identified in paragraph F.7.a.(7) above.* "Useful as an aid in the prevention of deficiency of vitamins named on the label and zinc in persons using alcohol to excess when the need for such therapy has been determined by a physician."

(4) *For products identified in paragraph F.7.a.(8) above.* "For the prevention of deficiency of vitamins named on the label and iron in pregnant women when the need for such therapy has been determined by a physician."

b. *For treatment—For combinations containing only vitamins.* "For the treatment of deficiencies of vitamins named on the label when the need for such therapy has been determined by a physician."

10. *Warnings.* The warnings identified elsewhere in this document for individual vitamin and/or mineral active ingredients are equally applicable to labeling of any combination containing these ingredients.

11. *Category II combination products.* A combination is classified by the Panel as a Category II product, i.e., one that is not generally recognized as safe and/or not generally recognized as effective, if any of the following apply:

a. A combination containing any ingredient which is not recommended for inclusion in Category I combinations, either as a Category I vitamin or mineral, as an acceptable source of a vitamin or mineral, or as an inactive ingredient used in formulation as a pharmaceutic necessity.

b. A combination containing any ingredient that is listed elsewhere in this document as a Category II ingredient. The exceptions are pantothenic acid and vitamin E as noted elsewhere. (See part III. paragraph A.7. below—Pantothenic acid and part III. paragraph A.13. below—Vitamin E.)

c. A combination containing any Category I ingredient in excess of the maximum dosage set by the Panel for such ingredient.

d. A combination containing any Category I ingredient which is present at less than the minimum dosage set for each respective ingredient. When more than one source of a vitamin or mineral is present in a combination, the total quantity of the vitamin or mineral from all sources must be present in at least the minimum dosage level established by the Panel.

e. A combination contains any active vitamin or mineral ingredient that has not been reviewed by the Panel and, accordingly, not evaluated in this document.

f. Combinations containing iron must not be labeled for prevention of deficiency in persons who use alcohol to excess.

12. *Miscellaneous Category II combinations*—a. *Vitamin and mineral combinations for infants under 1 year of age.* There are certain circumstances in which infants under 1 year of age may require vitamin and/or mineral supplementation. For example, infants fed other than by human breast milk, e.g., those on cow's milk, may be at risk of vitamin C depletion and vitamin C should be specifically added to the diet in food or as an individual ingredient supplement. Children on a

diet based upon unfortified skim milk may require vitamin A as a single supplement. Vitamin D is rarely required, but may also be supplemented. When special, highly unsaturated fat formulas are used, vitamin E needs should be monitored and therapy prescribed by a physician. Therefore, the Panel concludes that the individual recognized needs for infant use are best handled by individual ingredient supplements or under the advice and supervision of a physician. A combination of vitamins and minerals for infants under 1 year of age does not have a basis for effectiveness and is not recommended by the Panel. The Nutrition Committee of the Academy of pediatrics also does not recommend a combination for infant use (Ref. 1).

b. *Vitamin and mineral combinations for use in children.* The needs of growing children for vitamins and minerals are most appropriately met by an adequate balanced diet, and when the diet is restricted for whatever reason, such needs may be met by combinations of Category I vitamins and minerals. Thus, the preparations recommended in Category I are entirely adequate to the needs of individuals in the pediatric age group from 1 to 12 years of age. The dose range for individual nutrients referred to above under Category I encompasses safe and effective doses for children as well as for adults and therefore no special preparations for pediatric use are recommended and labeling claims specifically for pediatric or childhood use are not recognized as necessary. The Panel does not object to labeling claims on Category I preparations for use by both adults and children except for calcium and iron, where specific dose ranges are indicated for specific age groups. The Panel recognizes that there may be special formulations, such as liquid preparations, that may be specially formulated and marketed for use by children.

c. *The use of vitamins and minerals by the elderly.* Neither the Food and Nutrition Board of the NAS/NRC nor the World Health Organization (WHO) recognizes any need for increasing the vitamin and mineral allowances for healthy elderly individuals above those recommended for young and healthy adults. In fact, the Food and Nutrition Board decreases slightly the recommended dietary allowances for adult males over the age of 51 years for niacin, riboflavin, thiamine, and iodine, and for females over the age of 51 years, it decreases the allowances of niacin, riboflavin, iodine, and iron.

Although requirements for vitamins and minerals are not increased by age, socioeconomic conditions and reduced physical activity among the aged may lead to sharp curtailment in the intake of vitamin- or mineral-containing foods. Under such conditions of dietary restriction, the use of a vitamin and mineral preparation in the prevention or for the treatment of deficiency may be indicated. When such is the case, the doses of vitamins and minerals recommended elsewhere in this document as effective in the prevention and treatment of specific deficiency states or multiple-deficiency states in adults are adequate for use in the elderly population. Therefore, the Panel finds no indication or need for any special OTC vitamin or mineral preparation for geriatric use and any claims referring to such need are false and misleading.

d. *Combinations of folic acid and vitamin B-12 or of folic acid, vitamin B-12, and iron.* The Panel recognizes no justification for a combination containing only vitamin B-12 and folic acid for treatment of a combined deficiency or of megaloblastic anemia. This combination is considered not safe in view of the fact that the situations under which combined folate and vitamin B-12 deficiency occur are likely to be associated with malabsorption of one or both of the vitamins. While malabsorption of folic acid may be overcome by large oral doses of folic acid, vitamin B-12 should be given parenterally in these circumstances. Dietary deficiency of both these vitamins will rarely occur. When such a situation exists, multiple-vitamin deficiencies requiring multiple-vitamin therapy may be expected. Thus, a combination of only folic acid and vitamin B-12 is irrational. The same is true of conditions under which a combination of iron, folic acid, and vitamin B-12 deficiency exists. When all three deficiencies exist due to severe malabsorption, vitamin B-12 should be given parenterally; therefore an oral preparation of the three is irrational. When all three deficiencies exist due to severe dietary depletion, a combination product containing other vitamins and minerals should be employed.

e. *Combinations of fat-soluble vitamins.* The Panel does not recognize any indication for OTC vitamin combinations restricted to the fat-soluble vitamins A, D, E, and K, since depletion of water-soluble vitamins would be expected in clinical situations associated with deficiency of multiple fat-soluble vitamins. In the rare circumstances under which a bile salt deficiency occurs due to obstruction or malabsorption, prevention or treatment of fat-soluble vitamin deficiencies may require doses higher than those recommended for OTC use and will always require careful, continued monitoring by a physician and, therefore, are best handled by prescription.

f. *Preparations of multiple minerals.* As individual ingredients, only iron, zinc, and calcium are considered appropriate for Category I designation. In the case of other minerals, deficiencies in man are recognized only under clinical situations requiring presciption medication and close supervision by a physician because of the severity of the underlying condition or the risk of toxicity from mineral therapy. Unlike the situation with vitamins, multiple-mineral deficiencies rarely occur as a complication of the same condition, e.g., iron deficiency occurs in women of childbearing age from a different cause than would precipitate deficiency of zinc or calcium. Thus, there is no rational basis for a multimineral preparation.

g. *Category II vitamins for users of oral contraceptives.* Recent observations documenting alterations in circulating levels of vitamins as well as clinically detectable vitamin-deficiency states in women taking oral contraceptive preparations obviously bear consideration. Although circulating levels of folic acid, vitamin B-12, vitamin B-6, riboflavin, and vitamin C are lowered in oral contraceptive users, clinical manifestations of vitamin-deficiency syndromes have been adequately described only in women with vitamine B-6 and folic acid deficiency (Ref. 2), although in some instances, i.e., vitamin B-12, drastic reductions in serum levels occur without detectable effects (Ref. 3). It should be emphasized that the data regarding potentially detrimental vitamin-deficiency states in oral contraceptive users derive primarily from studies with contraceptive pills containing 50 micrograms (μg) or more of ethinyl estradiol or mestranol. Studies on patients taking low-dose estrogen pills, i.e., 20 to 30 μg estrogen, are not yet available for evaluation. Despite observations that depression and glucose intolerance apparently result from vitamin B-6 deficiency, and that megaloblastic anemia has been identified in folic acid deficient oral contraceptive users, the causal relationship has not been established. It appears unjustified at this time to recommend that a specific multivitamin preparation, i.e., one containing vitamins C, riboflavin, B-12, B-6, and folic acid, be made available for oral contraceptive users. Since vitamin B-12 levels may be less than 100 nanograms/milliliter (ng/ml) in oral contraceptive users without evidence of clinical deficiency or alteration in circulating hematocrit values (Ref. 3), the need for supplementation is presently unjustified. Similar arguments could be made for vitamins C and riboflavin (Ref. 2). Although the observation that the majority of women taking high estrogen-containing oral contraceptives has been shown to have abnormal tryptophan metabolism with some exhibiting absolute clinical vita-

min B-6 deficiency syndromes (Ref. 4), it appears still unjustified medically to market a combined oral contraceptive-vitamin B-6 product. It may ultimately be totally inappropriate since newer oral contraceptive preparations with lower estrogen content may, in fact, fail to induce the vitamin alterations observed with the high estrogen-containing preparations.

REFERENCES

(1) Committee on Nutrition, "Vitamin K Supplementation for Infants Receiving Milk Substitute Infant Formulas and for Those with Fat Malabsorption," *Pediatrics*, 48:483-487, 1971.

(2) Wyan, V., "Vitamins and Oral Contraceptive Use," *Lancet*, 1:561-564, 1975.

(3) Wertalik, L. F. et al., "Decreased Serum B-12 Levels with Oral Contraceptive Use," *Journal of the American Medical Association*, 221:1371-1374, 1972.

(4) Rose, D. P. et al., "Experimental Vitamin B-6 Deficiency and the Effect of Oestrogen-Containing Oral Contrasceptives on Tryptophan Metabolism and Vitamin B-6 Requirements," *Clinical Science*, 42:465-477, 1972.

G. CATEGORY III TESTING GUIDELINES

Claims for vitamins and minerals for which there are insufficient data for classification in either Category I or Category II are placed in Category III. The inference here is that studies are in process, or are contemplated, that eventually will justify the transfer of the claim, dosage, or product to Category I or Category II. In the meantime, any appropriate Category I claims as well as Category III claims are permitted on the labeling, and the products involved may continue to be marketed until a final disposition is made, assuming there are no other legal obstacles. The problem facing the Panel is the development of testing procedures for the justification of a transfer of Category III claims, dosage, and/or products to Category I in a reasonable period of time. FDA should develop, in conjunction with other workers in the field, whatever criteria are useful in view of the state of the art and in recognition of the ethics of human testing.

In order to do this, and in order to be able to evaluate the results of and claims made for studies conducted, one will have to consider each ingredient and each claim individually for the following reasons:

(1) The various ingredients differ markedly in the degree and duration of their deficiency required before the development of clinical signs and symptoms.

2. The various ingredients differ in the size of the dose necessary to treat a deficiency relative to the dose necessary to prevent deficiency.

3. Generally, deficiency states that develop acutely respond rapidly to the pertinent treatment, while those that develop slowly over a long period of time, either because of previous large body stores or because of a low degree of dietary inadequacy, might well be expected to respond more slowly to treatment.

4. The various diseases and abnormal metabolic and clinical conditions, for which various vitamins and minerals are claimed to be therapeutic in various amounts, also vary widely in their severity, duration, and response to treatment. The natural history of any disease or abnormality for which a therapeutic claim is made must be known.

5. No study can be accepted as disproving any claim made unless that study, while otherwise adequate, employs at least the doses and therapeutic trial periods and regimen advocated by the proponents of a particular ingredient therapy for a specific disease or condition.

III. VITAMINS

A commonly accepted definition of vitamins is that they are chemically unrelated organic substances that are essential in small amounts for the maintenance of normal metabolic functions but are not synthesized within the body and, therefore, must be furnished from exogenous sources (Refs. 1, 2, and 3). Amino acids and essential fatty acids are excluded from this definition. From a clinical point of view, the agents that are generally considered to be vitamins are those organic compounds the absence or inadequacy of which can cause specific metabolic defects (Ref. 2).

This definition has exceptions in that a few organic compounds generally recognized to be vitamins for man can be and are synthesized within the human body and, under suitable conditions, in adequate amounts to support normal metabolic processes. Vitamin D is formed by the activation of 7-dehydrocholesterol in the skin by sunlight. Vitamin A is synthesized within the body from a number of carotenoids with varying degrees of efficiency, and niacin can be made within the body from tryptophan. However, deficiencies of vitamins A, D, and niacin resulting in serious metabolic defects are known to occur and exogenous sources of the preformed vitamins would appear to be essential for most people under most circumstances.

It must also be borne in mind that the exogenous sources referred to are not always foods in the conventional sense. Both vitamin K and biotin are normally synthesized, probably in adequate amounts, by the bacteria of the intestine. The vitamin B-12 formed by bacterial action in the colon is distal to the absorption sites and not normally available to the human host living under modern hygienic conditions.

Vitamins A, D, E, and K are fat soluble and the others are more or less water soluble. This does not imply any other common characteristic among the vitamins within each solubility group other than the fact that, generally, the fat-soluble vitamins are stored better and longer in the body than are the water-soluble vitamins. The dosages for vitamins A, D, and E are usually stated in terms of international units (I.U.) based on standardized bioassays rather than in mg or μg as the other vitamins and minerals discussed in this document.

The dosages recommended in this document for vitamins have been derived from the available data. The Panel is aware of the RDA (Ref. 4) and the dietary supplement regulations published in the FEDERAL REGISTER of October 19, 1976 (41 FR 45156). However, the Panel emphasizes that these considerations were not applicable to the "OTC drug use" recommendations contained in this document.

REFERENCES

(1) Grollman, A. and E. F. Grollman, "Pharmacology and Therapeutics," 7th Ed., Lea and Febiger, Philadelphia, 1970.

(2) Guyton, A. C., "Vitamin and Mineral Metabolism," *in* "Textbook of Medical Physiology," 5th Ed., W. B. Saunders Co., Philadelphia, pp. 979-986, 1976.

(3) Greengard, P., "The Vitamins," *in* "The Pharmacological Basis of Therapeutics," 5th Ed., Edited by Goodman, L. S. and A. Gilman, Macmillan Publishing Co., Inc., New York, pp. 1544-1548, 1975.

(4) "Recommended Dietary Allowances," 8th Ed., National Academy of Sciences, Washington, DC, 1974.

The Panel has classified the following vitamin active ingredients as Category I for OTC drug use for the prevention and/or treatment of deficiency:

Vitamin C
- Ascorbic acid
- Ascorbyl palmitate
- Calcium ascorbate
- Niacinamide ascorbate (Category I only when in combination requiring both niacin and vitamin C activity)
- Sodium ascorbate

Vitamin B-12
- Cyanocobalamin

Folacin
- Folic acid

Niacin
- Niacin
- Niacinamide
- Niacinamide ascorbate (Category I only when in combinations requiring both niacin and vitamin C activity)
- Pantothenic acid (Category I only when in combination)
- Calcium pantothenate
- Dexpanthenol
- Pantothenic acid

Vitamin B-6
- Pyridoxine hydrochloride

Riboflavin
- Riboflavin

Riboflavin-5-phosphate sodium
Thiamine
Thiamie hydrochloride
Thiamine mononitrate
Vitamin A
Vitamin A
Vitamin A acetate
Vitamin A palmitate
Vitamin D
Cholecalciferol
Ergocalciferol
Vitamin E (Category I only when in combination)
Tocophersolan
alpha-tocopheryl acetate
alpha-Tocopheryl acid succinate
Vitamin E

The Panel has classified the following vitamin active ingredients as Category II for OTC drug use for the prevention and/or treatment of deficiency:

Biotin
Biotin
Choline
Choline bitartrate
Choline chloride
Choline citrate
Niacin
Nicotinic acid
Pantothenic acid (Category II as a single ingredient)
Calcium pantothenate
Dexpanthenol
Pantothenic acid
Vitamin D
25-Hydroxylated vitamin D
1, 25-Hydroxylated vitamin D
24, 25-Hydroxylated vitamin D
1-alpha-Vitamin D
5, 6-trans-Vitamin D
Vitamin E (Category II as a single ingredient)
Tocophersolan
alpha-Tocopheryl acetate
alpha-Tocopheryl acid succinate
Vitamin E
Vitamin K
Phytonadione

1. *Vitamin C.* The Panel's statement on vitamin C includes the following ingredients: Ascorbic acid, ascorbyl palmitate, calcium ascorbate, niacinamide ascorbate, and sodium ascorbate.

a. *Reference form.* Dosages recommended in this document for vitamin C are based on the *L*-ascorbic acid equivalent ($C_6H_8O_6$, molecular weight 176.2).

b. *Description.* Vitamin C is present in many foodstuffs, and the average daily consumption in ordinary diets ranges from 30 to 250 mg. The lesser amount is sufficient to prevent the occurrence of scurvy in all persons who are free from specific organic disorders in which the in vivo rate of utilization or destruction of ascorbic acid is adversely affected. In those persons with such disorders as peptic ulcer, achlorhydria, chronic diarrhea, burns, surgical wounds, neoplastic disease, and hyerthyroidism, and also during pregnancy and lactation, ascorbic acid needs are increased but not beyond the ability of a carefully selected diet to meet them (Refs. 1, 2, and 3). Several studies have shown that cigarette smokers have lower plasma/serum and leukocyte ascorbic acid levels than nonsmokers, but the magnitude of differences appears to vary with the level of vitamin C intake (Refs. 4 and 5). In one study, no differences were found between the plasma ascorbic acid levels of smokers and nonsmokers with intakes of about 100 to 500 mg vitamin C daily (Ref. 6). This author attributed his results to the high vitamin C intake of his subjects. The Panel concludes that there is no evidence that oral intake of vitamin C greater than 100 mg daily is necessary to maintain adequate vitamin C status in even heavy smokers. The administration of such drugs as oral contraceptives (Refs. 7, 8, and 9), antibiotics (Refs. 10 and 11), or salicylates (Refs. 12 and 13) has been reported to decrease plasma or platelet ascorbic acid levels and may therefore also increase the vitamin C requirement. There are no data, however, to suggest that these situations require or would benefit from adjunctive therapy with ascorbic acid.

Ascorbic acid functions as a cofactor in specific essential biolgical reactions in the human body for the utilization of absorbed metabolites in maintaining the body economy. It has antioxidant activity and is reversibly oxidized to dehydroascorbic acid, which also has antixcorbutic activity. This oxidation-reduction property of ascorbic acid is important in the extablishment of proper in vivio environments for specific biological reactions involving other reactants, e.g., regulation of intracellular oxidation-reduction potentials and intermidiate conversions of one substrate to another in the process of metabolism. As a cofactor, ascorbic acid acts in concert with other factors and is used up in the process at an average rate of about 3 percent of the existing pool daily so that constant replenishment of the body's pool is essential. Scurvy develops when this pool (approximately 1,500 mg in a well-nourished adult) becomes depleted. Deficiency is usually obvious when the body pool drops below 300 mg and the whole blood level drops below 0.3 mg/100 ml (Refs. 14 and 15). Symptoms include fatigue, spontaneous hemorrhaging and swollen joints, swollen, bleeding guns, follicular hyperkeratosis, muscular aches and pains, and emotional changes. Medical assessment is required to associate these symptoms with measurable biochemical parameters such as ascorbic acid blood levels in order to determine the existence of the ascorbutic syndrome (scurvy).

c. *Safety.* The present clinical and experimental findings indicate that consumption of vitamin C in excess of 1,000 mg daily is not without potential hazard in some individuals, and hence cannot be considered entirely safe (Refs. 16 through 37).

Ingestion of doses of 4 to 15 g daily may cause gastrointestinal disturbances, with nausea followed by diarrhea, due to the high osmolarity and laxative effect (Refs. 16 and 17).

With the administration of greater than 1,000 mg vitamin C, oxalate (Refs. 18 and 19), uric acid (Ref. 20), and calcium (Ref. 21) excretion may be increased, which in turn may enhance the risk of crystal formation in the kidney and bladder. A lowered urinary pH, i.e., increased acidity, resulting from the excreation of large quantities of vitamin C would tend to favor uric acid crystallization (Ref. 22). Recent data defining the supersaturation of normal urine with respect to calcium oxalate (Ref. 23), as well as those citing the mild oxaluria, i.e., increases of urinary oxalate, as little as 20 percent above normal, or patients prone to renal stone formation (Ref. 24) and the formation of renal calculi with relatively small increments in urinary oxalate (Ref. 25), suggest that an increased danger of oxalate crystal formation also exists in persons taking 1 g or more of vitamin C daily.

L-Ascorbic acid serves as a precursor of urinary oxalate in man, normally providing as much as one-third of the oxalate present in urine (Ref. 26). Values reported in the literature for the normal 24-hour urinary oxalate excretion of man range from 14 to 64 mg, with averages of 30 to 38 mg oxalic acid (Ref. 19). Extradietary ascorbic acid is not converted as efficiently, and significant detectable increases of urinary oxalate in a group of normal human subjects were seen only when 4 g or more vitamin C were fed. Increases of from 12 mg oxalate daily with the ingestion of 4 g vitamin C daily, up to 68 mg oxalate daily when ingesting 9 g vitamin C daily, seem modest when compared to the large amounts of ascorbic acid fed (Ref. 19). However, relative to normal urinary oxalate levels, these increases of 40 to 200 percent over normal ranges may result in calcium oxalate precipitation within the urinary tract of potential stone-forming populations (Ref. 25). Increased urinary oxalate upon ingesting as little as 750 mg vitamin C daily has been reported in two patients having iron-overload disorders (Ref. 27).

Moreover, since high oxalate intakes from certain foods, e.g., spinach, rhubarb, chocolate, tea, and/or low calcium intakes also promote increments in urinary oxalate (Ref. 28), vitamin C intakes greater than 1,000 mg daily may prove harmful to individuals with unusual dietary patterns resulting in high oxalate-low calcium intakes. An additional risk factor exists for individuals who reportedly convert ascor-

bic acid to oxalate with considerably greater than normal efficiency (Ref. 29).

In addition to these potential complications in individuals with normal intestinal absorption, others with small intestinal disease (especially those with partial resections) function as a unique population (Refs. 28 and 31). The increased urinary oxalates in these acquired disorders may place these patients at greater risk of forming oxalate stones if they are also subjected to higher doses of vitamin C.

Two clinical problems in making diagnoses involving glycosuria testing have arisen which result from the ingestion of large quantities (more than 1,000 mg daily) of vitamin C. The first is a false-negative glucose oxidase enzyme strip-test, which is given by ascorbic acid concentrations as low as 10 mg/100 ml in the urine (Ref. 34). The second is a false-positive copper reduction test with "Clinitest Tablets" (Ref. 34). Glycosuria testing is important in the monitoring of a diabetic's condition.

Another clinical testing problem resulting from excessive vitamin C ingestion has been the observation of false-negative stool occult blood tests, confirmed by in vitro studies. Fecal examination for occult blood is an important ancillary procedure in the assessment and management of gastrointestinal diseases and gastrointestinal irritation caused by drugs. Amine-dependent occult blood tests such as the Hemoccult test and the Derman test can be inhibited by a fecal excretion of 55 mg ascorbic acid daily, resulting in false-negative indications. A vitamin C intake of 1,000 to 2,000 mg daily has resulted in such false-negative occult blood tests. It has been recommended that no exogenous ascorbic acid should be ingested for 48 to 72 hours prior to conducting amine-dependent stool occult blood tests (Ref. 35).

Sodium comprises approximately 11.6 percent of the weight of sodium ascorbate. Therefore 50 mg sodium ascorbate contains 5.8 mg (0.25 milliequivalent (meq)) sodium, while 1,000 mg of sodium ascorbate will provide 116 mg (5.0 meq) sodium. There is a need for patients on sodium-restricted diets to know the sodium content of the daily dose of an ascorbic acid product which contains sodium ascorbate. This information should be available in the product labeling, to warn patients on severe sodium restriction diets of the potential danger in using high daily dosages of sodium ascorbate products.

Finally, ascorbic acid has been reported to block the anticoagulant effect of heparin in the proportion of about 200 mg ascorbic acid to 100 units (about 1.0 mg) heparin (Ref. 36), and to interfere with the prophylactic use of warfarin sodium (coumadin) in a woman ingesting 16 g ascorbic acid daily (Ref. 37).

In summary, patients prone to recurrent renal calculi (kidney stones), diabetics, patients undergoing stool occult blood tests, and patients on sodium-restricted diets or anticoagulant therapy should be warned of the above effects as a possible consequence of the ingestion of vitamin C products for extended periods in excess of the recommended dosage. The above-mentioned observations also suggest that, because of the possibility that several of the risk factors cited may occur in the same individual, the setting of the upper limit of daily dosage for products marketed for the treatment of vitamin C deficiency at 500 mg would be appropriate to provide an adequate margin of safety when the product is used as directed.

d. *Effectiveness.* The effectiveness of products containing vitamin C is evaluated by the quantitative assay determination of *L*-ascorbic acid by an acceptable, validated method and the determination of ascorbic acid levels in human serum, leukocytes, and urine before and after an appropriate "loading test" (Refs. 38 through 42).

Although as little as 6.5 mg vitamin C daily has been reported to ameliorate symptoms of scurvy, larger doses result in more rapid improvement and in substantial rates of storage in body pools (Ref. 14). In practice, 300 to 500 mg vitamin C daily is often given orally in divided doses of 100 mg for the treatment of vitamin C deficiency. This level of medication is continued until a total of 4,000 mg has been ingested, after which daily doses of 100 mg are used to prevent the recurrence of symptoms. In florid and symptomatic vitamin C deficiency, at which time the patient is under close and careful observation by the physician, larger daily doses, e.g., 1,000 mg, have been recommended until symptoms are controlled (Ref. 1), but such doses have not been shown to be superior to a 500-mg daily dosage and do not provide the margin of safety mentioned in the previous section. Single doses of vitamin C of 100 to 500 mg are effective, i.e., are absorbed and retained by the body, if plasma levels of ascorbic acid are low (Ref. 43). Therefore, the recommended maximum effective daily dose for the treatment of vitamin C deficiency is 500 mg. This dose is considered safe.

e. *Conclusion.* The Panel has reviewed the scientific literature, the submitted data, and the marketing history of vitamin and mineral ingredients. Based upon the available data, the Panel concludes that vitamin C, in the dosage and forms identified under Category I conditions below, is safe and effective for use in the prevention and treatment of vitamin C deficiency when the need for such therapy has been determined by a physician.

f. *Category I conditions under which vitamin C is generally recognized as safe and effective and is not misbranded.* The Panel recommends that the Category I conditions be effective 30 days after the date of publication of the final monograph in the FEDERAL REGISTER.

Acceptance sources of vitamin C activity are ascorbic acid, ascorbyl palmitate, calcium ascorbate, niacinamide ascorbate (for use only in combinations requiring both niacin and vitamin C), and sodium ascorbate. Dosage must be based on the *L*-ascorbic acid equivalent ($C_6H_8O_6$, molecular weight 176.2).

(1) *Dosage*—(i) *For prevention of deficiency.* For adults and children 1 year of age and older, the oral dosage is 50 to 100 mg daily. For children under 1 year of age, the Panel recommends the advice and supervision of a physician.

(ii) *For treatment of deficiency.* For adults and children 1 year of age and older, the oral dosage is 300 to 500 mg daily. For children under 1 year of age, the Panel recommends the advice and supervision of a physician.

(2) *Labeling.* The Panel recommends the following Category I labeling:

(i) *Indications*—(*a*) *For prevention of deficiency.* "For use in the prevention of vitamin C deficiency when the need for such therapy has been determined by a physician."

(*b*) *For treatment of deficiency.* "For use in the treatment of vitamin C deficiency when the need for such therapy has been determined by a physician."

(ii) *Warnings*—(*a*) *For products containing 0.2 meq (5 mg) or higher of sodium per unit of dose.* The sodium content must be stated per dosage unit (e.g., tablet, teaspoonful) when some or all of the source of vitamin C is sodium ascorbate if the sodium content is 0.2 meq (5 mg) or higher.

(*b*) *For products containing more than 5 meq (125 mg) sodium per unit of dose.* "Do not take this product if you are on a sodium-restricted diet except under the advice and supervision of a physician."

(*c*) *For products containing vitamin C for the treatment of deficiency.* (*1*) "Patients with gout and/or a tendency to form kidney stones may be at increased risk when taking more than the recommended dose."

(*2*) "Diabetics taking more than 500 mg vitamin C daily may obtain false readings in their urinary glucose test."

(iii) *Professional labeling.* The Panel recommends that labeling provided to health professionals (but not to the general public) should contain the following additional information: (*a*) "When diabetics ingest large quantities (greater than 500 mg daily) of vi-

tamin C, the following false results may occur when testing for glycosuria: (*1*) False-negatives for glucose oxidase enzyme strip-tests;

(*2*) False-positives for tests based on copper reduction."

(*b*) "The ingestion of daily doses of 1,000 mg or more vitamin C may result in harmful effects due to hyperoxaluria and to increased urinary acidity and uric acid excretion; oxalate and uric acid crystalization may occur in the kidney or bladder, especially in patients prone to renal stone formation. Additional risk factors include consumption of foods containing high levels of oxalate, and small intestinal disease states, e.g., resectioning, evidencing increased urinary oxalate. Persons consuming these excessive amounts of vitamin C should be under a physician's supervision."

(c) "No exogenous vitamin C should be ingested for 48 to 72 hours prior to conducting amine-dependent stool occult blood tests, to prevent a false-negative test resulting from a high fecal excretion of ascorbic acid."

g. *Category II conditions under which vitamin C is not generally recognized as safe and effective or is misbranded.* The Panel recommends that the Category II conditions be eliminated from OTC Vitamin C drug products effective 6 months after the date of publication of the final monograph in the FEDERAL REGISTER.

The OTC drug use of any source of vitamin C under the following conditions is unsupported by scientific data, and in some instances by sound theoretical reasoning.

The Panel concludes that the following suggested indications appearing in the literature or in the submissions to the Panel for the use of vitamin C sources are presently not supported by adequate controlled clinical studies, or in some instances may require direct supervision by a physican and should not be permitted on the market until scientific testing supports their OTC use:

(i) "Atherosclerosis."

(ii) "Allergy."

(iii) "Mental disease, schizophrenia."

(iv) "Corneal ulcers."

(v) "Idiopathic methemoglobinemia."

(vi) "Thrombosis."

(vii) "Megaloblastic anemia and capillary fragility in the absence of vitamin C deficiency."

(vii) "Adjunctive treatment of iron deficiency anemia in doses less than 200 mg."

(ix) "Treatment of patients on long-term steroid therapy."

(x) "Treatment of immobilized patients and those with pressure sores."

(xi) "Protective or therapeutic effect on the course of the common cold." Although claims have been made for the beneficial effects of 500 to 1,000 mg or more daily of vitamin C for the treatment and/or prevention of the common cold (Ref. 44), double-blind studies have been less than corroborative in this regard (Refs. 45 through 50). Further double-blind studies are required to evaluate fully the validity of the claim. No claims may be made for the use of vitamin C in the treatment of the common cold.

h. *Category III conditions for which the available data are insufficient to permit final classification at this time.* The Panel recommends that a period of 2 years be permitted for the completion of studies to support the movement of Category III conditions to Category I.

None.

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2. *Biotin.*—a. *Description.* Biotin is a water-soluble vitamin which is found widely distributed in nature in small quantities (Ref. 1). Biotin functions in the body as a cofactor in numerous carboxylation and decarboxylation reactions. It is essential for the intermediate metabolism of carbohydrates, the synthesis of fatty acids, and the interconversions of amino acids.

The potency of the vitamin is reflected in the microgram amounts of normal daily intake which appear to be more than adequate for the body's needs. The average American diet has been estimated to provide 100 to 300 μg biotin daily (Ref. 2). In addition, biotin is synthesized by many of the micro-organisms which normally inhabit the human gastrointestinal tract. In studies of several animal species, the amounts of biotin synthesized in the gut are adequate to meet the host's nutritional needs under normal conditions (Ref. 1). The production of relatively large amounts of biotin in the lower gut of man frequently results in total excretion in urine and feces in excess of dietary intake (Refs. 2 through 6). For this reason, it is unknown whether a dietary requirement for biotin exists in human beings (Ref. 2). Experimental evidence indicates that a clinical biotin deficiency cannot be established by mere removal of the vitamin from the diet (Ref. 2).

Increases in urinary biotin concentration following oral administration of large doses indicates that biotin from the diet is relatively well absorbed (Ref. 3). The mechanism by which this absorption takes place is not known. Absorption at the site of bacterial synthesis, in the large intestine, has also been shown by instillation of an aqueous biotin solution directly into the distal colon. Subsequent increases in blood and urine levels of biotin provide evidence that biotin produced by bacteria in the colon is available for absorption (Ref. 7).

b. *Safety.* Little information regarding toxicity of biotin is available. In the treatment of infantile seborrheic dermatitis (Leiner's disease), infants aged 6-months-old and younger, or their mothers, were given biotin by injection in amounts up to 5 mg daily for as long as 6 to 12 days in some cases. No overt toxic symptoms were noted in mothers or infants in the few studies in which these doses of biotin were administered (Refs. 8, 9, and 10). While animal studies further indicate the biotin is a relatively nontoxic substance (Refs. 1 and 11), the upper human safety limit of biotin intake cannot be estimated from available data.

c. *Effectiveness.* Attempts to produce experimental biotin deficiency in some species of animals and in man have required use of the potent biotin inactivator, avidin, which is present in raw egg whites and is destroyed by heat (Ref. 2). When experimental biotin deficiency has been produced in man by feeding large amounts of raw egg white and additionally limiting biotin intake, deficiency symptoms have occurred after several weeks of the dietary regimen (Refs. 12 and 13). The symptom most characteristic of such a deficiency has been a red, scaly dermatitis which responded rapidly to injected doses of 150 to 300 μg biotin daily for 3 to 5 days. Without such treatment, more sever symptoms involving nerual abnormalities subsequently developed (Refs. 12 and 13). Besides experimentally produced deficiencies, occurrence of clinical biotin deficiency in the human population has been reported in only two individuals. In both cases, the persons affected followed the unusual dietary practice of consuming numerous raw eggs daily, combined with few other nutrient sources, for periods of time ranging from several months to many years. Removal of the raw eggs from the diet, or supplementation with foods containing biotin reversed the deficienty symptoms as seen (Refs. 1, 14, and 15).

Slightly decreased concentrations of biotin have been found in the blood of pregnant women, which suggests the possibility of increased utilization of the vitamin during pregnancy or a dilutional effect caused by increased blood volume which normally accompanies the pregnant state (Ref. 16). If increased demands for biotin exist during pregnancy, there is no evidence that such needs are not met by dietary intake of biotin, coupled with intestinal synthesis of the vitamin.

Two extremely rare genetic biotin dependency syndromes, beta-methylcrotonyl-glycinuria and propionic acidaemia, have been described in man and are caused by genetic occurrence of altered biotin-dependent enzymes with a lowered affinity for biotin. Administration of excess biotin alleviated metabolic symptoms of the disorders in the two cases reported (Refs. 17 and 18). An OTC preparation of biotin is not warranted for use in these disorders, however, because they occur very rarely and would require a physician's diagnosis.

In a limited number of studies, biotin has been claimed to be of value in altering the course of infantile seborrheic dermatitis (Leiner's disease) of breast-fed infants of malnourished mothers (Refs. 8, 9, and 10). However, biotin treatment has not always alleviated the disease symptoms. In addition, the fact that substances besides biotin, such as antibiotics and preparations containing several B-vitamins, have been effective in treating some cases of seborrheic dermatitis (Ref. 10) indicates that biotin deficiency may not be a causal factor in this disease. While some of the cases reported suggest low biotin content of the milk of malnourished mothers to be the cause of the disorder, it has not been demonstrated conclusively that levels of

biotin in human milk are responsive to levels of dietary biotin (Ref. 2). Furthermore, it has been found that seborrheic dermatitis occurs among infants fed formula diets containing larger amounts of biotin than does human milk of healthy individuals (Ref. 10). It is therefore doubtful that biotin deficiency is the cause of seborrheic dermatitis in these instances. In conclusion, it appears from the evidence cited that several factors may be responsible for the onset of infantile seborrheic dermatitis. Further research is therefore needed to elucidate the role of biotin in the development of this disease before a recommendation can be made regarding the effectiveness of biotin in prevention or treatment of infantile seborrheic dermatitis. It should also be noted that if biotin were eventually proven to be valuable in the treatment of infantile seborrheic dermatitis, the disease would still require a physican's diagnosis. In addition, the large amounts used (1 to 5 mg) in attempts to treat the disease indicate the possibility of an individual abnormality of biotin utilization and not a simple deficiency state. It is for these reasons that no recommendation for an OTC preparation of biotin for use in treating infantile seborrheic dermatitis can be made.

A limited number of investigations have been conducted to determine the effect of long-term antimicrobial therapy an microbial biotin synthesis in the intestine (Refs. 13 and 19). Theoretically, if bacterial synthesis of biotin were greatly diminished by administration of antimicrobial agents for sufficiently long periods of time, a deficiency of biotin could develop. However, results have been variable in the few reports available and no conclusion of increased dietary need for biotin under conditions of prolonged antimicrobial therapy can be made at this time.

d. *Conclusion.* The Panel has reviewed the scientific literature, the submitted data, and the marketing history of vitamin and mineral ingredients. Based upon the available data, the Panel concludes that biotin deficiency is virtually nonexistent in the U.S. population and that an OTC preparation of biotin, singly or in conbination, is not warranted.

e. *Category I conditions under which biotin is generally recognized as safe and effective and is not misbranded.* The Panel recommends that the Category I conditions be effective 30 days after the date of publication of the final monograph in the FEDERAL REGISTER.

None.

f. *Category II conditions under which biotin is not generally recognized as safe and effective or is misbranded.* The Panel recommends that the Category II conditions be eliminated from OTC biotin drug products effective 6 months after the date of publication of the final monograph in the FEDERAL REGISTER.

The Panel concludes that adequate and reliable scientific evidence excludes any basis for claims for the effective use of an OTC drug preparation of biotin, singly or in combination, for prevention or treatment of biotin deficiency. Biotin is available in the diet from numerous plant and animal sources. Synthesis of biotin by intestinal micro-organisms further assures against a biotin deficiency even under conditions of minimal dietary intake.

The Panel further concludes that the use of biotin in the treatment of infantile seborrheic dermatitis (Leiner's disease) is not supported by adequate scientific evidence and that labels purporting such indications are neither truthful nor accurate.

g. *Category III conditions for which the available data are insufficient to permit final classification.* The Panel recommends that a period of 2 years be permitted for the completion of studies to support the movement of Category III conditions to Category I.

None.

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3. *Choline.* The Panel's statement on choline includes the following ingredients: choline bitartrate, choline chloride, and choline citrate.

a. *Description.* Choline ($C_5H_{15}NO_2$) is a white, water-soluble substance of widespread occurrence, found in abundant quantities in both plant and animal foods (Refs. 1 and 2). Estimates of choline intake in the average American diet range from 150 (Ref. 1) to 900 mg daily (Refs. 1 and 3). Choline is available not only from the diet, but the evidence from a variety of animals and plants studied indicates that choline is synthesized throughout nature (Ref. 4). Choline is synthesized in the human body also by two known pathways. Choline synthesis by transmethylation requires the presence of methyl groups from sources such as methionine. De novo sythesis of methyl groups, requiring adequate amounts of vitamin B-12 and folic acid, can also result in formation of choline in the variety of animal species studied (Ref. 4). Amounts of choline synthesized by these mechanisms in relation to dietary need are not known and appear to depend on a variety of other factors (Refs. 3 and 4). Dietary need for choline, beyond the amount which can be endogenously synthesized, has been demonstrated in a number of animal species (Refs. 1 and 3 through 6). It is possible that a need for dietary choline could also be demonstrated in man under experimental conditions involving systematic removal of choline from the diet (Ref. 3). However, choline deficiency has

not yet been produced in man, and there is no evidence that a dietary need for choline exists for man.

Biochemically, choline functions as a constituent of phospholipids, notably sphingomyelin and lecithin (Refs. 2, 3, and 4). It also serves in the formation of acetylcholine, a substance necessary for neural transmission. Choline further functions as part of a labile methly pool, capable of contributing methyl groups for the synthesis of the amino acid methionine and other methylated compounds necessary for proper growth and cell function (Ref. 4).

Toxic substances known to interfere with choline metabolism in the rat include 2-amino-2-methyl propanol and alpha, alpha-dimethyltriethyl-choline (Refs. 7 and 8). Effects of these inhibitors are overcome by inclusion of excess choline in the diet. Recent research with rats indicates possible interference with choline utilization by phenobarbital (Ref. 9) and by methotrexate, a drug used in treatment of cancer (Ref. 10).

b. *Safety.* Few studies of the toxicity of choline in man are available. However, data concerning various species of animals studied indicate that oral doses are generally less toxic than injected doses (Ref. 1). Choline has been found to be lethal to rabbits when administered subcutaneously in doses of 500 mg/kg of body weight (Ref. 2). Choline chloride is lethal to mice when give interparenterally in doses of 31.3 mg/kg of body weight (Ref. 2). A study of choline toxicity in rats revealed that both the dosage of choline and the vehicle used for its oral administration affected its toxicity. For example, choline chloride fed at 2.7 to 5.0 percent of the diet resulted in decreased growth rate but no deaths among rats studied for 3 to 4 months, while choline chloride fed as 4 percent of the drinking water resulted in the death of all rats studied within 3 months (Ref. 1). It is possible that the greater toxicity seen when choline was fed in the drinking water was an indirect effect of decreased water consumption and not due to the choline itself. The death rate from choline toxicity was found to be comparable between rats and guinea pigs given intraparenteral doses of choline of 45 or 60 mg/100 g of body weight. At the lower dosage, 20 to 29 percent of the animals tested died, while 60 to 74 percent died when the 60 mg dose was injected (Ref. 11).

No reports of choline toxicity in human beings are apparent. Therapeutic doses of choline chloride and of choline dihydrogen citrate, in amounts ranging from 3 to 12 g daily, have been used in the treatment of alcoholic cirrhosis for periods of time ranging from a few days to 4 months as described below, with no toxic effects reported (Refs. 12 through 16). While no data are available regarding the effect of large doses of choline given to normal individuals for indefinite periods of time, there is not evidence from the few cirrhotic patients studied that choline would be toxic at levels several times those commonly ingested in the diet.

c. *Effectiveness.* Bioavailability of choline from any pharmaceutical product can be determined by analysis in plasma and tissues for choline content, using a microbiological assay (Ref. 4). Choline cholride and choline dihydrogen citrate are the forms of choline most frequently used in human studies (Refs. 12, 13, and 14). In addition, choline gluconate and choline phosphate appear to have equal absorptive value (Ref. 1).

Choline deficiency has been induced in a number of animal species, including the rat, guinea pig, dog, pig, monkey, and several species of poultry (Refs. 4, 5, and 6). In most cases the diet used to produce such a deficiency is low in both choline and protein content. Symptoms vary depending on the species studied. However, the most common symptoms found are low growth rate, fatty infiltration of the liver, and hemorrhagic kidney disease.

The fatty liver sign of choline deficiency in animals has received much attention because of its similarity to fatty livers seen in human beings suffering from alcoholism, and to the fatty liver of kwashiorkor. However, animal studies reveal that complex factors are involved in deposition of liver fat. While insufficient amounts of choline is one factor which can bring about fatty infiltration of the liver, other nutritional and physiological factors appear to greatly modify the amount of choline necessary to prevent such liver damage. These influences include the amount of dietary protein (Refs. 17 and 18) and fat (Refs. 4, 5, 19, and 20), type of dietary carbohydrate (Refs. 21 through 24), number of calories fed (Refs. 4, 20, and 25), and possibly the amount of dietary cholesterol (Refs. 6 and 20). In addition, other nutrients, including vitamin B-12 (Refs. 4 and 26) and methionine, threonine, and other amino acids (Refs. 21 and 27) have been shown to prevent or reverse fatty liver symptoms in animals fed low choline diets.

Physiological factors shown to influence choline needs in animals include hormone imbalances, sex, age, and environmental temperature (Refs. 4, 5, 13, and 26). Because of the interplay of these various nutritional and physiological factors, results of studies of choline deficiency in animals have varied widely. It has, therefore, been difficult to assess the importance of dietary choline alone in prevention of fat deposition in the liver. It is likely further that the numerous nutritional and physiological factors influencing the amount of choline required by animals influence choline needs in man.

It is presently believed by the majority of researchers that protein deficiency is the critical element resulting in fat deposition in the liver of children suffering from kwashiorkor (Refs. 4 and 28). The possibility that cirrhosis of chronic alcoholism is a result of inadequate amounts of dietary choline has prompted numerous animal studies, conducted to determine the role of choline and other nutritional factors in ethanol-induced liver damage (Refs. 4, 13, 19, 22, 24, 25, 29, and 30).

As might be expected from results of studies cited concerning choline deficiency alone, results of the effect of choline and other nutritional factors on the fatty liver of cirrhosis are varied. The physiological and nutritional factors determining the need for dietary choline are further complicated by introduction of ethanol.

As a result, it has not yet been determined whether alcoholic cirrhosis in man or animals is caused by one or more nutritional deficiencies, a toxic effect of alcohol itself, an effect of increased calories from alcohol, or a combination of these factors or some other unknown factor (Refs. 4, 13, 19, 22, 24, 25, 29, 30, and 31). In extrapolating animal studies on nutritional factors in alcoholism to human beings, caution must be used for several reasons. In general, it can be said that choline has been shown to have an effect on development of ethanol-induced fatty livers in animals when the choline is supplied at low or marginal amounts in the diet (Ref. 29). However, no relation between dietary choline levels and the occurrence and severity of alcoholic fatty livers in man has ever been demonstrated. In addition, while rats have been used in the majority of ethanol studies in animals, a limited number of enzyme studies suggest possible basic difference between choline metabolism in rats and man and other primates (Refs. 1, 32, 33, and 34). Such differences could, theoretically, reduce the applicability of choline-ethanol relationships in rats to those in man. Furthermore, the correlation between fatty livers in animals and those seen in human beings has not been conclusively established (Ref. 4), nor has the presence of fat in the liver been determined to be causally related to cirrhosis in man (Refs. 15 and 29).

Studies of the effect of choline therapy in alcoholic cirrhosis of human beings are limited and with varying results (Refs. 12 through 15 and 35). In general, such studies often lack ade-

quate controls, employ few numbers of patients, and are carried out over periods of time which are too short in duration to allow for reliable evaluation of results. In addition, most subjects suffering from alcoholism exhibit multiple nutritional deficiencies and vary greatly in response to treatment, making evaluation of any single factor extremely difficult (Refs. 1, 4, and 13).

It does seem quite clear that choline is of no benefit in the treatment of cirrhosis. The majority of the evidence indicates that a diet adequate in all essential nutrients is the most effective in the treatment of cirrhosis. There is no reason to believe that optimal amounts of choline and its precursors are not supplied by such a balanced diet (Refs. 1, 4, 12 through 15, and 35). Also, there is not evidence that alcohol intake increases the need for choline, although, of course, it frequently causes anorexia and decreased food intake (Refs. 1, 4, and 12 through 14).

Choline deficiency has not been demonstrated in man and, in view of the widespread occurrence of choline and methionine in plant and animal foodstuffs, it seems unlikely that is would occur, except possibly in infants or young children with diets severely deficient in protein and rich in highly refined products (Ref. 3). Mixed diets are estimated to provide adults with 400 to 900 mg choline daily (Ref. 3). Such amounts are evidently adequate but, as the quantity of choline synthesized by the body is not known and as mixed diets also provide methionine and probably other methyl donors, these amounts should not be equated with either requirements or dietary allowances (Ref. 3).

d. *Conclusion.* The Panel has reviewed the scientific literature, the submitted data, and the marketing history of vitamin and mineral ingredients. Based upon the available data, the Panel concludes that choline deficiency is virtually nonexistent in the U.S. population and that an OTC drug preparation of choline, singly or in combination, is not warranted.

e. *Category I conditions under which choline is generally recognized as safe and effective and is not misbranded.* The Panel recommends that the Category I conditions be effective 30 days after the date of publication of the final monograph in the FEDERAL REGISTER.

None.

f. *Category II conditions under which choline is not generally recognized as safe and effective or is misbranded.* The Panel recommends that the Category II conditions be eliminated from OTC choline drug products effective 6 months after the date of publication of the final monograph in the FEDERAL REGISTER.

The Panel concludes that the OTC drug use of choline chloride, choline bitartrate, and choline citrate is not supported by adequate scientific evidence. A choline deficiency syndrome has never been demonstrated in man, and because choline can readily be manufactured within the body from a number of dietary sources of labile methyl groups and there cannot be said to be, for man, a dietary requirement for preformed choline, the Panel concludes that there is no evidence of any drug need for an OTC choline preparation of any kind.

g. *Category III conditions for which the available data are insufficient to permit final classification.* The Panel recommends that a period of 2 years be permitted for the completion of studies to support the movement of Category III conditions to Category I.

None.

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4. *Vitamin B-12.* The Panel's statement on vitamin B-12 includes the following ingredient: cyanocobalamin.

a. *Reference form.* Dosages recommended in this document are based on the cyanocobalamin equivalent ($C_{63}H_{88}CoN_{14}O_{14}P$, molecular weight 1355.4).

b. *Description.* Vitamin B-12 is a term in common usage to refer to a series of cobalt-containing, nutritionally active corrinoids. The two metabolically active coenzyme forms in man and those found in mammalian tissues are 5-deoxyadenosyl cobalamin (coenzyme B-12) and methyl cobalamin (methyl B-12). The most commonly used oral form of vitamin B-12 is cyanocobalamin. Other semisynthetic forms of vitamin B-12, equipotent with cyanocobalamin for treatment or prevention of vitamin B-12 deficiency, include hydroxycobalamin, aqua cobalamin, and nitritocobalamin. However, the Panel concludes that only cyanocobalamin is acceptable as an OTC drug source of vitamin B-12 activity.

Vitamin B-12 is required for DNA synthesis and cell replication by all mammalian species. As a cofactor in methionine synthesis, vitamin B-12 participates in the conversion to tetrahydrofolate from methyl tetrahydrofolate, thus generating the cofactor for the synthesis of thymidine. In addition, vitamin B-12 is a required cofactor in the interconversion of methyl malonic acid and succinic acid by methyl malonyl CoA mutase (Ref. 1). Vitamin B-12 deficiency is characterized by megaloblastic anemia and similar megaloblastic alterations in other tissues such as the gastrointestinal tract epithelium. Methyl malonic acid or precursors may appear abnormally in urine in vitamin B-12 deficient subjects or in those with genetic defects in vitamin B-12 utilization. Neurologic degeneration may occur when deficiency is prolonged and severe (Ref. 2).

Animal meat including liver, fish, seafood, and eggs are good sources of vitamin B-12. Daily requirements are small, in the range of 0.3 to 2.5 μg (Refs. 3 and 4) and an efficient enterohepatic circulation is capable of conserving several times that amount daily (Ref. 4). The liver can store 1,000 to 1,500 μg in a normal adult, an amount capable of sustaining vitamin B-12 needs for 3 to 5 years.

c. *Safety.* No toxic effects of oral vitamin B-12 have been demonstrated in humans. As a water-soluble substance, excess vitamin B-12 is excreted in urine. Single oral doses ranging from 0.5 to 100 mg have been administered to humans. No apparent side effects were observed (Refs. 5 through 8).

During long-term therapy (3 to 5 years) with weekly oral doses of 1 mg crystalline vitamin B-12, no adverse effects were observed (Ref. 9).

d. *Effectiveness.* Normal absorption of dietary vitamin B-12 occurs by two mechanisms. One mechanism is operative under usual dietary conditions and the other mechanism operates at a significant rate only at vitamin intakes far beyond those in the usual diet. The first absorption mechanism requires the participation of a gastric factor, Intrinsic Factor of Castle (IF), a glycoprotein secreted by the parietal cells of the stomach. The glycoprotein forms a complex with ingested vitamin B-12 in the presence of gastric acid, and the vitamin B-12-IF complex then passes to the distal small intestine or terminal ileum where vitamin B-12 is taken up into the ileal epithelial cells with the aid of specific membrane receptors. This mechanism has an efficiency of about 50 percent when the dose is up to 10 μg. At doses higher than 10 μg the efficiency of absoprtion decreases (Ref. 10). Thus a 10 μg oral dose is considered by this Panel to be an effective dose for the prevention of dietary deficiency because increasing the quantity will produce no additional benefit. The second mechanism of absorption occurs by diffusion at a very low rate with an efficiency of about 1 percent and is quantitatively significant only at oral doses in excess of 100 μg (Ref. 11).

Dietary deficiency of vitamin B-12 is rare. For practical purposes, dietary deficiency occurs in individuals with normal gastrointestinal function only after several years on a very strict vegetarian diet. Dietary deficiency does not occur in ovolacto vegetarians (those who add eggs and milk to a vegetarin diet).

Vitamin B-12 deficiency usually occurs when gastric intrinsic factor is lacking (e.g., pernicious anemia) or when the ileal absorption site is lost or damaged by surgery or disease (Ref. 12). Under these conditions, injected vitamin B-12 is the only entirely reliable means of ensuring an adequate vitamin supply (Ref. 13). Vitamin B-12 deficiency may occur as an acquired condition when the intestine is overgrown abnormally with bacteria or infested with fish tapeworm. In both instances, the deficiency is due to a competition with the offending organism for binding and utilization of vitamin B-12. Therapy consists of eradication of the infestation and treatment of deficiency, if severe, with a single parenteral dose of vitamin B-12.

Vitamin B-12 deficiency may occur due to rare genetic metabolic defects in spite of an adequate amount of dietary intake of vitamin B-12. These metabolic defects include abnormalities in the synthesis of intrinsic factor, ileal receptors, vitamin B-12 transfer proteins (transcobalamins), and enzymes which convert vitamin B-12 to coenzyme forms (Ref. 14). Defective apoenzymes may result in vitamin B-12 requirements 20 to 100 times the usual needs. It should be emphasized that these genetic conditions are rare and require the skill and technology of a sophisticated medical center for diagnosis and managment.

When vitamin B-12 deficiency is due to inadequate absorption, 1 μg parenteral vitamin B-12 daily is adequate (Refs. 10 and 13) and a single 100 μg injection is almost always curtive of all manifestations of deficiency. These conditions are most reliably treated with regular intramuscular vitamin B-12 therapy. The pharmacologic mechanism of absorption could only be utilized safely in therapy if large doses (greater than 100 μg) of oral vitamin B-12 were used under careful medicial supervision to document adequate absorption and utilization. Therapy of the genetic defects requires high dose therapy (20 to 100 times normal) by the intramuscular route under medical care (Refs. 14 and 15).

The documented indications for reliable oral vitamin B-12 therapy are limited to dietary vitamin B-12 deficiency in the rare vegan (an individual adhering to a strict vegetarian diet including no animal products) or in individuals adhering to certain other types of vegetarian diets. Deficiency due to malabsorption associated with diseases of the stomach (e.g., pernicious anemia) and/or the small intestine (e.g., ileal resection, bacterial overgrowth, tropical sprue) or due to rare

genetic defects resulting in malabsorption or block in the metabolic utilization requires parenteral therapy and the careful surveillance of a physician.

The physiologic mechanism of vitamin B-12 absorption has a capacity of 1.5 to 3 μg per dose (Ref. 10). At approximately a 50 percent efficiency, an oral dose of 3 to 10 μg results in an adequate dose of bioavailable vitamin B-12 in the normal individual.

e. *Conclusion.* The Panel has reviewed the scientific literature, the submitted data, and the marketing history of vitamin and mineral ingredients. Based upon the available data, the Panel concludes that vitamin B-12, in the dosage and form identified under Category I conditions below, is safe and effective for use in the prevention of vitamin B-12 dietary deficiency when the need for such therapy has been determined by a physician.

f. *Category I conditions under which vitamin B-12 is generally recognized as safe and effective and is not misbranded.* The Panel recommends that the Category I conditions be effective 30 days after the date of publication of the final monograph in the FEDERAL REGISTER.

Cyanocobalamin is the only acceptable source of vitamin B-12 activity. Dosage must be based on the cyanocobalamin equivalent ($C_{63}H_{88}CoN_{14}O_{14}P$, molecular weight 1355.4.).

(1) *Dosage—For prevention of dietary deficiency.* For adults and children 1 year of age and older, the oral dosage is 3 to 10 μg daily. For children under 1 year of age, the Panel recommends the advice and supervision of a physician.

(2) *Labeling.* The Panel recommends the following Category I labeling:

(i) *Indication—For prevention of dietary deficiency. "For use in the prevention of vitamin B-12 dietary deficiency when the need for such therapy has been determined by a physician."*

(ii) *Warnings—(a) For products containing vitamin B-12 as the only active ingredient.* "Caution: This preparation is for the prevention of vitamin B-12 dietary deficiency and cannot be safely used for the treatment of vitamin B-12 dietary deficiency."

(b) For combination products for the treatment of multiple deficiencies which contain a prevention dose of 10 μg. "This product cannot be safely used for the treatment of vitamin B-12 deficiency."

g. *Category II conditions under which vitamin B-12 is not generally recognized as safe and effective or is misbranded.* The Panel recommends that the Category II conditions be eliminated from OTC vitamin B-12 drug products effective 6 months after the date of publication of the final monograph in the FEDERAL REGISTER.

The Panel concludes that the OTC oral drug use of cyanocobalamin, for the following indications, is not supported by adequate scientific evidence and that labels purporting such indications are neither truthful nor accurate: (1) "For the treatment of vitamin B-12 deficiency secondary to pernicious anemia."

(2) "For vitamin B-12 deficiency secondary to gastrointestinal malabsorption."

(3) "For use in genetic vitamin B-12 or dependency syndromes, e.g., methyl malonic aciduria."

h. *Category III conditions for which the available data are insufficient to permit final classification at this time.* The Panel recommends that a period of 2 years by permitted for the completion of studies to support the movement of Category III conditions to Category I.

(1) *Proposed dosage—For prevention of dietary deficiency.* For women taking oral contraceptives, the oral dosage is 3 to 10 μg daily.

(2) *Proposed labeling.* The Panel recommends the following specific labeling for vitamin B-12 for use in women taking oral contraceptives:

Indication—For prevention of dietary deficiency. "For use in the prevention of vitamin B-12 deficiency in women taking oral contraceptives when the need for such therapy has been determined by a physician."

(3) *Evaluation.* Further study is required to document the following: (i) That vitamin B-12 deficiency, characterized by a lowering of serum vitamin B-12 and by morphologic changes in blood or bone marrow, occurs at increased prevalence in women on oral contraceptives relative to appropriate controls.

(ii) That such deficiency is prevented by a daily oral dose of vitamin B-12.

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5. *Folacin.* The Panel's statement on folacin includes the following ingredient: folic acid.

a. *Reference form.* Dosages recommended in this document are based on the pteroyl mono-*L*-glutamic acid equivalent ($C_{19}H_{19}N_7O_6$, molecular weight 441.4).

B. *Description.* Folacin is the generic term for folic acid (pteroylmonoglutamic acid, PGA) and related compounds exhibiting qualitatively the biologic activity of folic acid. Most of the vitamin is present in food as polyglutamates (Ref. 1), which require the action of an intestinal peptidase to free the vitamin for release into the circulation (Ref. 2) Folacin is present in a wide variety of foods, especially liver, leafy vegetables, certain fruit, and yeast.

While dietary folacin consists largely of reduced folates in monoglutamyl or polyglutamyl form, the only synthetic preparation commercially available for oral use is PGA. Once folic acid is absorbed, it must undergo further metabolic conversion to its coenzymatic forms via a series of reduction reactions. The final products, tetrahydrofolates, function primarily in single carbon transfers and along with vitamin B-12 in nucleic acid synthesis. A deficiency characteristically leads to megaloblastic anemia (Ref. 3).

c. *Safety.* Prior to 1973, regulations limited the content of folic acid in multivitamin dietary supplement preparations to 0.1 mg. This limitation was based largely on studies which showed that injections of PGA in doses greater than 0.4 mg could cause remission of the hematologic but not the neurologic complications of pernicious anemia and could, therefore, mask that diagnosis and prevent early intervention and reversal of the neurologic complications of that disease (Refs. 4, 5, and 6). It has also been shown that oral doses of folic acid, at or near the daily requirement of 0.1 to 0.4 mg, would not correct the hematologic complications of vitamin B-12 deficiency anemia (given an absorption efficiency of approximately 50 percent). The effective oral dose required to mask the diagnosis of pernicious anemia would be greater than the 0.4 mg parenteral dose (Ref. 7). Therefore, the case against the widespread use of folic acid in vitamins based on the potential missed diagnosis of pernicious anemia is not substantial and must be weighed against the prevention of folic acid deficiency.

No toxic effects of folic acid are known at doses as high as 15 mg daily. It has been claimed that larger doses of folic acid may reverse effects of anticonvulsants and contribute to seizures (Refs. 8 and 9). These claims are under study.

d. *Effectiveness.* The average daily requirement of crystalline folic acid is based upon hematologic responses to minimal doses of PGA in deficient subjects and a variety of deficiency induction experiments in human volunteers. Evidence exists that daily 0.05 mg PGA orally will induce a complete hematologic remission in most, if not all, patients with folic acid deficiency anemia which is not due to malabsorption (Ref. 4). Similarly, 0.05 mg PGA daily will prevent biochemical evidence of folic acid deficiency in experimental subjects ingesting diets severely deficient in folacin (Ref. 10). Furthermore, the classic time-depletion study in a normal volunteer in whom tissue stores were estimated to be 7.5 mg indicated that about 0.05 mg folic acid were utilized each day (Ref. 11). For normal adults most evidence would place the daily requirement at approximately 0.05 mg crystalline folic acid daily. Doses of 0.1 to 0.2 mg daily are necessary, however, to induce normal serum levels of folic acid in deficient individuals (Refs. 4 and 5).

PGA administered to normal, fasting subjects in doses between 0.2 and 1 mg is absorbed with an efficiency ranging from 45 to 79 percent based upon urinary excretion of labeled folate (Refs. 2 and 12). Disease of the gastrointestinal tract, alcoholism, and drugs such as diphenylhydantoin may depress absorption of the crystalline PGA to 10 to 30 percent (Refs. 2 and 12). Allowing for a wide range of absorption of oral PGA, the recommended upper dose is set at 0.4 mg. For the pregnant and lactating female, the recommendation is for approximately twice that value (1 mg) to insure adequate folate in the presence of increased requirement. Folacin deficiency has been documented in high prevalence among pregnant women (Refs. 10, 13, and 14); patients with diseases affecting the gastrointestinal tract, including celiac disease and other forms of malabsorption, ulcerative colitis, and regional enteritis; patients with intestinal resection; alcoholics; and patients who use certain medications such as anticonvulsants (Ref. 9). Low serum folate levels have been reported in patients taking oral contraceptive pills (Ref. 15). However, an increased incidence of folate deficiency anemia has not been proven and the changes in serum may represent changes in folate binding in serum rather than folate depletion. Initial reports that oral contraceptives interfere with absorption of natural folates are not confirmed (Ref. 16).

Some drugs may cause or contribute to folate deficiency by interfering with either absorption or utilization of folate (Ref. 17). Diagnosis is based on evidence of low serum folate levels and low red cell folate levels, with or without characteristic changes in blood morphology.

e. *Conclusion.* The Panel has reviewed the scientific literature, the submitted data, and the marketing history of vitamin and mineral ingredients. Based upon the available data, the Panel concludes that folic acid, in the dosage and form identified under Category I conditions below, is safe and effective for use in the prevention of folic acid deficiency when the need for such therapy has been determined by a physician.

f. *Category I conditions under which folacin is generally recognized as safe and effective and is not misbranded for the prevention of folic acid deficiency.* The Panel recommends that the Category I conditions be effective 30 days after the date of publication of the final monograph in the FEDERAL REGISTER.

Folic acid is the only acceptable source of folacin activity. Dosage must be based on the pteroyl mono-*L*-glutamic acid equivalent ($C_{19}H_{19}N_7O_6$, molecular weight 441.4).

(1) *Dosage—For prevention of deficiency.* For adults and children 1 year of age and older, the oral dosage is 0.1 to 0.4 mg daily. For pregnant and lactating women, the oral dosage is 1.0 mg daily. For those persons who use alcohol to excess, the oral dosage is 1.0 mg daily. For children under 1 year of age, the Panel recommends the advice and supervision of a physician.

(2) *Labeling.* The Panel recommends the following Category I labeling:

(i) *Indication—For prevention of deficiency.* "For use in the prevention of folic acid deficiency when the need for such therapy has been determined by a physician."

(ii) *Warnings—(a) For products containing 1 mg folic acid per unit of dose.* (*1*) "Caution: The use of folic acid for treatment of anemia without the direction of a physician may be dangerous."

(*2*) "Do not exceed the recommended daily dosage."

(*b*) *For combination products for the treatment of multiple deficiencies which contain a prevention dose of 1 mg folic acid.* "This product cannot be safely used for the treatment of folic acid deficiency."

g. *Category II conditions under which folacin is not generally recognized as safe and effective or is misbranded.* The Panel recommends that the Category II conditions be eliminated from OTC folacin drug products effective 6 months after the date of publication of the final monograph in the FEDERAL REGISTER.

The OTC drug use of folacin under the following condition is unsupported by scientific data and by sound theoretical reasoning.

The Panel concludes that the use of folacin for the treatment of folic acid deficiency is not supported and can be safely undertaken only under the direct supervision of a physician and therefore requires a prescription mode of therapy.

h. *Category III conditions for which the available data are insufficient to permit final classification at this time.* The Panel recommends that a period of 2 years be permitted for the completion of studies to support the movement of Category III conditions to Category I.

(1) *Proposed dosage—For prevention of deficiency.* For women taking oral contraceptives, the oral dosage is 0.1 to 1.0 mg daily.

(2) *Proposed labeling.* The Panel recommends the following specific labeling for folic acid for use with oral contraceptives:

Indication. "For use in the prevention of folic acid deficiency in women taking oral contraceptives when the need for such therapy has been determined by a physician."

(3) *Evaluation.* Further study is required to document the following: (i) That folic acid deficiency, characterized by a lowering of red cell folic acid or by morphological changes in blood or bone marrow (macrocytosis, hyperlobation of polymorphonuclear leukocytes, megaloblastic changes in marrow), occurs at increased preva-

lence with women on oral contraceptives relative to appropriate controls.

(ii) That such deficiency is prevented by a daily oral dose of folic acid from 0.1 to 1.0 mg.

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6. *Niacin.* The Panel's statement on niacin includes the following ingredients: niacin (nicotinic acid), niacinamide, and niacinamide ascorbate.

a. *Reference form.* Dosages recommended in this document for niacin are based on the niacinamide equivalent ($C_6H_6N_2O$, molecular weight 122.1).

b. *Description.* Niacin is the generic descriptor for compounds exhibiting the biologic activity of niacinamide, including niacin (nicotinic acid) and niacinamide. It occurs in biologic materials as nicotinic acid and niacinamide, plus two coenzymatic forms, nicotinamide (niacinamide) adenine dinucleotide (NAD) and nicotinamide adenide dinucleotide phosphate (NADP). These coenzymes act as electron transfer agents and catalyze a variety of basic biochemical reactions involving carbohydrates, amino acids, and fats. Dietary tryptophan is a major precursor of niacin, approximately 60 mg tryptophan being converted into 1 mg niacin (Refs. 1 and 2). Niacin is excreted in urine in a number of forms. In man, the principal metabolites are N'-methylnicotinamide and the N'-methyl-6-pyridone-3-carboxamide. Excretion of niacin metabolites is influenced not only by intake, but also by the need of the body, the amount of methyl donors, the efficiency of the methylating mechanisms, the amount of biosynthesis from tryptophan, and other factors (Ref. 3). On a niacin-deficient diet, urinary levels usually drop rapidly to a low and constant level before any sumptoms of deficiency become evident (Ref. 3).

c. *Safety.* Niacinamide (nicotinamide) is the preferred OTC form of the vitamin because of fewer side effects at higher levels.

(1) *Studies comparing nicotinic acid with nicotinamide.* In a study comparing equal amounts of nicotinic acid and nicotinamide (3 to 7.5 g) in eight subjects, ages 38 to 61, serum cholesterol levels dropped with nicotinic acid treatment lasting 30 weeks (Ref. 4). Symptoms included flushing, dryness of the skin, and irritable bowel symptoms. After 12 weeks of nicotinamide administration, neither the hypolipidemic effect nor other side effects were observed.

Altschul, Hoffer, and Stephen (Ref. 5) administered 1 g nicotinic acid four times daily to 11 healthy young people, and 1 g nicotinic acid daily to 57 patients with various diseases. Nicotinic acid decreased serum cholesterol levels. Similar tests with the same doses of nicotinamide in 20 healthy young adults showed no definite influence on serum cholesterol levels. Flushing and burning of the skin were side effects in the patients receiving nicotinic acid treatment, but no symptoms were noted for those receiving nicotinamide.

Using 3 to 6 mg/100 ml serum uric acid as a normal range, Parsons noted that of 49 patients receiving 3 to 6 g nicotinic acid daily for over 2 years, 38 persons had elevated serum uric acid levels (6.5 mg/100 ml) (Ref. 6). During 12-week therapy with an equal dosage of nicotinamide, in a 10-patient sample, 7 showed average serum uric acid levels of 6.5 mg/100 ml or greater. No gouty arthritis or renal calculi were observed with either drug.

(2) *Nicotinamide tolerance.* There are only a few other studies which help to determine the minimum toxic level of nicotinamide. These few studies, most of which are with animals, confirm the previously cited studies showing that this substance has no observed toxicity up to a range of 3 to 9 g daily. The exact level over a long time is not known. Only one case history appears to have been published showing evidence of toxicity at this level (9 g) in man, so the total evidence is weak.

In this case history, the 35-year-old patient developed severe signs of toxicity after taking 9 g nicotinamide for 7 days, including nausea, vomiting, anorexia, and fatigue (Ref. 7). A liver biopsy revealed portal fibrosis and swollen parenchymal cells. Liver function tests returned to normal 3 weeks after nicotinamide treatment was stopped.

(3) *Nicotinic acid tolerance.* Human studies with nicotinic acid alone show that even relatively small doses give a pharmacological effect. Spies et al. (Ref. 8) noted cutaneous flushing, burning, itching of the skin, and increased sensation of heat in five individuals when 50 mg nicotinic acid in aqueous solution was given as a single oral dose to 100 adult nonpellagrins on an empty stomach. When 100 mg was given under the conditions, about 50 percent of the group exhibited these symptoms. A majority had a reaction when 200 mg was given, and all had some degree of flushing when 500 mg was administered. Four of these 100 adults complained of nausea and cramps after single oral doses of nicotinic acid ranging from 300 to 1,500 mg administered while the stomach was empty.

Goldsmith and Cordill (Ref. 9) administered single oral 50 mg doses of nicotinic acid in aqueous solution to three normal subjects. Responses varied from no skin reaction to severe flushing reaction, with the time of onset from 4 to 23 minutes after administration, and duration of flush from 10 to 90 minutes. When six subjects were given single oral doses of 100 mg, they showed mild to severe flushing reactions. A dose of 200 mg under the same conditions resulted in the same range of response for three persons.

Because of the known serum cholesterol-lowering effect of nicotinic acid, it has been used at relatively high

levels in therapy with hypercholesterolemia. Seventeen female and 31 male patients (ages 35 to 70) with elevated serum cholesterol levels were administered nicotinic acid beginning with 350 or 500 mg doses three times daily, and increasing to 3,000 mg daily if tolerated (Ref. 10). All 48 patients showed flushing. In the period of study from 1 to 10 months, 16 stopped medication because of the severity of the reaction. Forty percent of the patients (19) reported gastrointestinal distress, and 25 percent (12) complained of pruritis. Two individuals suffered from reactivation of peptic ulcers, and six individuals developed "unusual nervousness." Activation of peptic ulcer symptoms in five patients is reported by Parsons at 3 to 7.5 g daily of unbuffered nicotinic acid (Ref. 11). Gastrointestinal symptoms were absent when 1 g buffered nicotinic acid (0.6 g sodium bicarbonate for each g of acid) was administered three times daily for 2 weeks to 12 young adults (Ref. 12). Other human studies with 3 g nicotinic acid confirm these side effects (Refs. 13 through 16). Several individual cases of jaundice and hepatic abnormalities have also been reported with an intake of 3 g nicotinic acid (Refs. 17, 18, and 19).

Of 47 patients (average age 29) who completed at least 24 months of nicotinic acid therapy (3 g daily) for schizophrenia, it was reported that one-third of the subjects developed pigmented hyperkeratosis resembling acanthosis nigricans after several months (Ref. 20).

Glucose intolerance (100 mg glucose load) was demonstrated in five subjects given a 4.5 g treatment of nicotinic acid daily for 4 weeks. Pruritis, nausea, elevated plasma insulin, and elevated plasma uric acid were also side effects which returned to normal within 1 week after nicotinic acid treatment was stopped (Ref. 21). Glucose intolerance was also observed in three diabetics and seven nondiabetics (Ref. 22).

In summary, nicotinic acid produces side effects beginning with single 50 mg oral doses daily, whereas no untoward effects accompany intake of nicotinamide until 3 to 9 g doses are reached.

d. *Effectiveness.* Extra niacin is desirable when taking drugs or chemicals which exhibit antiniacin activity, such as 6-mercaptopurine, or when experiencing conditions which increase the need for the vitamin, such as alcoholism (Ref. 23). A dose of 50 mg daily is recommended under these circumstances.

Body depletion of niacin leads to pellagra with diarrhea, dermatitis, and mental abnormalities. A deficiency state may also be associated with reduced growth, weight loss, loss of appetite, and difficulties in reproduction and lactation (Ref. 24). Pathologic changes include dilation of skin blood vessels, abnormalities of keratinization, ulceration of mucous membranes, and chromatolysis of ganglion cells in the brain. Molecular mechanisms for these manifestations have not been defined. A deficiency state is accompanied by decreased blood and urine levels of niacin and its metabolites, reduced tissue phosphopyridine nucleotides (Ref. 25).

Niacin deficiency, which has been greatly reduced by the enrichment of flour, continues to be a problem among food faddists, alcoholics, and patients with debilitating illness. A survey revealed low circulating levels of niacin in 34 percent of Chinese, 46 percent of Black, 56 percent of Caucasian, and 60 percent of Puerto Rican school children tested in New York City (Ref. 26). Twenty-nine percent of randomly selected hospitalized patients in a municipal hospital in New Jersey had a deficiency of this vitamin (Ref. 27). Dietary histories revealed that this was attributable to a deficient intake of the vitamin in one-third of the patients (Ref. 27).

A variety of methods have been used to test for niacin bioavailability. OTC niacin-containing products should be evaluated with respect to their ability to increase tissue or body fluid niacin levels. Absorbability of niacin in an unknown preparation may be documented by measuring urinary excretion of N'-methylnicotinamide and N'-methyl-6-pyridone-3-carboxamide (Ref. 28). Results are expressed in terms of milligrams per gram (mg/g) creatinine excreted in 24 hours. Alternatively, microbiologic methods may be used to measure blood or urine levels of niacin after a test dose of the vitamin (Ref. 29). Both of these approaches require subjects with no abnormality in intestinal transport or intermediary tryptophan metabolism, and who are not receiving drugs which may influence niacin metabolism. The normal male should excrete approximately 50 percent of a 10 mg dose in the form of niacin metabolites.

e. *Conclusion.* The Panel has reviewed the scientific literature, the submitted data, and the marketing history of vitamin and mineral ingredients. Based upon the available data, the Panel concludes that niacin, in the dosage and forms identified under Category I conditions below, is safe and effective for use in the prevention of niacin deficiency when the need for such therapy has been determined by a physician.

f. *Category I conditions under which niacin is generally recognized as safe and effective and is not misbranded.* The Panel recommends that the Category I conditions be effective 30 days after the date of publication of the final monograph in the FEDERAL REGISTER.

Acceptable sources of niacin activity are niacinamide and niacinamide ascorbate. Dosage must be based on the niacinamide equivalent ($C_6H_6N_2O$, molecular weight 122.1).

(1) *Dosage*—(i) *For prevention of deficiency.* For adults and children 1 year of age and older, the oral dosage is 10 to 20 mg daily. For children under 1 year of age, the Panel recommends the advice and supervision of a physician.

(ii) *For treatment of deficiency.* For adults and children 1 year of age and older, the oral dosage is 25 to 50 mg daily. For children under 1 year of age, the Panel recommends the advice and supervision of a physician.

(2) *Labeling.* The Panel recommends the following Category I labeling:

Indications—(*a*) *For prevention of deficiency.* "For use in the prevention of niacin deficiency when the neeed for such therapy has been determined by a physician."

(*b*) *For treatment of deficiency.* "For use in the treatment of niacin deficiency when the need for such therapy has been determined by a physician."

g. *Category II conditions under which nicotinic acid as a source of niacin activity is not generally recognized as safe and effective or is misbranded.* The Panel recommends that the Category II conditions be eliminated from nicotinic acid drug products effective 6 months after the date of publication of the final monograph in the FEDERAL REGISTER.

The Panel concludes that there is no reason for the OTC drug use of nicotinic acid since all the benefits of niacin activity are provided by Category I niacin sources for the prevention and treatment of niacin deficiency. Large doses of nicotinic acid have been used to reduce elevated serum triglycerides, free fatty acids and cholesterol. This quantity of nicotinic acid often causes vasodilation or flushing and may produce hyperglycemia, hyperuricemia, and in some instances liver injury (Ref. 31). Such therapy requires continuous monitoring by a physician so that an OTC dosage is not recommended for this purpose.

h. *Category III conditions for which the available data are insufficient to permit final classification at this time.* The Panel recommends that a period of 2 years be permitted for the completion of studies to support the movement of Category III conditions to Category I.

None.

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7. *Pantothenic acid.* The Panel's statement on pantothenic acid includes the following ingredients: calcium pantothenate, dexpanthenol, and pantothenic acid.

a. *Reference form.* Dosages recommended in this document for pantothenic acid activity, for use in combination products only and not as a single ingredient, are based on the *D*-pantothenic acid equivalent ($C_9H_{17}NO_5$, molecular weight 219.2).

b. *Description.* Pantothenic acid is a water-soluble vitamin, named for its universal occurrence in nature (pantothenic—from Greek, meaning "from everywhere") (Ref. 1). The vitamin is found in abundant quantities in animal products, whole grains, and vegetables (Refs. 2 through 5). The amount of pantothenic acid found in natural products may vary with maturity of the product, variety of plant or animal, and environmental factors, including soil conditions and diet fed (Ref. 5).

Estimates of the pantothenic acid content of average American diets have been made by a number of researchers (Refs. 2 and 5 through 11) with findings ranging from approximately 5 to 20 mg daily. In addition, biosynthesis of pantothenic acid by intestinal microflora is suspected, but amounts produced and the availability of this source of the vitamin are unknown (Refs. 2, 5, 8, and 12). Bacterial synthesis may further be dependent on adequate sources of folic acid, biotin, ascorbic acid, or other factors (Ref. 4).

Studies of a variety of plant and animal species have revealed the apparently universal function of pantothenic acid as an essential constituent of coenzyme A (Refs. 2, 5, 11, 12, and 13). This important factor, necessary for acyl transfer reactions in living systems, has far-reaching effects on the metabolism of carbohydrate, fat, and protein. Its activity is essential for processes including energy release, gluconeogenesis, fatty acid synthesis, sterol synthesis, and others (Refs. 2, 5, and 11).

c. *Safety* From evidence available, pantothenic acid appears to be a relatively nontoxic substance in humans and several animal species studied (Refs. 5 and 14). For example, an experiment in which humans ingested daily doses of 10 to 20 g pantothenic acid resulted in the relatively mild symptoms of occasional diarrhea and water retention (Ref. 5).

d. *Effectiveness.* Pantothenic acid exists in several forms in nature and in common pharmaceutical products. *D*-Pantothenic acid, calcium pantothenate (calcium *D*-pantothenate), sodium *D*-pantothenate, dexpanthenol (pantothenyl alcohol, which is panthernol commercially), and *D*-pantothenamide are commonly found in pharmaceutical preparations (Ref. 15). These various forms are recognized to be of equal biological value in human beings. The pantothenic acid activity of any pharmaceutical product may be determined by chemical assay (Ref. 15).

Tests of the bioavailability of pantothenic acid have shown that it is well absorbed in man, in any of the above-named forms (Refs. 5, 7, 16, and 17). In these tests, using a microbiological assay, increased amounts of pantothenic acid were found in the blood and urine of individuals following oral administration of the vitamin (Refs. 7 and 15 through 18). In human blood samples, the major amount of pantothenic acid is found as coenzyme A in the erythrocytes, while lesser amounts of free pantothenic acid are found in the serum (Ref. 18). Pantothenic acid in the urine apparently occurs in the free form only (Ref. 18).

Estimates of total pantothenic acid content of human blood, made by a number of researchers, range from 140

to 420 ng/ml (Ref. 4). With slight changes in methods used, average values as high as 464 ng/ml have been found (Refs. 4 and 18). Blood levels of total pantothenic acid in infants and young children appear to be greater than adults (Ref. 19).

In addition, a relatively greater proportion of free pantothenic acid to bound pantothenic acid exists in the serum of infants and children as compared to the serum of adults (Ref. 4). However, considerable variation in these blood parameters exists among individuals. It has been reported that the total concentration of pantothenic acid is decreased in the serum of pregnant women, indicating an increased utilization of the vitamin (Refs. 6 and 20) or a dilutional effect of volume expansion (increased blood volume), which is normal in pregnancy. Supplements of pantothenic acid given late in pregnancy have been shown to elevate the concentration of free pantothenic acid in the serum, but no change was effected in the bulk of the vitamin bound in the erythrocytes until after delivery (Ref. 20). It is possible that the decreases in levels of bound pantothenic acid in the blood occur early in pregnancy. Limited evidence further suggests a decline in pantothenic acid content of the blood as a consequence of aging in women (Ref. 21). However, in each of these studies of pantothenic acid status in pregnancy and in aging, no indications of clinical pantothenic acid deficiency were found. No beneficial effects of pantothenic acid in women taking oral contraceptives have been reported.

Estimates of the normal range of urinary pantothenic acid excretion in healthy individuals of 2 to 7 mg daily (Ref. 2) and 2.5 to 9.6 mg daily (Ref. 22) have been made. Several investigations have shown urinary pantothenic acid excretion to fall within these ranges (Refs. 8, 17, and 18). Slightly lower values appear to be normal for children studied (Refs. 7 and 19). Urinary excretion is generally found to correlate with dietary intake, although individual variation is large (Refs 2, 6, 7, 8, and 17). Urinary excretion of 1 mg pantothenic acid or less per 24 hours has been considered by several investigators to represent a deficient state (Refs. 6, 7, and 17). However, clinical pantothenic acid deficiency has not been reported in conjunction with excretion of this low level of the vitamin.

A number of studies have been conducted in efforts to establish a pantothenic acid deficiency in man (Refs. 23 through 27). In most of these studies, no clinical symptoms of pantothenic acid deficiency were obtained with only the removal of the vitamin from the diet. Inclusion of the pantothenic acid antagonist, omega-methyl pantothenic acid, resulted in symptoms including fatigue, insomnia, neurological disorders, decreased eosinopenic response to ACTH, and increased sensitivity to insulin (Refs. 23 and 25). However, much variability was found among individuals studied. A number of symptoms were not reproduced in subsequent trials, and pantothenic acid alone did not completely reverse all of the symptoms found (Refs. 23 and 25). It is possible that the antagonist itself exerted a toxic effect, causing some of the symptoms seen; in one of this series of investigations, depletion of pantothenic acid from the diet, without use of the antagonist, resulted in some of the above symptoms in the two individuals given the pantothenic acid-deficient diet. These symptoms were less severe, and slower to develop, however, than when the antagonist was used (Ref. 24). In another report of the deprivation of pantothenic acid in human subjects, without use of a vitamin antagonist, urine and blood levels of pantothenic acid decreased, but no clinical deficiency signs were seen after 9 weeks of the dietary regimen (Ref. 27). No conclusive response of decreased antibody formation, previously seen in pantothenic acid deficient animals, could be demonstrated in a study of pantothenic acid deficiency in human beings (Ref. 26).

Neurological symptoms of malnutrition, found among rural populations of Asia and among prisoners of war who subsisted on a severely restricted diet for long periods of time, were found to respond to pantothenic acid therapy in some cases (Refs. 5, 28, and 29). The symptom, commonly called "the burning feet syndrome," has shown inconsistent response to treatment with pantothenic acid, however. In addition, it is generally the case that those individuals studied were suffering from multiple vitamin deficiencies so that evaluation of a single causal factor is difficult.

There is evidence to indicate that various groups in the American population consume low to marginal amounts of pantothenic acid in their diets. In most of these studies, adequacy of dietary intake was determined by a comparison between dietary intake of groups with suspected pantothenic acid deficiency and the U.S. RDA's of 3 to 10 mg. Comparison was also made between urinary excretion levels and standard excretion values for normal individuals. It has been found that pregnant and nonpregnant teenage girls (Refs. 2 and 6) and a group of low-income women (Ref. 9) consumed a level of pantothenic acid below recommended amounts in self-selected diets. In addition, the amount of pantothenic acid in the diet has been shown to vary with protein content of the diet (Ref. 7) and the cost of the diet in general (Refs. 8 and 10). In no case, however, was any clinical indication of pantothenic acid deficiency found.

Interrelationships of pantothenic acid with other nutrients have been proposed in a few studies. A sparing action has been attributed to vitamin B-12 in rats fed low pantothenic acid diets (Refs. 30 and 31), while it has been suggested that an increase in copper intake results in greater need for pantothenic acid, in rats also (Ref. 32). Administration of 5 mg thiamine daily for 1 week was found to elevate blood and urine levels of pantothenic acid in a group of human subjects studied for 3 weeks (Ref. 33). The importance of these findings in human nutrition cannot be assessed at this time.

Investigations of pantothenic acid status in human beings suffering from a number of diseases have been conducted. While some studies of cirrhosis due to chronic alcoholism and other liver diseases have shown decreased urine or blood levels of pantothenic acid, other studies show no correlation of urine or blood levels of pantothenic acid with the incidence of the diseases (Refs. 34 through 37). Response of alcoholic neuropathy to pantothenic acid therapy has varied, with most indications that the neurological problems result from multiple nutritional factors (Refs. 34 and 35). The evidence suggests, therefore, that supplementation with pantothenic acid alone would be of virtually no value in the vast majority of cases.

In other studies diabetic patients have been shown to excrete relatively large amounts of pantothenic acid in the urine, but decreased blood concentrations were not found (Ref. 38). The therapeutic use of pantothenic acid has been attempted in some cases of osteoarthrosis and rheumatoid arthritis (Refs. 39 and 40). However, too few patients have been studied to evaluate the results. The amounts of pantothenic acid necessary to alleviate symptoms indicate possibility of a metabolic disorder of the invididual and not a deficiency of pantothenic acid in the usual sense. Pantothenic acid has also been claimed to be of value in the treatment of postoperative ileus (Ref. 5). However, confirmation of the findings is needed. In general, the use of pantothenic acid for any of these abnormal conditions mentioned is not conclusively supported by available experimental evidence. In addition, most of these conditions would require a physician's treatment, and the use of pantothenic acid would be at his direction and not as an OTC product.

e. *Conclusion.* The Panel has reviewed the scientific literature, the submitted data, and the marketing

history of vitamin and mineral ingredients. Based upon the available data, the Panel concludes that pantothenic acid deficiency is virtually unknown in the U.S. population and that pantothenic acid, as a single ingredient, is not warranted for OTC drug use. However, the Panel concludes that pantothenic acid may be safely used in daily dosage of 5 to 20 mg in combination products containing other essential nutrients for use in the prevention of multiple vitamin deficincies such as may occur in conjunction with chronic alcoholism, malabsorption syndromes, or severely restricted nutrient intake caused by lack of a nutritionally balanced diet. (See part II. paragraph F.2. above—Safety and part II. paragraph F.7. above—Category I combinations.)

f. *Category I conditions under which pantothenic acid is generally recognized as safe and effective and is not misbranded.* The Panel recommends that the Category I conditions be effective 30 days after the date of publicaton of the final monograph in the FEDERAL REGISTER.

There are no Category I conditions for pantothenic acid as a single ingredient. However, the Panel concludes that calcium pantothenate, dexpanthenol, and panthenol are acceptable sources of pantothenic acid. Daily dosages of 5 to 20 mg based on the *D*-pantothenic acid equivalent ($C_9H_{17}NO_5$, molecular weight 219.2) may be added to certain combinations of other essential nutrients for use in the prevention of multiple vitamin deficiencies such as may occur in conjunction with chronic alcoholism, mal- absorption syndromes, or severely restricted nutrient intake caused by lack of a nutritionally balanced diet. (See part II. paragraph F.2. above—Safety and part II. paragraph F.7. above—Category I combinations.)

g. *Category II conditions under which pantothenic acid is not generally recognized as safe and effective or is misbranded.* The Panel recommends that the Category II conditions be eliminated from OTC pantothenic acid drug products effective 6 months after the date of publication of the final monograph in the FEDERAL REGISTER.

The Panel concludes that there is no need for an OTC drug preparation of pantothenic acid as a single ingredient since a deficiency of this vitamin occurring as a single vitamin deficiency is virtually unknown in the U.S. population.

h. *Category III conditions for which the available data are insufficient to permit final classification at this time.* The Panel recommends that a period of 2 years be permitted for the completion of studies to support the movement of Category III conditions to Category I.

None.

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8. *Vitamin B-6.* The Panel's statement on vitamin B-6 includes the following ingredient: pyridoxine hydrochloride.

a. *Reference form.* Dosages recommended in this document for vitamin B-6 are based on the pyridoxine hydrochloride equivalent ($C_8H_{12}ClNO_3$, molecular weight 205.6).

b. *Description.* Vitamin B-6 exists in nature as pyridoxine, pyridoxal, and pyridoxamine. These forms are converted in the body to pyridoxal-5-phosphate, the major coenzyme form of the vitamin, although pyridoxamine exhibits cofactor activity in some circumstances. The only form of vitamin B-6 used in commercial preparations is pyridoxine hydrochloride.

More than 60 enzymatic reactions are known in which pyridoxal phosphate is the cofactor. These reactions are concerned primarily with amino acid and protein metabolism and, to a lesser extent, with nucleic acid synthesis, and carbohydrate and lipid metabolism. Some of the reactions catalyzed by these enzymes include transamination, racemization, decarboxylation, cleavage, synthesis, dehydration, and desulfhydration. The conversion of tryptophan to niacin, the synthesis of regulator amines (norepinephrine, serotonin, and histamine), and the production of porphyrins and hemoglobin are important functions of pyridoxal coenzymes (Refs. 1, 2, and 3).

Deficiency symptoms have been induced in humans by feeding vitamin B-6 deficient diets and/or by administering vitamin B-6 specific antagonists. Clinical observations include inflamation of the mouth and tongue, peripheral neuropathy, increased irritability, mental depression, convulsions, abnormal electroencephalograms, and hypochromic anemia. Biochemical derangements associated with vitamin B-6 deficiency are altered tryptophan metabolism with an increase in the excretion of xanthurenic acid and the inability to convert trytophan to nicotinic acid; low or absent urinary pyridoxine and pyridoxic acid, the major pyridoxine hydrochloride excretory product; impairment in the formation of antibodies; decreased plasma and blood pyridoxal phosphate; and decreased glutamic-oxaloacetic transaminase (GOT) and glutamic-pyruvic transaminase (GPT) activities in blood and erythrocytes.

Since many of the clinical symptoms are indistinguishable from deficiency symptoms associated with some or all of the other B-vitamins, biochemical findings and response to pyridoxine hydrochloride are relied on to implicate vitamin B-6 as the deficient nutrient. The biochemical assessment of nutritional status has been recently reviewed and evaluated by Sauberlich et al. (Ref. 4). The most reliable tests appear to be as follows: (1) *Direct.* (i) Plasma, erythrocyte, and whole blood vitamin B-6 levels which fall rapidly during vitamin B-6 depletion and rise following supplementation, reflecting intake. Normal plasma or serum levels of vitamin B-6 measured by protozoan assay, are in excess of 50 ng/ml, while levels fall below 25 ng/ml in subjects with biochemical evidence of deficiency. (Ref. 4).

(ii) Progressive decline in urinary pyridoxine and rise following supplementation. Urinary pyridoxine excretions of less than 20 micrograms per gram ($\mu g/g$) excreted creatinine are indicative of marginal or inadequate dietary intakes.

(iii) Enzymic determination of pyridoxal-5-phosphate by tyrosine decarboxylation (Ref. 5).

(2) *Indirect.* (i) Increased excretion of tryptophan metabolites (xanthurenic acid, 3-hydroxykynurenine, and kynurenine) after a 2 to 5 g *L*-tryptophan load test.

(ii) Decrease in erythrocyte GOT and GPT activities. The in vitro stimulation of enzyme activity by pyridoxal phosphate is also greater in deficient subjects (E-GOT or E-GPT activation test).

(iii) Urinary excretion of 4-pyridoxic acid.

c. *Safety.* Pyridoxine hydrochloride is readily absorbed and extensively metabolized by man. The major metabolite is 4-pyridoxic acid which accounts for 20 to 40 percent of pyridoxine ingested (Ref. 2).

(1) *Acute toxicity.* No acute toxicity after pyridoxine hydrochloride ingestion has been reported in humans. Oral administration of 4.0 to 5.5 grams/kilogram (g/kg) body weight to rats or mice is lethal to 50 percent of the animals (Ref. 6).

(2) *Chronic toxicity.* (i) "In man, toxic effects were not encountered with daily administation of 50 to 200 mg pyridoxine hydrochloride over periods of months" (Ref. 6). Untoward effects have been observed, however, by some investigators. In one patient with encephalitis, severe aggravation of seizures occurred, and in another deterioration of the encephalographic pattern was observed when pyridoxine hydrochloride was given. Improvement occurred in both individuals after vitamin B-6 therapy was discontinued (Ref. 6).

(ii) Transient induced pyridoxine dependency has been reported (Refs. 7 and 8). Eight normal adult males consumed 200 mg supplementary pyridoxine hydrochloride for 33 days. Eight days following cessation of supplementation, three subjects had abnormal electroencephalographic (EEG) patterns which were normal one week later. All three complained of nervousness, tremulousness, and other ill-defined symptoms of a similar nature. Further experiments using daily supplementation of 300 mg showed similar findings; in addition EEG's became slightly abnormal in three individuals in the final week of supplementation.

(iii) Transient taurinuria and long-lasting general amino-aciduria occurred in a child during pyridoxine hydrochloride treatment for 2 years with 120 mg daily (Ref. 8).

(iv) Diminution in the effectiveness of l-dopa in the treatment of Parkinsonism when pyridoxine hydrochloride, 5 mg or more daily was given (Ref. 9).

(v) Six hundred mg pyridoxine hydrochloride daily has been used to inhibit lactation in postpartum women not wishing to breast feed (Ref. 11). The effect of high levels of pyridoxine on established lactation has not been reported.

Other side effects are less well documented. (*1*) Lethargy was reported for one woman taking 50 mg pyridoxine hydrochloride orally daily (Ref. 12).

(*2*) Excessive energy and insomnia were reported for one woman taking 100 mg pyridoxine hydrochloride orally daily. Symptoms were prevented by the reduction of the dose to 50 mg daily (Ref. 12).

(*3*) Patients treated with large amounts of pyridoxine hydrochloride for homocystinuria may develop folate deficiency (Ref. 13).

(*4*) Somnolence is reported in some individuals treated with as little as 5 mg pyridoxine hydrochloride daily (Ref. 14). Such individuals are considered pyridoxine-sensitive by the author.

(5) An infant with a requirement for extradietary vitamin B-6 was born to a mother who had received large doses of pyridoxine hydrochloride during pregnancy. Since the fetus has the ability to concentrate pyridoxal phosphate, the effect of large doses to the mother, concentrated by the fetus, on fetal metabolism is unknown (Refs. 15 and 16).

d. *Effectiveness.* The requirement for vitamin B-6 by young adults has been based on depletion and repletion studies which show a range of 1.25 to 1.5 mg daily required on a low protein diet and 1.75 to 2.0 mg daily for a high protein diet (Ref. 3). Experience with infant formulas suggest that metabolic requirements are satisfied if vitamin

B-6 is present in amounts of 0.015 mg/g protein (Ref. 3). The requirements of pregnant and lactating women and of the elderly may be higher. Dietary surveys by a number of workers indicate that an appreciable fraction of the United States adult population is not obtaining 1.5 mg vitamin B-6 (Ref. 17). Those segments of the population most vulnerable to low or deficient vitamin B-6 intake are as follows:

(1) *Low income.* Leevy et al. (Ref. 18) found that of the 105 out of 120 randomly selected municipal hospital patients exhibiting hypovitaminemia, 27 percent had low serum levels of vitamin B-6. This finding appeared to correlate with low dietary intakes of the vitamin (based on dietary history) rather than on the nature of the disease. The patients were indigent or of a low-income group.

(2) *Infants.* (i) If the mother has marginal vitamin B-6 intake during pregnancy, or is preeclamptic, the infant may be born with inadequate vitamin B-6 reserves (Ref. 19).

(ii) Clinical signs of vitamin B-6 deficiency were observed in two breast-fed infants receiving maternal milk with a pyridoxine hydrochloride concentration of 0.06 to 0.08 mg/liter. Normal human milk contains about 0.10 mg/liter (Ref. 3).

(iii) Infants fed autoclaved commercial milk formulas low in vitamin B-6 developed symptoms of deficiency responsive to pyrodoxine hydrochloride (Refs. 2 and 3). About 300 cases were reported in the 1950's.

(3) *Pregnant women.* During normal gestation, pyridoxal phosphate is concentrated by the fetus 6.6 times above the plasma concentration of the mother (Ref. 19). Concommitantly, maternal blood or plasma pyridoxal phosphate declines progessively during the course of pregnancy (Refs. 16 and 20) to about one-fourth that of nonpregnant women. Other biochemical changes include increased urinary excretion of xanthurenic acid after an oral tryptophan load (Refs. 21 through 24) which could be normalized by prior pyridoxine hydrochloride administration and low urinary 4-pyridoxic acid excretion after pyridoxine hydrochloride adminstration (Ref. 25).

Forty to 60 percent of 458 normal, pregnant women tested by Heller, Salkeld, and Korner (Ref. 26) were found to be suboptimally supplied with vitamin B-6 in order to saturate erythrocyte GOT (EGOT activation test). Shane and Contractor (Ref. 16) studying 10 pregnant women did not confirm this. The National Research Council recommends a daily intake of 2.5 mg vitamin B-6 daily during pregnancy, a 0.5 mg increase over the normal adult allowance (Ref. 3). Whether this amount of vitamin B-6 is adequate to meet most needs during pregnancy is the subject of current concern (Ref. 27). These changes in metabolism of pregnancy can be shifted toward "biochemical normality" by supplemental pyridoxine hydrochloride of up to 15 or 20 mg daily (Ref. 27). This amount is in excess of the maximum of about 3 mg daily which can be obtained from a well-planned diet (Ref. 17). Heller, Salkeld, and Korner (Ref. 26) after finding biochemical evidence for vitamin B-6 coenzyme depletion in 40 to 60 percent of 458 pregnant women commented: "No evidence was found that this form of vitamin B-6 deficiency had any clinical sequelae for the mother or the fetus during the pregnancy and delivery," but they concluded, "Our results suggest that pyridoxine supplementation is necessary in approximately 50 percent of the pregnant women in order to maintain normal coenzyme saturation" (of EGOT). Shane and Contractor (Ref. 16), who found decreased blood pyridoxal phosphate in pregnant women, cautioned:

> Correction of abnormal metabolism by large doses of pyridoxine may not indicate a vitamin deficiency per se. In pregnancy, for example, it is debatable whether enough pyridoxine hydrochloride should be administered to correct the abnormal metabolism or whether it is even necessary to produce a normal, i.e., nonpregnant, state. As tryptophan metabolism is the most deranged vitamin B-6 status indicator in pregnancy, correction of xanthurenic acid excretion to the levels found in nonpregnants, by administering pyridoxine, would result in high pyridoxal phosphate levels in the fetus. It is possible that this could have an adverse effect on the synthesis of fetal pyridoxal phosphate enzymes and, at worst, lead to high vitamin pyridoxine hydrochloride requirements for the fetus after birth.

Krishnaswamy (Ref. 28) and Iyengar (Ref. 29) reported that many cases of mild to severe stomatitis seen in pregnant women in India responded to treatment with 10 mg for 10 days of pyridoxine hydrochloride.

Thirteen of 14 pregnant women with gestational diabetes were observed to have an increased xanthurenic acid excretion after a tryptophan load test. All were treated orally with pyridoxine hydrochloride 100 mg daily for 14 days. Only two of the fourteen failed to respond with an improved glucose tolerance test. The authors hypothesize that increased xanthurenic acid synthesis during pregnancy may cause gestational diabetes (Ref. 30). They refer to work by Kotake and Murakami (Ref. 31) which shows that xanthurenic acid forms a complex with insulin, acts as an insulin antagonist, and has a diabetogenic effect in animals. Diabetes in pregnancy as at other times requires the skillful management of a physician.

(4) *Women taking oral contraceptives (O.C.).* Many of the biochemical changes in vitamin B-6 metabolism observed during pregnancy are also seen in women taking oral contraceptives. The most notable is a marked disturbance of tryptophan metabolism along the kynurenine-niacin pathway, with abnormally high urinary xanthurenic acid excretion after a loading dose of tryptophan (Refs. 32 through 37). This occurs in 75 to 100 percent of O.C. users (Ref. 38). The abnormality persists as long as the contraceptives are taken and becomes more marked with time (Ref. 36). Abnormal tryptophan metabolism is implicated in the development of depression, which many workers report as a side effect of O.C. use (Refs. 39 and 40), the frequency being as high as 6.6 percent (Ref. 41). Pyridoxine hydrochloride has been used with mixed success by a number of workers to relieve O.C.-related depression (Ref. 12). The most rigorous study was by Adams et al. (Ref. 40). In a double-blind crossover trial of the effect of pyridoxine hydrochloride on depression, 11 of 22 women showing biochemical evidence of vitamine B-6 deficiency responded by significant relief of symptoms to 20 mg pyridoxine hydrochloride, twice daily for 2 months. Placebo administration was without effect.

The increased xanthurenic acid excretion associated with O.C. use may be involved in the development of impaired glucose tolerance tests observed in women taking oral contraceptives (Ref. 42), and improved by pyridoxine hydrochloride administration (Ref. 43).

Other metablic alterations in vitamin B-6 metabolism observed with O.C. use are lowered blood pyridoxal phosphate levels (Refs. 16 and 44), significantly increased in vitro erythrocyte GOT activation in 48 percent of 233 women on oral contraceptives, compared to 18 percent of controls (Ref. 38), elevated E-GPT in vitro stimulation or activation values (Refs. 45 and 46), and 30 percent lower urinary excretion of vitamin B-6 (Ref. 47) than in controls.

A minimum of 20 to 25 mg pyridoxine hydrochloride daily is necessary to normalize tryptophan metabolism in the majority of O.C. users (Refs. 35 and 36), an amount far in excess of that obtainable in the diet. To counteract depression and other possible manifestations of vitamin B-6 deficiency, some workers support the concept of routine pyridoxine hydrochloride supplementation for O.C. users (Refs. 35 and 38).

Leklem et al. (Ref. 48) studied parameters of vitamin B-6 deficiency in 15 O.C. users and 9 controls in a vitamin B-6 depletion and repletion format. Biochemical response to depletion and repletion were parallel in both groups. The only major alter-

ation in metabolism was the response to tryptophan loading. Repletion with 2.0 mg pyridoxine daily for 4 weeks restored all indices in both groups to predepletion or ultra-normal levels. The authors conclude "that if the use of oral contraceptives * * * does alter the requirement for vitamin B-6, the effect is a minor one and of doubtful clinical significance to the majority of women taking these steroid preparations." They suggest that the abnormality in tryptophan metabolism may reflect other metabolic effects of the drug than vitamin B-6 deficiency or antagonism.

(5) *The elderly.* Hamfelt (Ref. 49) and Rose et al. (Ref. 50) measured plasma pyridoxal phosphate and found levels decrease with age. The decrease was associated with alterations in tryptophan metabolism and serum transaminase activity. Pyridoxine hydrochloride supplements (100 mg daily for 14 days) markedly increased the plasma pyridoxal phosphate and corrected other biochemical alterations.

Jacobs, Cavill, and Hughes (Ref. 51) observed a decline in erythrocyte GPT activity with age, by both direct and stimulated measurement. It is uncertain whether or not this reflects pyridoxine deficiency, as no other parameter of pyridoxine metabolism was studied. The diet supplied about 1.5 mg Vitamin B-6 daily. Supplementing the elderly subjects with 10 mg pyridoxine hydrochloride daily for 6 weeks produced a significant increase in transaminase activities. No subjective changes were induced by dietary supplementation.

(6) *Alcoholics.* General vitamin deficiency, which includes vitamin B-6 deficiency, is observed in alcoholics and is thought to be caused by a combination of factors which includes inadequate food intake, possible malabsorption of vitamin B-6 from food (but not of crystalline pyridoxine hydrochloride) (Ref. 52), increased clearance of pyridoxal phosphate, possibly due to increased liver degradation secondary to liver disease (Ref. 53) and possible ethanol-associated release of the vitamin from liver stores and inhibition of new storage (Ref. 54). Individuals with chronic alcohol abuse frequently exhibit lowered plasma levels of pyridoxal-5-phosphate. Acetaldehyde accelerates the degradation of intracellular pyridoxal phosphate (Ref. 55), and a decrease in pyridoxal phosphate enhances the cytotoxicity of acetaldehyde (Ref. 56).

(7) *Conditioned deficiency.* Wohl et al. (Ref. 57) reported deranged tryptophan metabolism in 14 hyperthyroid patients which could be corrected by 50 mg pyridoxine hydrochloride intramuscularly. The normal vitamin B-6 intake of the patients was calculated to be 2.0 to 2.5 mg daily. Although no overt clinical manifestations of deficiency were observed, one of the patients who showed obvious signs of muscular weakness improved after daily treatment with pyridoxine hydrochloride and without other antithyroid therapy. The dose and duration of treatment was not reported.

Depression of plasma pyridoxal phosphate was observed in eight children after accidental burning or scalding. The concentrations remaind low for several weeks with a dietary pyriodoxine hydrochloride supplement of 0.25 mg daily but were restored rapidly to saturation levels, with large doses of 250 mg daily.

An area of potential concern, as yet unstudied in humans, is the effect of pollution on vitamin requirements. Mitchell and Schandl (Ref. 58) refer to animal experiments by Russian workers who found a greatly increased requirement for vitamin B-6 after chronic exposure to an industrially polluted atmosphere or to carbon monoxide, nitrogen peroxide, and ammonia.

Certain other conditions have been reported to be helped by pyridoxine hydrochloride therapy. These include severe atopic dermatitis in children (Ref. 59), infantile convulsions, and childhood bronchial asthma (Ref. 60). Such uncontrolled observations have not demonstrated any consistent relationship of these diseases to vitamin B-6 deficiencies, although a genetic defect responsive to large doses of pyridoxine hydrochloride may be present in some infants with convulsions (Refs. 15, 61, and 62).

(8) *Vitamin B-6 responsive genetic disorders.* Pyridoxine hydrochloride far in excess of that obtainable by diet has been found useful in the treatment of a range of genetic disorders (Ref. 61). These include cystathioninuria treated with 400 mg daily (Refs. 63 and 64), pyridoxine-responsive anemia treated with 5 to 200 mg daily (Ref. 62), pyridoxine-responsive homocystinuria improved with 150 to 15,000 mg daily (Refs. 13 and 65), and xanthurenic aciduria responsive to 80 mg daily (Ref. 66). These conditions are rare, and when diagnosed by sophisticated medical techniques, require the regular and consistent care of a physician for vitamin as well as other forms of therapy.

(9) *Drug-induced deficiency.* The use of drugs in the treatment of a number of diseases induces a vitamin B-6 deficient state if not supplemented with additional large doses of pyridoxine hydrochloride (Ref. 67). These include isoniazid (isonicotinic acid hydrazide), semicarbazide, carbohydrazide, thiosemicarbazide, and cycloserine for the treatment of tuberculosis, penicillamine for Wilson's disease and heavy metal poisoning, hydralazine for hypertension, and hydantoin and succinamide for epilepsy (Ref. 68). Pyridoxine hydrochloride therapy in association with these prescription drugs is most safely administered by prescription also.

e. *Conclusion.* The Panel has reviewed the scientific literature, the submitted data, and the marketing history of vitamin and mineral ingredients. Based upon the available data, the Panel concludes that pyridoxine, in the dosage and form identified under Category I conditions below, is safe and effective for use in the prevention and treatment of vitamin B-6 deficiency when the need for such therapy has been determined by a physician.

f. *Category I conditions under which vitamin B-6 is generally recognized as safe and effective and is not misbranded.* The Panel recommends that the Category I conditions be effective 30 days after the date of publication of the final monograph in the FEDERAL REGISTER.

Pyridoxine hydrochloride is the only acceptable source of vitamin B-6 activity. Dosage is based on the pyridoxine hydrochloride equivalent ($C_8H_{12}ClNO_3$, molecular weight 205.6).

(1) *Dosage*—(i) *For prevention of deficiency.* For adults and children 1 year of age and older, the oral dosage is 1.5 to 2.5 mg daily. For children under 1 year of age, the Panel recommends the advice and supervision of a physician.

(ii) *For treatment of deficiency.* For adults and children 1 year of age and older, the oral dosage is 7.5 to 25 mg daily. For children under 1 year of age, the Panel recommends the advice and supervision of a physician.

(2) *Labeling.*—The Panel recommends the following Category I labeling:

(i) *Indications.* (*a*) *For prevention of deficiency.* "For use in th prevention of vitamin B-6 deficiency when the need for such therapy has been determined by a physician."

(*b*) *For treatment of deficiency.* "For use in the treatment of vitamin B-6 deficiency when the need for such therapy has been determined by a physician."

(ii) *Warning.* "Caution: Do not take this product if you have Parkinsonism and are currently taking 1-dopa except under the advice and supervision of a physician."

(iii) *Professional labeling.* The Panel recommends that labeling provided to health professionals (but not to the general public) should contain the following additional information:

"Increased pyridoxine hydrochloride doses are required in vitamin B-6 dependency syndromes (pyridoxine-responsive anemia, seizures, familial

xanthurenic aciduria, cystationiuria). Supplemental levels of pyridoxine hydrochloride are required when patients take (during receipt of) drugs or chemicals which bind and inactivate pyridoxine hydrochloride (isonicotinic acid hydrazide, cycloserine, hydralazine, penicillamine, semicarbazide)."

g. *Category II conditions under which vitamin B-6 is not generally recognized as safe and effective or is misbranded.* The Panel recommends that the Category II conditions be eliminated from OTC vitamin B-6 drug products effective 6 months after the date of publication of the final monograph in the FEDERAL REGISTER.

The Panel concludes that the OTC drug use of vitamin B-6 for the following indications is not supported by adequate scientific evidence and that labels purporting such indications are neither truthful nor accurate:

(1) *"For the prevention of kidney stones."* Although vitamin B-6 deficiency in animals (Refs. 69 and 70) can produce increased urinary oxalate and the formation of calcium oxalate renal stones, the role of dietary B-6 deficiency in human stone formation is as yet unclear. Oxaluria may occur in persons ingesting B-6 antagonists such as deoxypyridoxine or isoniazid (Refs. 71 and 72), and occasionally oxalate stone formation is observed. However, the high incidence of urolithiasis found in the Southern United States, and to a greater extent in Asia, has not been associated directly with B-6 deficiency (Refs. 73 and 74) or dependency. The effectiveness of pharmacologic doses of pyridoxine hydrochloride in the treatment of urolithiasis has been studied to a limited extent. Dhanamitta, Valyasevi, and Van Reen (Ref. 75) found no beneficial affect of 3 mg pyridoxine hydrochloride daily for the relief of oxalcrystalluria in 14 Thai infants, whereas supplementation with orthophosphate completely eliminated oxalcrystalluria. Prien and Gershoff (Ref. 74) report in a study of 5 years duration that a regimen of 10 mg pyridoxine hydrochloride daily plus 300 mg magnesium oxide daily is effective in reducing or preventing recurrent urinary calculi in most idiopathic stone formers. Control groups receiving magnesium oxide alone or pyridoxine alone were included. Earlier trials where magnesium oxide alone was used reported similar success in stone prevention (Refs 76, 77, and 78) thus casting doubt on any beneficial role of B-6 in this regimen. Thus, the balance of evidence argues against the use of pyridoxine hydrochloride as effective for therapy or prevention of urolithiasis.

(2) *"For pernicious vomiting of pregnancy."* Reinken and Gant (Ref. 79) found that 24 women with hyperemesis gravidarum had the low serum pyridoxal phosphate levels compared to other pregnant women without vomiting and anorexia in the first trimester. Treatment for 7 days with 100 mg pyridoxine hydrochloride daily produced a normalization of biochemical values and "clinical return to normal." Numbers improved are not recorded and no controls were used. No data are available on the women before vomiting began. Thus, no evidence was presented to support a causal relationship between hyperemesis and vitamin B-6 deficiency.

h. *Category III conditions for which the available data are insufficient to permit final classification at this time.* The Panel recommends that a period of 2 years be permitted for the completion of studies to support the movement of Category III conditions to Category I.

Vitamin B-6 singly or in combination labeled specifically for use by women taking oral contraceptives.

(1) *Proposed dosage—For prevention of deficiency.* For women taking oral contraceptives, the oral dosage is 20 to 25 mg daily.

(2) *Proposed labeling.* The Panel recommends the following proposed labeling for vitamin B-6 for use with oral contraceptives:

Indication—For prevention of deficiency. "For use in the prevention of vitamin B-6 deficiency in women taking oral contraceptives when the need for such therapy has been determined by a physician."

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9. *Riboflavin.* The Panel's statement on riboflavin includes the following in-

gredients: Riboflavin and riboflavin-5-phosphate sodium.

a. *Reference form.* Dosages recommended in this document for riboflavin are based on the riboflavin equivalent ($C_{17}H_{20}N_4O_6$, molecular weight 376.4).

b. *Description.* Riboflavin is essential for growth and tissue repair in all animals. Riboflavin-5'-phosphate (flavin mononucleotide) and riboflavin-5'-adenosine phosphate (flavin adenine dinucleotide) serve as coenzymes which combine with apoenzymes to form flavoprotein enzymes, a series of oxidation-reduction catalysts including *D*-amino acid oxidase, xanthine oxidase, diaphorase, cytochrome, c reductase, and Warburg's yellow enzyme (Ref. 1). Riboflavin is involved in the conversion of tryptophan to nicotinic acid. Its absence causes a derangement of tryptophan metabolism with increased formation and urinary excretion of anthranilic acid and kynurenine (Ref. 2). Absorption of riboflavin, which occurs primarily in the proximal intestine, is regulated by a saturable transport process. Absorption is decreased by a deficiency of bile acids.

c. *Safety.* No toxicity has been encountered in patients receiving oral riboflavin. Absorbability and bioavailability of riboflavin are not altered by the pressence of other vitamins.

d. *Effectiveness.* Daily requirements for riboflavin in healthy individuals depend on protein intake and energy expenditure. Increased riboflavin of 2.5 to 5.0 mg daily is required in patients with biliary obstruction (Ref. 3) and by individuals with large intakes of alcoholic beverages (Refs. 4 and 5). Women on oral contraceptives have been reported with decreased urinary riboflavin. However, no other evidence of riboflavin deficiency has been reported in such persons.

Clinical episodes of riboflavin deficiency are rare. They include oral, cutaneous, corneal, neurologic, and hematologic lesions. There is atrophy of the epidermis and other changes leading to angular cheilosis, glossitis, scrotal dermatitis, vascularization of the cornea, cataracts, corneal ulcers, and abnormal pigmentation of the iris. Peripheral neuropathy and anemia may be associated with ariboflavinosis (Refs. 6 and 7). Studies with galactoflavin, a riboflavin antagonist, showed that subjects receiving this agent developed anemia which may be due to its directly toxicity or a secondary effect on liver folic acid (Ref. 8). In experimental animals, maternal deficiency of riboflavin may lead to fetal abnormalities including shortening of long bones, micrognathia, cleft palate, hydrocephalus, heart malformations, and eye lesions (Ref. 9). Also, in animal experiments, diminished tissue levels of riboflavin enhance the development of liver tumors in response to the ingestion of carcinogenic azo dyes (Ref. 10).

Depletion of riboflavin produces a decrease in circulating and urinary levels of the vitamin and an increase in glutathione reductase activity following the in vitro addition of flavine adenine dinucleotide to erythrocyte hemolysates (Refs. 4 and 11). A subclinical deficiency occurs in pregnancy (Ref. 12); in the sick and injured (Ref. 13); in normal school children, being present in approximately one-half of 642 New York City school children tested (Ref. 14); and commonly among alcoholics (Ref. 5).

OTC riboflavin-containing products should be evaluated with respect to their ability to increase tissue or body fluid riboflavin levels. Riboflavin absorbability may be documented by measuring urinary excretion of riboflavin, expressing the results in terms relative to creatinine excretion (Ref. 3). The normal male should excrete over 40 percent of a 10 mg dose. Riboflavin may be measured by a fluorometric procedure (Ref. 15), or by microbiological assay (Ref. 16). Riboflavin-deficient patients exhibit a return to normal in erythrocyte glutathione reductase activity after receiving 5 mg riboflavin (Ref. 4).

e. *Conclusion.* The Panel has reviewed the scientific literature, the submitted data, and the marketing history of vitamin and mineral ingredients. Based upon the available data, the Panel concludes that riboflavin, in the dosage and forms identified under Category I conditions below, is safe and effective for use in the prevention and treatment of riboflavin deficiency when the need for such therapy has been determined by a physician.

f. *Category I conditions under which riboflavin is generally recognized as safe and effective and is not misbranded.* The Panel recommends that the Category I conditions be effective 30 days after the date of publication of the final monograph in the FEDERAL REGISTER.

Acceptable sources of riboflavin activity are riboflavin and riboflavin-5-phosphate sodium. Dosage must be based on the riboflavin equivalent ($C_{17}H_{20}N_4O_6$, molecular weight 376.4).

(1) *Dosage*—(i) *For prevention of deficiency.* For adults and children 1 year of age and older, the oral dosage is 1 to 2 mg daily. For children under 1 year of age, the Panel recommends the advice and supervision of a physician.

(ii) *For treatment of deficiency.* For adults and children 1 year of age and older, the oral dosage is 5 to 25 mg daily. For children under 1 year of age, the Panel recommends the advice and supervision of a physician.

(2) *Labeling.* The Panel recommends the following Category I labeling:

(i) *Indications—(a) For prevention of deficiency.* "For use in the prevention of riboflavin deficiency when the need for such therapy has been determined by a physician."

(*b*) *For treatment of deficiency.* "For use in the treatment of riboflavin deficiency when the need for such therapy has been determined by a physician."

(ii) *Warning—For products for the treatment of deficiency.* "Do not exceed the recommended dosage except under the advice and supervision of a physician."

(iii) *Professional labeling.* The Panel recommends that labeling provided to health professionals (but not to the general public) should contain the following additional information:

Indications. "Certain persons may require increased levels of riboflavin such as individuals with biliary obstruction, individuals on oral contraceptives, and individuals consuming large quantities of alcohol."

g. *Category II conditions under which riboflavin is not generally recognized as safe and effective or is misbranded.* The Panel recommends that the Category II conditions be eliminated from OTC riboflavin drug products effective 6 months after the date of publication of the final monograph in the FEDERAL REGISTER.

Timed-release preparations of riboflavin have been shown to be erratic in their ability to increase the excretion of riboflavin in urine (Ref. 18). The Panel concludes that adequate and reliable scientific evidence is at present not available to permit the assumption of therapeutic effectiveness for OTC timed-release drug preparations.

h. *Category III conditions for which the available data are insufficient to permit final classification at this time.* The Panel recommends that a period of 2 years be permitted for the completion of studies to support the movement of category III conditions to Category I.

None.

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(18) OTC Volume 150098.

10. *Thiamine.* The Panel's statement on thiamine includes the following ingredients: thiamine hydrochloride and thiamine mononitrate.

a. *Reference form.* Dosages recommended in this document for thiamine are based on the thiamine chloride hydrochloride equivalent ($C_{12}H_{17}ClN_4OS.HCl$, molecular weight 337.3).

b. *Description.* Thiamine functions as a coenzyme in the metabolism of alpha-keto acids and 2-keto sugars (Ref. 1). It is responsible for the decarboxylation of pyruvic acid to acetyl coenzyme A (Embden-Meyerhof glycolytic pathway), the decarboxylation of alpha ketoglutarate to succinyl coenzyme A (citric acid cycle), and formation of sedoheptulose phosphate and fructose-6-phosphate (hexose monophosphate shunt). Three-forths of dietary thiamine comes from green vegetables, grains, and meats, and one-fourth from the fortification of flour, cereal, and other commerical food products.

c. *Safety.* Several reports have appeared in the literature of untoward effects resulting from doses of thiamine far exceeding effective therapeutic amounts. A woman taking 10,000 mg thiamine hydrochloride developed headache, irritability, insomnia, and weakness, all of which cleared when the vitamin was stopped, but recurred when only 5 mg thiamine hydrochloride were given for 4.5 weeks (Ref. 2). Since there are many reports in which 50 to 100 mg thiamine were taken daily without adverse effect, it is the view of the Panel that such episodes are individual idiosyncratic reactions.

Because one of the common sources of thiamine is the mononitrate, a question was raised regarding the safety of ingesting the nitrate part of this preparation. A 24.3 mg dose of thiamine mononitrate, which is equivalent to the maximum amount of thiamine hydrochloride (25 mg) that the Panel recognizes as safe and effective for the treatment of thiamine deficiency, would add 4.6 mg nitrate ion (NO_3^-) to the day's intake. An estiamted average daily ingestion of nitrate per capita in the United States is 86 mg. This comes principally from vegetables, but there is a great variation in intake depending upon the type and quantity of the vegetables consumed and the condition of the soil. Until elimination, chiefly via the urine, nitrate is recycled in the body by secretion in the saliva as nitrite. No toxic effects are produced in man by a dose of 1.0 to 1.5 g nitrate ion. The increment of 4.6 mg nitrate ion to the normal average intake from foods would cause the total nitrate intake to be less than one-tenth of the dose known to produce no toxic effects in humans. Since the quantity of nitrate contributed by the maximum recommended treatment dose of thiamine mononitrate would be within the normal variation of the total dietary nitrate contributed by foods alone, it is not reasonable to assign any significant added risk to this incremental source of nitrate. The safety of other thiamine compounds, such as thiamine propyl disulfide and certain phosphoric acid salts of thiamine, has not been evaluated by the Panel.

d. *Effectiveness.* Daily thiamine requirements depend on the number of calories ingested. However, the vitamin is required by those on reducing diets as well as those on complete food deprivation. There is no evidence that the absorption or activity of thiamine is affected when combined with other vitamins.

Pregnancy, lactation, malignancy, high oral carbohydrate intake, parenteral glucose, febrile states, and alcoholism predispose to thiamine deficiency. Administration of pyrithiamine, a thiamine antagonist, produces a deficiency similar to that obtained by withholding thiamine (Ref. 3). Thiaminases occur in tissues of fish (Ref. 4) and various vegetable (Ref. 5). However, they are not usually responsible for thiamine depletion in man. Depletion of thiamine produces biochemical alterations, including an increase in blood pyruvic and lactic acids, reduction in red blood cell transketolase, and clinical abnormalities, including neurologic and/or cardiac lesions, in experimental animals and man (Refs. 6 and 7).

Beriberi, the clinical symptom complex of thiamine depletion, may cause peripheral neuritis (Ref. 8), and may also lead to cardiovascular manifestations (Ref. 9). Symptoms of Wernicke's encephalopathy (Ref. 10) in chronic alcoholics are usually responsive to thiamine given parenterally in doses of 10 mg daily until body repletion of thiamine is obtained (Ref. 11). Occasionally, such symptoms exist in the absence of biochemical evidence of thiamine depletion and in these instances thiamine therapy is without effect (Ref. 11).

Subclinical thiamine deficiency reflected by deficient red blood cell transketolase activity, low blood thiamine, or reduced urinary excretion of thiamine without clinical symptomatology is found in the U.S. population. Subclinical thiamine deficiency occurs among pregnant women (Refs. 12 and 13), alcoholics (Ref. 14), the sick and injured (Ref. 15), school children (Ref. 16) and the aged (Ref 17). In the Ten State Nutrition Survey (Ref. 18), 12 percent of people tested had thiamine deficiency as reflected in urinary thiamine excretion. Biochemical evidence of thiamine deficiency has been reported to be present in 35 percent of pregnant women tested (Ref. 13), 31 percent of routine hospital admissions (Ref. 15), and 68 percent of Blacks as compared with 6 percent of Chinese and 52 percent of Caucasian school children studied in New York City (Ref. 16).

Intestinal absorption of thiamine hydrochloride is an active process (Ref. 19). In healthy subjects, as the dose of thiamine is increased, relatively less is absorbed (Ref. 20). There is a significant reduction of thiamine absorption in the untreated malnourished alcoholic (Ref. 21), in the presence of folate depletion (Ref. 22), and following ingestion of ethanol (Ref. 21). Other forms of thiamine such as the allithiamines (not currently marketed in the United States) exhibit a significantly greater absorbability and produce a higher tissue and body fluid levels of thiamine, with an increase in red blood cell transketolase activity, and there is a report that these compounds correct certain clinical abnormalities refractory to thiamine hydrochloride or thiamine mononitrate (Ref. 23).

The effectiveness of thiamine-containing products is evaluated by the increase in body tissue and fluid thiamine levels following their use. Thiamine-containing products are considered efficacious if they increase tissue or urinary levels of thiamine. Absorba-

bility or bioavailability is documented by mesuring the amount of thiamine in the urine before and after the administration of 5 mg of the drug given orally in a fasting state (Ref. 24). The thiocrome analytical method is employed for this detection.

e. *Conclusion.* The Panel has reviewed the scientific literature, the submitted data, and the marketing history of vitamin and mineral ingredients. Based upon the available data, the Panel concludes that thiamine, in the dosage and forms identified under Category I conditions below, is safe and effective for use in the prevention and treatment of thiamine deficiency when the need for such therapy has been determined by a physician.

f. *Category I conditions under which thiamine is generally recognized as safe and effective and is not misbranded.* The Panel recommends that the Category I conditions be effective 30 days after the date of publication of the final monograph in the FEDERAL REGISTER.

Acceptable sources of thiamine activity are thiamine hydrochloride and thiamine mononitrate. Dosage must be based on the thiamine chloride hydrochloride equivalent ($C_{12}H_{17}ClN_4OS.HCl$, molecular weight 337.3).

(1) *Dosage*—(i) *For prevention of deficiency.* For adults and children 1 year of age and older, the oral dosage is 1 to 2 mg daily. For children under 1 year of age, the Panel recommends the advice and supervision of a physician.

(ii) *For treatment of deficiency.* For adults and children 1 year of age and older, the oral dosage is 5 to 25 mg daily. For children under 1 year of age, the Panel recommends the advice and supervision of a physician.

(2) *Labeling.* The Panel recommends the following Category I labeling:

Indications—(*a*) *For prevention of deficiency.* "For use in the prevention of thiamine deficiency when the need for such therapy has been determined by a physician."

(*b*) *For treatment of deficiency.* "For use in the treatment of thiamine deficiency when the need for such therapy has been determined by a physician."

g. *Category II conditions under which thiamine is not generally recognized as safe and effective or is misbranded.* The Panel recommends that the Category II conditions be eliminated from OTC thiamine drug products effective 6 months after the date of publication of the final monograph in the FEDERAL REGISTER.

The Panel concludes that the OTC drug use of thiamine for the following suggested indications appearing in the literature or in the submissions to the Panel is presently not supported by adequate scientific evidence and that labels purporting such indications are neither truthful nor accurate: Dermatoses, multiple sclerosis, infection, drug toxicity, stimulation of mental responsiveness in the absence of thiamine deficiency, cancer, edema of infants, and impotence (Ref. 12).

Thiamine has been used to stimulate appetite, relieve tiredness, correct neurologic diseases, and improve mentation, without a demonstrated deficiency of this vitamin (Ref. 12). The Panel has reviewed data on such use and concludes that there is no evidence that thiamine is of benefit in any symptom complex in the absence of a thiamine deficiency.

h. *Category III conditions for which the available data are insufficient to permit final classification at this time.* The Panel recommends that a period of 2 years be permitted for the completion of studies to support the movement of Category III conditions to Category I.

None.

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11. *Vitamin A.* The Panel's statement on Vitamin A includes the following ingredients: vitamin A (retinol), Vitamin A acetate, and vitamin A palmitate.

a. *Reference form.* Dosages recommended in this document for vitamin A activity are based on the retinol equivalent expressed in international units (I.U.) ($C_{20}H_{30}O$, molecular weight 286.4 and 0.3 μg retinol is equivalent to 1.0 I.U.).

b. *Description.* Claims have been made for vitamin A sources including retinol (vitamin A alcohol) and its esters formed with edible fatty acids, principally retinyl acetate and retinyl palmitate, derived from synthetic or natural sources such as fish liver oils, particularly that of the cod.

Vitamin A is a generic term for a group of biologically active compounds, including retinol (vitamin A alcohol) and its esters which are of nutritional importance to man and are found in foods commonly consumed by man. Carotenoids have potential vitamin A

activity and after ingestion are converted by the body to a variable degree to the utilizable and physiologically active form. The degree and speed of conversion of the carotenoids, however, are not adequate and sufficiently uniform to recommend their use for therapeutic purposes. For this reason, the term "vitamin A" used subsequently in this document will refer only to retinol and its acetate and palmitate esters. The commercially produced retinyl esters and retinol are predominantly the all-trans isomer with a small and variable percentage of neo-vitamin A (Ref. 1).

Vitamin A is essential for the integrity of the membrane structure and function of all body cells. It also has a specific and vital role in the process of vision. Night blindness (defective dark adaptation) is one of the earliest signs of vitamin A deficiency. Other signs and symptoms include abnormal dryness of the eye and of the skin and other epithelial tissues, softening of the cornea and growth failure.

When vitamin A is absorbed through the intestinal mucosa, it is transported to the liver where it is stored and released into the blood to travel to all the tissues and cells of the body. The blood level of vitamin A is maintained within a normal range as long as the liver stores are capable of supplying the needs of the tissues (Ref. 2). When they are depleted, generally as a result of an insufficient dietary supply of the vitamin or its precursors, the blood level falls and, of course, the tissues are deprived of the amounts needed to maintain their integrity.

c. *Safety.* Acute toxicity in the adult occurs from a dose at or above 2,000,000 to 5,000,000 I.U. (30,000 to 75,000 I.U./kg for a 70 kg man). In the infant 17,000 to 33,000 I.U./kg of body weight can precipitate acute toxic signs. The signs of acute toxicity in adults, which can develop in 6 to 8 hours following ingestion of the dose, are severe headache centered in the forehead and eyes, dizziness, drowsiness, and nausea with vomiting, followed in 12 to 20 hours by redness and swelling of the skin which eventually begins to peel (Ref. 3). In infants, bulging fontanelles (the membrane-covered openings in the still-developing infant skull) caused by abnormal intracranial pressure, loss of appetite, hyperirritability, and vomiting generally occur within 12 hours after dosage and is followed in a few days by a flaking-off of the skin.

The chronic dose inducing toxicity varies with the individuals and doses of 12,000 to 350,000 I.U. daily for infants less than 1 year of age, and from 37,500 to 600,000 I.U. daily for the 1- to 5-year-old age group are reported. The lowest toxic dose of retinol recorded is 12,000 I.U. daily for 7 days. This amount was given to a 2.1 kg infant (probably of premature birth) who had been on parenteral alimentation for 18 weeks. Chronic toxicity developing in a few months is most commonly encountered in infants and children, whereas chronic toxicity in adults may take several months or even years to develop and become evident (Ref. 4). Chronic toxicity results in loss of appetite, headache, blurred vision, muscle soreness after exercise, hair loss, reddish pimples (maculoerythematous eruptions) on the shoulders and back, and general drying and flaking of the skin with pruritis, as well as all the symptoms associated with hypercalcemia (Refs. 3 and 5). Cracking and bleeding of lips, reddened gums, and nosebleed are also reported as signs of toxicity. Enlargement of the liver and spleen may be noted during physical examination, and anemia may also be present. Often painful subcutaneous swelling and swelling in the regions of muscle attachments to long bones due to overgrowth of bone are present. A "pagoda effect" (increased angle of metaphyseal flare) has been described in growing bones of children. Increased cerebrospinal fluid pressure (pseudotumor cerebri with papilledema) seems to be symptomatic of chronic intake in somewhat less than half the cases reported in adults. This syndrome in infants is generally diagnosed on the basis of bulging fontanelles. The most serious implied sequela to toxicity is irreparable damage to the liver, resulting in cell death, fibrosis and cirrhosis, or permanent stunting of bone growth. Two cases have been reported of adult hepatic injury from chronic hypervitaminosis A resulting in portal hypertension and effusion of serous fluid into the abdominal cavity (ascites) (Ref. 6). One patient was a 54-year-old woman who had been taking 100,000 to 1,250,000 I.U. vitamin A daily for 5 years. The other patient, a 62-year-old man, had been consuming 400,000 I.U. daily for 8 years. In the great majority of cases, complete withdrawal of vitamin A results in regression of signs of symptoms in a matter of days, with no apparent changes remaining in a few weeks (Ref. 3).

It is common manufacturing practice to include additional amounts (overages) of vitamins which are subject to deterioration and loss of potency, such as vitamin A, in commercial preparations in order to guarantee the user that he will receive at least the labeled potency before the expiration date set by the manufacturer for that particular preparation. It is not uncommon for vitamin A preparations to contain as much as a 40 percent overage. Overages of at least 25 percent are said to assure maintenance of product potency for 18 to 24 months. It is obvious, then, that much of the published case history data on toxicity may in fact have been observed in patients consuming up to 140 percent (or more) of the labeled amount of vitamin A. This has been taken into consideration in the limitations imposed by the Panel in its recommendation on vitamin A-containing products. Technological improvements in formulation should be developed so that shelf lives of up to 2 years can continue to be met with overages not exceeding 25 percent. Therefore, the Panel concludes that the actual amount of vitamin A present in OTC drug products should not contain overages exceeding 25 percent and that the maximum OTC quantity of vitamin A, including an overage, should not exceed 12,500 I.U. vitamin A based on the retinol equivalent per dosage unit.

d. *Effectiveness.* The Recommended Dietary Allowances (RDA) (Ref. 7) established by the Food and Nutrition Board, NAS/NRC appear to be in excess of the amount of vitamin A needed daily. However, these allowances are based on dietary sources of vitamin A activity of which about 50 percent consist of mixed carotenoids with *B*-carotene predominating. The carotenoids are poorly absorbed and converted by man, particularly when they are consumed in large amounts. Mixed carotenoids generally are assumed to have one-ninth the vitamin A activity, in man, of preformed retinol (Ref. 2).

The U.S. RDA as promulgated in the Dietary Supplement Regulations published in the FEDERAL REGISTER of October 19, 1976 (41 FR 46175) are definitely generous (in excess) when applied to the retinyl esters in pharmaceutical vitamin preparations. In the often cited "Sheffield experiment," it was found that 390 μg (1,300 I.U.) retinol daily was sufficient to restore defective dark adaptation but that it took 750 μg (2,500 I.U.) daily to bring the blood vitamin A level back to what it was before the depletion period (Ref. 8).

One I.U. of vitamin A activity is equivalent to 0.3 μg retinol, 0.344 μg retinyl acetate (Ref. 8) or 0.535 μg retinyl palmitate. Retinol and its esters are readily absorbed from the normal gastrointestinal tract. If the amount ingested is not much greater than the requirement, absorption is complete. Plasma levels reach a maximum about 4 hours after the ingestion of the vitamin and then fall rapidly. Until hepatic saturation takes place, the administration of vitamin A leads mainly to its accumulation in the liver rather than to increased blood levels.

Particular attention should be paid to vitamin A status in patients with diseases in which fat absorption is defective. Serum vitamin A levels are depressed in patients with celiac disease, sprue, obstructive jaundice, and cystic fibrosis. Blood vitamin A levels decrease during chronic disorders accompanied by fever. This is observed in children with rheumatic fever and in patients with infectious hepatitis. Pathology of the liver, as in the latter disease and in cirrhosis, affects vitamin A status. Cirrhosis of the liver usually results in extremely low and sometimes completely absent reserves of vitamin A in the liver. Cancer, tu-

berculosis, and chronic infections, particularly pneumonia, chronic nephrosis, urinary tract infections, and prostate diseases may be associated with increased urinary excretion of vitamin A (Ref. 2) and thus may increase the intake requirement. Chronic renal disease with uremia may result in elevated plasma vitamin A levels (Ref. 9).

The effectiveness of vitamin A preparations in restoring and maintaining blood levels and liver stores depends not only on administration of a suitable dosage regimen but also on the absorption efficiency of the vitamin in the product. It is of no consequence whether the vitamin A is in water solution (water-miscible), emulsion, or oil solution, except that at the highest dosages a water solution results in somewhat larger storage than an oil solution (Ref. 10). This observation may be important to consider in the treatment of persons with defective fat absorption.

As mentioned above, 750 μg (2,500 I.U.) vitamin A orally daily was found to be required to bring the blood levels of vitamin A of depleted adults back to what they were before depletion. This value, then, is the best estimate of a safe minimum effective daily dose for restoring and maintaining normal liver reserves in the healthy adult.

e. *Conclusion.* The Panel has reviewed the scientific literature, the submitted data and the marketing history of vitamin and mineral ingredients. Based upon the available data, the Panel concludes that vitamin A, in the dosage and forms identified under Category I conditions below, is safe and effective for use in the prevention and treatment of vitamin A deficiency when the need for such therapy has been determined by a physician.

f. *Category I conditions under which vitamin A activity is generally recognized as safe and effective and is not misbranded.* The Panel recommends that the Category I conditions be effective 30 days after the date of publication of the final monograph in the FEDERAL REGISTER.

Acceptable sources of vitamin A activity are vitamin A, vitamin A acetate, and vitamin A palmitate. Dosage must be based on the retinol equivalent expressed in international units (I.U.) ($C_{20}H_{30}O$, molecular weight 286.4 and 0.3 G2T1μg retinol is equivalent to 1.0 I.U.).

(1) *Dosage*—(i) *For prevention of deficiency.* For adults and children 1 year of age and older, the oral dosage is 1,250 to 2,500 I.U. daily. For children under 1 year of age, the Panel recommends the advice and supervision of a physician.

(ii) *For treatment of deficiency.* For adults and children 1 year of age and older, the oral dosage is 5,000 to 10,000 I.U. daily. For children under 1 year of age, the Panel recommends the advice and supervision of a physician.

(2) *Labeling.* The Panel recommends the following Category I labeling:

(i) *Indications—(a) For prevention of deficiency.* "For use in the prevention of vitamin A deficiency when the need for such therapy has been determined by a physician."

(b) For treatment of deficiency. "For use in the treatment of vitamin A deficiency when the need for such therapy has been determined by a physician."

(ii) *Warning—For products for the treatment of deficiency.* "Do not exceed the recommended dosage except under the advice and supervision of a physician. Excessive dosages may cause harm."

g. *Category II conditions under which vitamin A is not generally recognized as safe and effective or is misbranded.* The Panel recommends that the Category II conditions be eliminated from OTC vitamin A drug products effective 6 months after the date of publication of the final monograph in the FEDERAL REGISTER.

The OTC drug use of vitamin A under the following conditions is unsupported by scientific data and in some instances by sound theoretical reasoning. The Panel concludes that the following suggested indications appearing either in the literature or in the submissions to the Panel for the use of vitamin A are presently not supported by adequate controlled clinical studies and should not be permitted on the market until scientific testing supports their use.

(1) Claims for the value of vitamin A sources for prevention or treatment of the following conditions have not been proven safe or effective for OTC drug use:

(i) "Plantar warts."
(ii) "Acne."
(iii) "Ichthyosis."
(iv) "Hyperkeratosis."
(v) "Stress ulcers."
(vi) "Dry or wrinkled skin."
(vii) "Respiratory infections."
(viii) "Visual defects and diseases of the eye."

(2) Claims for superiority in effectiveness of naturally occurring vitamin A over synthetic vitamin A have not been proven. Evidence is lacking that the claim is valid. The effective form of vitamin A for overcoming vitamin A deficiency (i.e., predominantly all-trans isomers of retinol and its acetate and palmitate esters) is not dependent upon a particular source material or mode of synthesis.

h. *Category III conditions for which the available data are insufficient to permit final classification at this time.* The Panel recommends that a period of 2 years be permitted for the completion of studies to support the movement of Category III conditions to Category I.

Claims for advantages of water-soluble or water-miscible vitamin A over vitamin A in oil have not yet been substantiated. Evidence is insufficient to prove that the difference in vehicles or molecular dispersion has any effect on the bioavailability for humans and hence the effectiveness of vitamin A for overcoming vitamin A deficiency.

(1) *Evaluation.* Data required includes the demonstration of statistically significant differences between the absorption of vitamin A in oil and that of competing preparations after the administration of 10,000 I.U. of vitamin A per dosage unit, or less, to persons having proven lipid malabsorption from sundry causes. In this discussion we are not concerned about dosages larger than 10,000 I.U. per dosage unit, since such doses would not be OTC.

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12. *Vitamin D.* The Panel's statement on vitamin D includes the fol-

lowing ingredients: cholecalciferol and ergocalciferol.

a. *Reference forms.* Dosages recommended in this document for vitamin D are based on either the cholecalciferol equivalent ($C_{27}H_{44}O$, molecular weight 384.6) or the ergocalciferol equivalent ($C_{28}H_{44}O$, molecular weight 396.6) expressed in international units (I.U.) (0.025 μg vitamin D is equivalent to 1.0 I.U.).

b. *Description.* The importance of vitamin D in human nutrition is well recognized and deficiency states in children (rickets) and adults (osteomalacia) are well-defined.

Vitamin D exists in two forms, vitamin D-2 (ergocalciferol) and vitamin D-3 (cholecalciferol). Vitamin D-3, the naturally occurring form of the vitamin in animal tissues, is formed when ultraviolet irradiation is absorbed by 7-dehydrocholesterol (7-DHC). Areas of the skin in most adults contain 3 to 4 percent of 7-DHC and all of it is beneath the stratum corneum. Due to this unique anatomical relationship, the conversion of 7-DHC to vitamin D-3 is partially regulated by the amount of natural or induced pigment in the corneum. The endogenous production rate of vitamin D-3 is unknown in man, but it must be at least equivalent to the minimal vitamin dietary dose of 200 to 400 I.U. daily essential to cure rickets resulting from lack of vitamin D intake (Ref. 1) since it has been observed that brief ultraviolet skin irradiation is curative (Ref. 2). Vitamin D-2, a synthetic form of the vitamin produced by the ultraviolet irradiation of ergosterol (a plant sterol), is equally as effective in man as vitamin D-3 (Ref. 3).

Following its synthesis within the skin, vitamin D-3 is absorbed via the subepidermal microcirculation and admixes with circulating vitamin D-2 and vitamin D-3 absorbed from dietary sources.

Dietary vitamin D-3 and vitamin D-2 are absorbed primarily from the duodenum and jejunum into lymphatic channels; both bile salts and intraluminal lipids must be present for absorption to occur (Ref. 4). In healthy adults and children, vitamin D is almost completely absorbed by the intestine and the vehicle in which the vitamin is administered (aqueous suspension, oil, milk, or other food) does not affect absorption (Ref. 1). The total content of circulating vitamin D in man is estimated at 25 ng/ml (Ref. 5).

Assimilated vitamin D is then sequestered primarily by the liver for metabolic transformation, or transported to primary storage depots (adipose tissue and muscle) (Refs. 6 and 7), the latter presumably serving as reservoirs to be called upon during deprivation or lack of sunlight exposure. Vitamin D-3 and vitamin D-2 are subsequently metabolized to their respective 25-hydroxylated derivatives, 25-hydroxycholecalciferol (25-OHD_3) and 25-hydroxyergocalciferol (25-OHD_2) by the liver (Ref. 8). Although it has been established that this hepatic 25-hydroxylase system undergoes "feedback" inhibition by the product of the reaction, the feed-back control mechanism is limited and becomes inefficient when large doses of vitamin D are ingested (Refs. 9 and 10).

25-OHD (25-OHD_2 and 25-OHD_3) is the main circulating biologically active form of vitamin D at concentrations ranging between 17 to 23 ng/ml (Ref. 11). A direct correlation has been observed between circulating 25-OHD, calcium concentrations, vitamin D intake, and exposure to sunlight (Ref. 12). It has been demonstrated that 25-OHD is capable of increasing both bone resorption and the intestinal absorption of calcium (Refs. 13 and 14). 25-OHD also increases the renal reabsorption of calcium, sodium, and phosphate (Ref. 15).

The fate of 25-OHD_3 includes sequestration into fat and muscle storage sites and its biological hydroxylation to a number of biologically active metabolites such as 24,25-dihydroxycholecalciferol or 1,24,25-trihydroxycholecalciferol. However, the most important and most biologically active metabolite produced from the 25-hydroxylated vitamin D compounds is 1,25-dihydroxycholecalciferol or 1,25 dihydroxyergocalciferol, subsequently referred to as 1,25-$(OH)_2D$. This conversion occurs enzymatically in the kidney (Ref. 16) and is regulated by a variety of hormonal and ionic factors (Ref. 9), not the least of which is parathyroid hormone (Ref. 17). Reported levels of circulating 1,25-$(OH)_2D$ in adults average 29±2 picograms/ml (pg/ml) with higher levels (49 to 66 pg/ml) reported for the 9 to 18-year-old range (Ref. 18).

Thus, vitamin D is either metabolically transformed into biologically active metabolites by hepatic and renal hydroxylating enzyme systems, or stored in muscle and adipose tissues. However, the bioregulatory feedback system, which controls the metabolic transformation of vitamin D to its biologically active metabolites, appears inadequate to prevent their accumulation. These observations, together with those which demonstrate no urinary excretion of biologically active vitamin D metabolites in a normal population (Ref. 19) and others establishing almost a limitless adipose tissue-muscle reservoir for vitamin D and its biologically active metabolites (Ref. 20), make an evaluation of the minimal dietary requirements of vitamin D for normal skeletal growth and maturation essential.

When estimating total exposure to vitamin D, it is appropriate to consider the length and intensity of exposure to sunlight, the race in question, and the cumulative daily ingestion of the vitamin.

Vitamin D occurs naturally in such animal foods as fatty fish, egg yolk, liver, and butter. Meat (other than liver), human milk, and nonfortified cow's milk are all poor sources.

Much of the milk now available in the U.S. is supplemented with vitamin D to provide a concentration of 400 I.U. per quart (equivalent to 10 μg vitamin D-3 per quart), although a considerable amount of unfortified milk is ingested in certain rural areas of the country. In addition, all brands of evaporated milk and some powdered milk are fortified and a wide variety of other foods, including margarine, milk flavorings, breakfast cereals, bread, and chocolate bars contain vitamin D in varying amounts. Vitamin D is stable in foods. Storage, processing, and ordinary cooking do not affect its activity.

c. *Safety—Vitamin D toxicity.* The symptoms of vitamin D toxicity are due either to the direct effect of the induced hypercalcemia and accompanying electrolyte abnormalities on cognative functions, cardiac rhymicity, renal or gastrointestinal function, or to an indirect effect of diffuse metastic calcification in critical organs such as the kidney, heart, and blood vessels. Symptoms frequently noted first are weakness, fatigue, malaise, dry mouth, vague muscle and bone pains, headache, and metallic or bad taste. Weight loss, diarrhea, anorexia, nausea, and vomiting reflect the gastrointestinal response to hypercalcemia. Thirst, polyuria, nocturia, burning of the eyes, conjunctivitis, generalized pruritis, diminished libido, pancreatitis, renal calculi, diminished hearing acuity, photophobia, rhinorrhea, hyperthermia (in children), and hypertension have also been associated with the hypercalcemic state. Hemiplegia and mental impairment have been reported in children with hypercalcemia, as have a variety of anatomical cardiac defects.

There appears to be a fairly wide range of susceptibility to the toxic actions of vitamin D. Consumption of vitamin D above 2,000 I.U. daily (five times the recommended daily allowance) for prolonged periods has been associated with hypercalcemia in infants and nephrocalcinosis in infants and adults (Ref. 21). It also has been established that approximately 20 percent of normal adults who receive 100,000 I.U. of vitamin D daily will develop hypercalcemia (Ref. 22). Daily intakes of vitamin D ranging from

1,800 to 6,300 I.U. may inhibit linear growth of normal children (Ref. 23). Some children appear to be inordinately sensitive to vitamin D, developing hypercalcemia on vitamin D doses of 1,000 to 2,000 I.U. daily (Ref. 24). Signs and symptoms of vitamin D intoxication have been reported with as little as 25,000 I.U. daily (Ref. 25), although in most cases overt clinical signs of intoxication and hypercalcemia occur when the dose exceeds 50,000 I.U. daily (Ref. 26).

The mean daily dose ingested by patients who are clinically intoxicated with vitamin D has been estimated at 2,080 I.U./kg of body weight or 145,600 I.U. daily in a 70 kg adult (Ref. 27). Consideration of reported vitamin D dose-toxicity relationships must be tempered, however, with the knowledge or renal function and the clinical disorder for which the vitamin is administered. Data obtained from a treated hypoparathyroid population may be misleading since parathyroid hormone plays an essential role in activating vitamin D (Ref. 17). Moreover, although the mean dose of vitamin D essential for control of hypoparathyroid patients is approximately 80,000 I.U. daily (Ref. 18), doses required to correct the hypocalcemia for these patients may vary from 25,000 to 200,000 I.U. daily (Ref. 29). Along similar lines, levels of vitamin D which produce intoxication in patients with renal disease and chronic liver or biliary disease may bear little relationship to the response of normal healthy children or adults to vitamin supplementation since, in disorders characterized by hepatic or renal dysfunction, the response to vitamin D is diminished (Refs. 9, 30, and 31).

One must also bear in mind the hypersensitivity to vitamin D which exists in a variety of clinical states (Ref. 9). Patients with sarcoidosis are especially prone to develop hypercalcemia on very small doses (e.g., 1,000 I.U. daily) of vitamin D (Ref. 32). Recent data are also consistent with the observation that self-medication with multivitamin preparations containing vitamin D may lead to renal calculi in adults (Ref. 33). Direct correlations between the ingestion of vitamin D supplements and recurrent renal calculi have been made in individuals ingesting no more than 1,100 to 1,650 I.U. daily (Ref. 33). Finally, it should be emphasized that excessive calcium intakes (greater than 1.0 g daily) as may often exist in growing children predisposed to vitamin D intoxication (Ref. 34), and that clinical evidence of toxicity may appear as early as 12 days (Ref. 35) or not until years after vitamin D treatment is initiated (Ref. 36).

d. *Effectiveness.*—(1) *General comments on vitamin D requirements.* The amount of vitamin D essential to achieve optimal circulating levels of its biologically active metabolites in any given individual is dependent upon age, rate of growth, efficiency of intestinal absorption (especially of fat), the integrity of hepatic and renal function, length and intensity of exposure to sunlight, the nature of ingested drugs, and skin color. Heavily pigmented skins can prevent up to 95 percent of ultraviolet radiation from reaching the deeper layers of skin where vitamin D is synthesized (Ref. 37). In fact, children born of Black mothers may have relatively lower levels of circulating 25-OHD_3 because of these maternal deficits (Ref. 38). The effects of medications, such as phenobarbital and diphenylhydantoin, on circulating levels of calcium and 25-OHD exemplify the need to explore drug intake as well as dietary histories when assessing vitamin D status. In a clinical study of adult outpatient epileptics on both anticonvulsants, significantly lower levels of serum calcium (19 percent) and 25-OHD (33 percent) were observed (Ref. 39).

Similar but less marked changes were observed in individuals on single drug therapy. A subsequent study of 56 pediatric epileptic outpatients on anticonvulsant medication yielded similar results with the lowest levels of serum calcium, serum 25-OHD, and bone density observed in children on multiple anticonvulsant drug regimens (Ref. 40). These observations are consistent with the reported increased incidence of clinical rickets and osteomalacia in children and adults subjected to anticonvulsant medication (Refs. 41, 42, and 43). Cholestyramine, because of its ability to chelate vitamin D within the gastrointestinal tract, also results in lower plasma 25-OHD (Ref. 11).

Rickets and osteomalacia resulting from dietary vitamin D insufficiency are relatively rare in young or middle-aged adults in the United States, since the mature skeleton with its relatively slow turnover rate is able to withstand short periods of vitamin D deficiency without deleterious effects, and vitamin D depots in fat and muscle are often more than sufficient to maintain skeletal integrity. It has been documented, however, that nutritional or conditional deficiencies of vitamin D develop in British subjects of any age when the diet contains less than 70 I.U. vitamin D daily (Ref. 44). The usual dietary history obtained from vitamin D-depleted individuals is of avoidance of fatty foods or of being a strict vegetarian. Migratory immigrants, (Refs. 45 and 46), premature infants (Ref. 47), elderly females (Refs. 48 and 49), and individuals routinely ingesting food with excessive phytic acid content (Ref. 45), also appear to be most susceptible to the nutritional form of osteomalacia that characteristically responds to small doses of vitamin D.

Limited exposure to sunlight may contribute significantly to the osteomalacia of elderly females since they, as a group, particularly when living alone, tend to have physical disabilities which limit mobility, and then become apathetic and reluctant to go outdoors.

Since natural dietary sources and sunlight exposure may often prove insufficient to supply the vitamin D required to prevent rickets and osteomalacia especially in rapidly growing young infants and elderly individuals, the practice of fortification of foods with vitamin D has enjoyed considerable international success. Methods of supplementation have been haphazard, with practices and regulations not only differing from country to country but also changing from time to time (Ref. 1). Moreover, analyses of foods demonstrated that the actual content of vitamin D is often higher than stated on the label because of an excess or an overage of the vitamin added by the manufacturer to allow for possible deterioration over a 2-year shelf life (Ref. 1). The error intrinsic to the vitamin D bioassay, which often differs from the actual value by plus or minus 20 percent, plus factors in packaging and processing, all contribute to the overage needed by the manufacturer. Estimated overages for vitamin D in multivitamin drops approach 50 percent in order to offset an estimated 30-percent degradation. Vitamin D overage in chewable tablets may also approximate 30 to 40 percent, especially if the tablets also contain minerals. In fact, this overage may equal as much as 100 percent or more of the label claims in the United States. The Panel concludes that no more than 25 percent vitamin D may be included in any OTC drug product as an overage.

Concerns about overage, excess food fortification, and potential long-term toxic effects of cumulative doses of vitamin D led a select Committee on Nutrition of the American Academy of Pediatrics (Ref. 1) to recommend that "efforts be taken to ensure a total vitamin D intake of 400 I.U. daily by all infants and children. At the same time, an attempt should be made to restrict the intake from all sources to an amount not greatly in excess of this figure."

The Committee on Nutrition considered also the practice of fortifying foods other than milk or infant formula products with Vitamin D to be unjustified and recommended its discontinuation (Refs. 1 and 50).

(2) *Vitamin D prophylaxis in full-term and premature infants.* The minimal requirement of vitamin D has never been established for infants. Estimates of the essential dose range are from approximately 100 I.U. (Refs. 51 and 52) to approximately 400 I.U. daily (Refs. 53 and 54); although 2.5 μg (100 I.U.) vitamin D daily prevents rickets and ensures adequate intestinal absorption of calcium, it would appear that intakes of 300 to 600 I.U. daily promote better linear growth and are at least as effective as greater intakes (Refs. 52 and 54).

Studies in pregnant women during the last trimester (Ref. 55) and in formula-fed premature infants (Ref. 47) emphasize the need for initiation of vitamin D prophylaxis within the first 2 weeks of life and reveal that rickets is preventable and rates of linear growth are as rapid with vitamin D intakes of 100 to 200 I.U. daily as with intakes of 400 to 1,200 I.U. daily (Refs. 56, 57, and 58). Reports of rickets in premature infants treated with vitamin D doses as large as 5,000 I.U. daily (Ref. 59) may be due entirely to an inadequate dietary supply of calcium. A daily dose of 400 I.U. vitamin D in full-term infants or in premature infants when initiated within the first 2 weeks of life appears more than adequate. This dose is probably in excess of the actual need.

(3) *Vitamin D prophylaxis in children and adolescents.* With the exception of heavily pigmented populations and those of poor socioeconomic status, definitive evidence of rickets beyond infancy in the United States is rare. Maximal calcium absorption and skeletal growth can be achieved with total vitamin D intake of 400 I.U. daily (Ref. 60). There are also observations that 200 I.U. vitamin D daily in normal healthy children between 2 and 5 years of age promote maximal calcium absorption from the intestine (Ref. 61).

(4) *Vitamin D prophylaxis in adults.* The amount of vitamin D essential for normal skeletal turnover in the Caucasian adult is for all practical purposes satisfied by eating an average diet and casual exposure to sunlight. Osteomalacia may occur when vitamin D intakes are less than 70 I.U. daily, accompanied by a lack of sunlight exposure as might be expected in cloistered or relatively immobilized elderly individuals (Ref. 62). Reports of osteomalacia in pregnant (Ref. 63) and lactating female populations ingesting diets relatively deficient in vitamin D and calcium stress the need for adequate vitamin D intakes and sunlight exposure during the pregnancy to ensure the integrity of both the maternal and fetal skeleton (Ref. 55). A total daily intake of vitamin D of 400 to 500 I.U. should be quite sufficient for pregnant females with average sunlight exposure to maintain normal maternal and fetal 20-OHD levels.

(5) *Estimated intakes of vitamin D.* To date there are scanty data regarding vitamin D intake in the U.S. Recently, Hahn et al. (Ref. 12) were able to show that vitamin D intakes of adult individuals on random diets living in the metropolitan St. Louis area averaged 1,710 I.U. weekly. These estimates appear quite reasonable since the correlation between estimated intake and circulating 25-OHD proved to be quite good (Ref. 12). Surveys of vitamin D intakes of infants and children reveal wide variations in the amount ingested. Children whose intake approximates the recommended allowance are in the minority, the majority ingesting amounts which prove to be either considerably smaller or greater than the recommended allowance (Ref. 40). In 1964, a Canadian survey conducted in areas where dairies added varying amounts of vitamin D to fresh milk indicated that 6 percent of the children were getting less than 400 I.U. daily, 93 percent ingested between 400 and 2,000 I.U. daily, and 1 percent over 2,000 I.U. daily (Ref. 64). A second Canadian survey of 1,000 children was conducted in 1966 prior to governmental regulations restricting fortification of foods with vitamin D. The survey included children from birth to age 5.5 years and was made in areas where vitamin D was not added to fresh milk (Ref. 65). In 38 children, vitamin D was not ingested either as supplements or fortified milk; 259 children had estimated vitamin D intakes which were less than 400 I.U.; 389 children had intakes between 401 and 1,000 I.U.; 314 had intakes over 1,000 I.U., and in 22 the daily intake exceeded 1,800 I.U. Thus, in this study, over 70 percent of the children had daily vitamin D intakes greater than 400 I.U.; 33 percent were ingesting over 1,000 I.U. daily. No specific estimate was made of sunlight exposure.

A survey made in Britain in 1951 indicated that some children were ingesting at least 35,000 I.U. vitamin D daily from a variety of proprietary preparations. Three years following governmental regulations which led to a sharp reduction in vitamin D content of fortified foods and vitamin preparations in that country, a survey of 307 infants under the age of 1 year revealed that the average daily intake of vitamin D was 300 I.U. for the lowest quarter of the group and 1,100 I.U. for the highest quarter, whereas the average intake of the remaining infants was approximately 600 I.U. (Ref. 66). It appears that a detailed U.S. population survey of total vitamin D intake (diet plus supplemental vitamins) and total sunlight exposure is indicated. Additional measurements of average circulating 25-OHD levels of individuals of various ages and race should be included.

e. *Conclusion.* The Panel has reveiwed the scientific literature, the submitted data, and the marketing history of vitamin and mineral ingredients. Based upon the available data, the Panel concludes that vitamin D, in the dosage and forms identified under Category I conditions below, is safe and effective for use in the prevention of vitamin D deficiency when the need for such therapy has been determined by a physician.

The minimal effective dose of vitamin D is defined as either the amount of any vitamin D source(s) which would prevent the development of symptomatic or radiographic evidence of rickets in children or osteomalacia in the adult, or the amount of any vitamin D source(s) which, when combined with sunlight exposure, would maintain the circulating level of 25-OHD within the normal limits of 17 to 23 ng/ml.

In either case, 400 I.U. vitamin D daily would appear more than adequate in the growing child and 100 I.U. daily sufficient for the adult with a mature skeleton. The maximum effective dose in adults is 200 I.U. since greater concentrations do not appear to increase the intestinal absorption of calcium in mature people. The maximum safe dose has not yet been determined. However, for an adult it appears that dosages greater than 1,000 to 1,200 I.U. daily may ultimately prove toxic and contribute to the formation of renal calculi and myocardial infarction.

The Panel concludes that a total dose of 400 I.U. vitamin D to healthy infants, growing children, and pregnant women who are subjected to normal sunlight exposure is appropriate. The Panel also recognizes that there may be additional populations at risk such as elderly or cloistered individuals, food faddists, highly pigmented individuals, and persons of poor socioeconomic status, for whom routing daily ingestion of natural vitamin D-containing foodstuffs is difficult, and for whom an extradietary intake of vitamin D up to 400 I.U. daily may be indicated.

Concerns about overdosage with vitamin D in the form of fortified foods and OTC drugs, based on the known multisystemic effects of vitamin D-induced hypercalcemia, are well founded. However, data on potential long-term, deleterious effects of cumulative vitamin D intakes consumed by the average citizen in the form of OTC drugs and fortified foods, and the relationships of the cumulative vitamin D intake to working habits, age, sunlight exposure, race, and socioeconomic

status are essentially nonexistent. Recent studies are consistent with the hypothesis that long-term consumption of vitamin D may be a precipitating cause of myocardial infarction in man (Refs. 67, 68, and 69), and that a daily intake of 1,200 I.U. may be the critical level. Reports of renal calculi in patients self-medicated with multivitamin preparations containing vitamin D also warrant attention (Ref. 33). These data bear consideration, since the relationship between the increasing incidence of atherosclerotic vascular disease in man and the chronic ingestion of nonhypercalcemic doses of vitamin D is still unknown.

f. *Category I conditions under which vitamin D activity is generally recognized as safe and effective and is not misbranded.* The Panel recommends that the Category I conditions be effective 30 days after the date of publication of the final monograph in the FEDERAL REGISTER.

Acceptable sources of vitamin D activity are cholecalciferol and ergocalciferol. Dosage must be based on either the cholecalciferol equivalent ($C_{27}H_{44}O$, molecular weight 384.6) expressed in international units (I.U.) or the ergocalciferol equivalent ($C_{28}H_{44}O$, molecular weight 396.6) expressed in international units (I.U.) (0.025 ug vitamin D is equivalent to 1.0 I.U.).

(1) *Dosage—For prevention of deficiency.* For children under 18 years of age, the oral dosage is 400 I.U. daily. For adults 18 years of age and older, the oral dosage is 200 I.U. daily.

(2) *Labeling.* The Panel recommends the following Category I labeling:

(i) *Indication—For prevention of deficiency.* "For use in the prevention of vitamin D deficiency when the need for such therapy has been determined by a physician."

(ii) *Warning.* "Do not take this product if you have a history of kidney stones except under the advice and supervision of a physician."

g. *Category II conditions under which vitamin D activity is not generally recognized as safe and effective or is misbranded.* The Panel recommends that the Category II conditions be eliminated from OTC vitamin D drug products effective 6 months after the date of publication of the final monograph in the FEDERAL REGISTER.

The OTC drug use of vitamin D under the following conditions is unsupported by scientific data and, in some instances, by sound theoretical reasoning. The Panel concludes that the following labeling claims and forms of vitamin D should not be permitted on the OTC market until scientific testing supports their use: (1) Claims that vitamin D is effective in lowering serum cholesterol, preventing or curing senile osteoporosis.

(2) Claims which suggest that multivitamin preparations containing minerals and vitamin D are superior to forms containing vitamin D alone.

(3) The use of 25-, 1,25-, or 24,25-hydroxylated forms of vitamin D, or of synthetic derivatives such as 1-alpha-vitamin D and 5,6-trans-vitamin D, cannot be sanctioned at any dosage.

h. *Category III conditions for which the available data are insufficient to permit final classification at this time.* The Panel recommends that a period of 2 years be permitted for the completion of studies to support the movement of Category III conditions to Category I.

None.

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13. *Vitamin E.* The Panel's statement on vitamin E includes the following ingredients: Tocophersolan (*d*-alpha-tocopheryl polyethylene glycol 1,000 succinate), alpha-tocopheryl acetate, alpha-tocopheryl acid succinate, and vitamin E.

a. *Reference form.* Dosages recommended in this document for vitamin E, for use in combination products only and not as a single ingredient, are based on the *dl*-alpha-tocopheryl acetate equivalent expressed in international units (I.U.) ($C_{31}H_{52}O_3$, molecular weight 472.7, 1 mg *dl*-alpha-tocopheryl acetate is equivalent to 1 I.U.).

b. *Description.* Vitamin E is a form of alpha-tocopherol expressed in international units (I.U.) of vitamin E based on the following equivalents (Ref. 1):

1 mg *dl*-alpha-tocopheryl acetate=1 I.U.
1 mg *dl*-alpha-tocopheryl acid succinate=0.89 I.U.
1 mg *dl*-alpha-tocopherol=1.1 I.U.
1 mg *d*-alpha-tocopheryl acetate=1.36 I.U.
1 mg *d*-alpha-tocopherol=1.49 I.U.
1 mg *d*-alpha-tocopheryl acid succinate=1.21 I.U.

Preparations of *d*- or *dl*-alpha-tocopherol contain not less than 33 percent total tocopherols, of which not less than 50 percent consists of *d*- or *dl*-alpha-tocopherol (Ref. 1).

Preparations of *d*- or *dl*-alpha-tocopheryl acetate contain not less than 25 percent of *d*- or *dl*-alpha-tocopheryl acetate of which not less than 95 percent consists of *d*- or *dl*-alpha-tocopheryl acetate (Ref. 1).

The *d*- and *dl*- forms of alpha-tocopherol or its esters shall not be present in the same preparation except as a consequence of the dilution of a *dl*-form with suitable vehicles which may contain some *d*- form (Ref. 1).

Assay procedures are set forth in an official compendium (Ref. 1).

Marketed preparations of vitamin E include liquids (drops and elixir), soft or hard gel capsules, tablets, and injectables. Water-miscible or -soluble forms, made by emulsification with polyethylene glycol 1,000 or polysorbate 80, also are available.

c. *Safety.* An unpublished review of trials on over 9,000 cases by Salkeld (Ref. 2) showed that doses of vitamin E of 3,000 I.U. for up to 11 years and 55,000 I.U. for a few months in a few subjects had no detrimental effect on a variety of clinical and biochemical parameters. These high doses were well tolerated. Only 8 percent of approximately 1,000 patients complained, mostly about gastrointestinal disturbance. However, on the basis of animal studies, the Food and Nutrition Board, NAS/NRC (Ref. 3) and Bieri (Ref. 4) urged caution whenever consumption of large doses of vitamin E for long periods of time is encountered or contemplated. According to Bieri (Ref. 4), "conceivably, the ingestion of large doses of vitamin C or vitamin E could appreciably reduce an individual's vitamin A status."

In a letter to the editor, Briggs (Ref. 5) referred to six clinical cases of gastrointestinal irritation from the consumption of wheat germ oil, two cases of severe weakness with creatinuria after the daily ingestion of 800 I.U. vitamin E daily for 3 weeks, and a striking creatinuria in a physician who took 2 to 4 g vitamin E daily for several months.

d. *Effectiveness*—(1) *Requirement.* The requirement for vitamin E in body tissues is related to the polyunsaturated fatty acid (PUFA) content of cellular structures (Ref. 3). Since the composition of fatty acids in tissues can be affected by the type of dietary fat, it is not possible to establish a firm recommended allowance. Individuals ingesting diets low in PUFA will have lower intakes of vitamin E, and also lower requirements, than individuals consuming diets higher in PUFA (Ref. 3).

"The minimum adult requirement for vitamin E when the diet contains the minimum of essential fatty acids is not known, but is probably not more than 3 to 6 I.U. per day." The Food and Nutrition Board, NAS/NRC recommends a range of from 4 I.U. daily for infants to 15 I.U. daily for adult males and pregnant and lactating women (Ref. 3). Also recommended is a vitamin E:PUFA ratio of 0.4 mg Vitamin E to 1 g PUFA. Thompson et al. (Ref. 6) consider the use of the vitamin E:PUFA ratio to be impractical and, from analysis of the Canadian diet and the fact that there is no evidence of extrinsic vitamin E deficiency in adults in Canada, conclude that the adult requirement for vitamin E is less than 15 I.U. daily.

(2) *Deficiency.* Vitamin E deficiency has been experimentally produced in man with great difficulty (Ref. 7). After 30 months depletion, the experimental subjects were apparently unaffected in all respects except for slight reductions in erythrocyte survival time and, of course, lower tissue vitamin E levels. Leonard and Losowsky (Ref. 8) have reported beneficial effects on red cell survival time from the administration of alpha-tocopherols to persons with low (0.15 to 0.4 mg/100 ml) plasma levels of vitamin E. Their subjects consisted of six individuals with malabsorption disorders and two chronic alcoholics, one of whom failed to respond to therpay adequately as indicated by the plasma vitamin E level. Of the remaining seven, five showed an increased red cell survival time.

Low serum levels of vitamin E, and of lipoproteins, are found normally in newborn infants and they are lower still in premature infants. In the U.S., edema and anemia attributed to vitamin E deficiency have been reported in low birth weight infants fed commercial formulas that have a low content of the vitamin (Ref. 3). Other studies with low birth weight infants consuming similar formulas, however, have not revealed any deficiency signs or symptoms (Ref. 3). Leonard, Doyle, and Harrington (Ref. 9) found that infants born to mothers with plasma vitamin E levels below 0.7 mg/100 ml have extremely low plasma E levels and they recommend that all mothers with plasma vitamin E levels below 0.7 mg/100 ml in the last trimester of pregnancy be supplemented with vitamin E. Tancredi et al. (Ref. 10) have reported on six premature infants with anemia which failed to respond to vitamin E therapy.

The Committee on Nutrition of the American Academy of Pediatrics (Ref. 11) "concluded that supplementary administration of vitamin E is not required for premature or full-term infants receiving human milk or formulas of cow milk, except, possibly, when dietary intake of fat is markedly reduced. Dietary supplements of vitamin E seem desirable for patients with prolonged steatorrhea from any cause; relatively large doses may be needed to maintain normal plasma concentrations."

Persons afflicted with conditions that interfere with normal digestion or absorption of fats and fat-soluble vitamins may develop vitamin E deficiency (Ref. 12). Powell (Ref. 13) found that five of eight individuals with long-standing obstructive jaundice had low plasma vitamin E levels and increased in vitro hydrogen peroxide hemolysis. They also had reduced red cell survival times which did not always return to normal with vitamin E therapy. Three persons with normal plasma vitamin E levels also had reduced red cell survival times. A reduced survival time in hepatolenticular disease was not altered by vitamin E.

Deficiency is also found in patients with cirrhosis of the liver and, since vitamin E is normally transported in the blood in association with the beta-lipoprotein fraction, very low plasma levels of vitamin E are found in a-beta-lipoproteinemia.

The above statements are in essential agreement with a 1973 statement of the Food and Nutrition Board, NAS/NRC (Ref. 14), which says that "The wide distribution of vitamin E in vegetable oils, cereal grains, and animal fats makes a deficiency in humans very unlikely. Premature infants or individuals with impaired absorption of fats may require supplemental vitamin E, but they should, in any event, be under the care of a physician." Horwitt (Ref. 15), in his introduction to an international symposium on vitamin E, pointed out that "the application of knowledge from animal studies to human needs for vitamin E has proved to be extraordinarily difficult. Whereas deficiencies of vitamin E in animals cause a bewildering variety of pathological symptoms, correlations with human disorders have for the most part escaped us. The difference may not be due to the fact that animals have different requirements than man, but rather that man is rarely, if ever, so deficient in vitamin E as are animals fed diets that have no significant amounts of tocopherols."

Severe vitamin E deficiency in man may be associated with widespread tissue deposition of oxidized lipids, creatinuria, erythrocyte-membrane lipid intolerance to oxidants, and ceroid deposits in the intestines (Ref. 12).

(3) *Therapeutic claims.* Large (generally 400 I.U. or more) daily doses (Refs. 16, 17, and 18) of vitamin E have been claimed to benefit human fertility (Ref. 19), cardiovascular disease (Ref. 20), peripheral vascular diseases (Refs. 16 and 21), Dupuytren's contracture and Peyronie's disease (Refs. 22 and 23), and thromboembolic states. Beneficial results have also been claimed for the use of vitamin E in the treatment of leg cramps (Ref. 24), porphyria (Ref. 25), the anemia of protein-calorie malnutrition (Ref. 26) and the anemia and associated edema of low birth-weight infants (Refs. 27 and 28). All of these claims, and others, have been denied (Refs. 14, 17, and 29 through 33) with perhaps some room left open for further study of the effectiveness of vitamin E in the treatment of hemolytic anemia in low birth-weight infants, intermittent claudication, dupuytren's contracture, and Peyronie's disease.

There is some evidence that Caucasian women on combined-type oral contraceptives may experience a decrease in plasma tocopherol levels (Ref. 34). Also, Mustafa (Ref. 35) has reported that animals (rats) receiving 66 parts per million (ppm) vitamin E were insensitive to 0.1 ppm ozone, and exhibited fewer pulmonary biochemical complications from 0.2 ppm ozone as compared with animals receiving 11 ppm vitamin E. He suggests that "the findings may be of relevance to human population exposed to photochemical smog."

(4) *Absorption of commercial vitamin E preparations.* The tocopherols are readily subject to destruction in the digestive tract. Therefore, the acetate or succinate esters, which are quite stable, are generally used in commercial preparations. The esters are readily split in the intestinal wall and the alcohol is absorbed as such, mainly into the lymph stream attached to chylomicrons. After transport to the liver, they enter the blood stream attached to beta-lipoproteins. Normally,

the plasma vitamin E level varies directly with that of the plasma cholesterol.

The following information about the absorption of tritiated alpha-tocopherol is available (Ref. 36). Control subjects absorb between 55 to 78 percent of an orally administered dose of between 12 to 25 micro Curie (uCi) in 1 mg of unlabeled vitamin. Radioactivity appears in the plasma between 1 and 3 hours, peaks between 5 and 9 hours, and falls exponentially with a mean half-life of 53 hours. Chemically, almost all of this radioactivity is associated with free alpha-tocopherol. In patients with malabsorption due to impaired intraluminal digestion with obstructive jaundice, the absorption of a test dose varied from 6 to 16 percent. All these patients had steatorrhea, but there was no correlation between the degree of steatorrhea and the malabsorption of the vitamin. After surgical relief of obstructive jaundice in one of these patients, vitamin E absorption returned to normal. In three patients with chronic pancreatic insufficiency, without malabsorption, net absorption of vitamin E ranged from 32 to 39 percent; the abnormally low absorption was corrected in one patient by the addition of pancreatic supplements. In five patients with untreated adult celiac disease, absorption ranged from 23 to 58 percent. In this group of patients, there was a significant statistical correlation between failure to absorb the vitamin and the degree of steatorrhea. Two patients with intestinal lymphangiectasis absorbed only 29 percent of the orally administered dose, despite a coefficient of fat absorption of over 85 percent.

Beckman (Ref. 37) found a dose of 100 mg of alpha-tocopherol to bring about a peak serum tocopherol level in 4 hours. When the tocopherol was given as drops, a rise in the serum level of 25±14 percent was observed; with tablets there was a rise of 34±14 percent. Goldbloom (Ref. 38) also found that a single dose of either 2 mg or 10 mg tocopherol caused a peak rise in the tocopherol serum level to occur 4 hours after the administration to healthy full-term newborn infants. He found no difference in the absorption of *d*-alpha-tocopheryl acetate, *dl*-alpha-tocopheryl acetate, and *d*-alpha-tocopheryl polyethylene glycol 1,000 succinate. Hashim and Schuttringer (Ref. 39) reported a serum peak 7.5 hours after an oral dose of 600 mg *d*-alpha-tocopherol to a healthy adult male. An adult male with malabsorption associated with chronic pancreatitis had a flat curve. Gounelle and Rouquette (Ref. 40) reported a blood level two to three times normal from the 6th to the 9th hours after the administration of a 200 mg dose of tocopherol. Kelleher and Losowsky (Ref. 41) found that, of a dose of 200 mg of labeled vitamin E acetate, 20 controls absorbed 75 percent on the average. Nineteen steatorrhea cases averaged 61 percent absorption. Absorption was dose-related. They also reported (Ref. 42) that radioactivity in the plasma was maximal 6 to 12 hours after dosing. In some patients with severe deficiency and severe steatorrhea, they found no detectable plasma response even with absorption of up to 40 percent of an orally administered "physiological" dose. Schmandke, Sima, and Maune (Ref. 43) reported 96.9±13 percent of a 10 mg dose of alpha-tocopherol to be absorbed. The percentage absorbed decreased as the dose was increased, e.g., 87.3±13.5 percent of a 30 mg dose was absorbed as compared to 81.5±6 percent of a 100 mg dose and 55.2±28.8 percent of a 2,000 mg dose.

As indicated in the report by Kelleher and Losowsky (Ref. 42), plasma levels of alpha-tocopherol may be misleading in some types of lipid abnormalities. Bieri and Poukka (Ref. 44), in several cases of a-beta-lipoproteinemia, found normal red blood cell tocopherol content and normal resistance to hemolysis after vitamin E therapy, although plasma tocopherol levels remained very low. The red blood cell alpha-tocopherol content may be more informative than the plasma level.

There is not much information available by which to judge the relative efficacy of water-miscible or -soluble forms of vitamin E. Melhorn and Gross (Ref. 45) found *d*-alpha-tocopheryl polyethylene glycol 1,000 succinate to be much better utilized by premature infants than alpha-tocopheryl acetate. The addition of bile salts or emulsification in Tween 80 had no effect on the absorption of oily preparations of vitamins A and E in a patient with xanthomatous biliary cirrhosis (Ref. 46). In children with biliary obstruction, there was a severe defect in the absorption of both fat-soluble and water-soluble vitamin E preparations (Refs. 47 and 48). And, as mentioned above, no advantage of *d*-alpha-tocopheryl polyethylene glycol 1,000 succinate over the fat-soluble esters was found in healthy full-term newborn infants (Ref. 38).

In children and adults with cystic fibrosis, Melhorn (Ref. 49) obtained the best intestinal absorption with alpha-tocopheryl polyethylene glycol 1,000 succinate (TPEGS) in combination with a pancreatic enzyme preparation (cotazyme). Next best was alpha-tocopheryl acetate plus pancreatic enzyme. Last and quite poor was alpha-tocopheryl acetate alone. Unfortunately TPEGS without pancreatic enzyme was not used in comparison, nor were any other tocopherol preparations. With TPEGS plus pancreatic enzyme, the serum vitamin E level peaked in 8 hours at more than seven times the pretreatment level. Melhorn (Ref. 50) does state that, in his opinion, "the ideal approach to the therapy and prophylaxis of the vitamin E deficiency of prematurity would be a water-soluble form of the vitamin."

(5) *Nutrient interrelationships.* The dietary requirement for vitamin E increases when the intake of polyunsaturated fatty acids (PUFA) increases (Refs. 2 and 51). Vitamin E appears to enhance the absorption, lymphatic transport, and storage of vitamin A (Ref. 52). It may also have a stabilizing effect on the vitamin A of the cell membranes (Ref. 53). Large doses of vitamin E may counteract the toxic effects of excessive amounts of vitamin A (Ref. 54). However, as emphasized by Bieri (Ref. 4), whereas small amounts of alpha-tocopherol enhance carotene utilization (in the rat), large doses markedly reduce the amount of vitamin A formed from carotene and stored in the liver.

According to Melhorn and Gross (Ref. 55), red blood cell hydrogen peroxide fragility was markedly increased in children with vitamin E sufficiency but with iron deficiency anemia of moderate to severe degree, and the sensitivity to hydrogen peroxide was raised significantly during the administration of iron dextran. The rise in peroxide fragility could be prevented by priming patients with vitamin E during the administration of iron. Patients who received vitamin E therapy in addition to iron dextran showed a delay in reticulocyte response and also a rise in hemoglobin.

Asfour and Firzli (Ref. 56), in a study of undernourished and anemic Lebanese children, found no evidence that low serum vitamin E was causally related to either iron deficiency anemia or increased red blood cell hemolysis.

Selenium and vitamin E appear to have a sparing effect upon each other (Refs. 57 and 58). This appears to be of no practical importance in human nutrition. Although Money (Ref. 59) suggests a possible etiological role of vitamin E and selenium deficiencies in the sudden death syndrome of infants, this has not been confirmed.

Corrigan and Marcus (Ref. 51) have reported one case of a 55-year-old man with arteriosclerotic heart disease and type IV hyperlipoproteinemia who developed a prolonged prothrombin time and ecchymoses while on warfarin therapy and self-prescribed vitamin E (up to 1,200 I.U. daily for two months). A subsequent trial showed that the effect of warfarin on coagulation time was demonstrably enhanced after 4 weeks of daily vitamin E ingestion (800 I.U. daily). Vitamin K-dependent coagulation factors II, VII, IX, and X de-

clined, reaching their lowest point by the 42d day. On that day, multiple ecchymoses appeared. Vitamin E therapy was immediately stopped but warfarin was continued. In seven days, the levels of vitamin K-dependent coagulation factors returned to pre-vitamin E values, and concomitantly all clinical evidence of bleeding disappeared.

e. *Conclusion.* The Panel has reviewed the scientific literature, the submitted data, and the marketing history of vitamin and mineral ingredients. Based upon the available data, the Panel concludes that vitamin E is safe, but that there is no proven therapeutic indication for its use as an OTC vitamin and mineral drug product as a single ingredient as discussed below under Category II conditions. The Panel does recognize the use of vitamin E, but only when in combination, as discussed below in Category I conditions. (See also Part II. paragraph F. above—Combination Policy.)

The minimum effective oral dose might be defined as the daily amount of any vitamin E scource which would raise a low plasma tocopherol level to within the normal range and maintain it there, and/or would reduce an elevated in vitro peroxide erythrocyte hemolysis to normal. A dose of 3 to 6 I.U. daily might be more than adequate for healthy adults on diets containing a minimum of PUFA and for infants. Similar persons on diets high in PUFA may require as much as 30 I.U. daily (Ref. 60). Individuals with intestinal malabsorption, cirrhosis of the liver, or a-beta-lipoproteinemia may require daily doses of vitamin E varying from within the normal range to 400 I.U. or more daily. In such cases, the effective doses would have to be individually determined by a physician. Therefore, the Panel concludes that, although Vitamin E is safe, it is not appropriate for OTC use as a single ingredient. Allowable combinations containing vitamin E are discussed elsewhere in this document. (See Part II. Paragraph F.7. above—Category I combinations.)

The maximum safe dose has not been determined. For an adult, it certainly is higher than 400 I.U. daily.

f. *Category I conditions under which vitamin E is generally recognized as safe and effective and is not misbranded.* The Panel recommends that the Category I conditions be effective 30 days after the date of publication of the final monograph in the FEDERAL REGISTER.

There are no Category I conditions for vitamin E as a single ingredient. However, the Panel concludes that tocophersolan, alpha-tocopheryl acetate, alpha-tocopheryl acid succinate, and vitamin E are acceptable sources of vitamin E activity. Daily dosages of 30 I.U. based on the *dl*-alpha-tocopheryl acetate equivalent ($C_{31}H_{52}O_3$, molecular weight 472.7 and 1 mg *dl*-alpha-tocopheryl acetate is equivalent to 1 I.U.) vitamin E may be added to certain combinations of other essential nutrients in the prevention of multiple vitamin deficiencies such as may occur in conjuction with chronic alcoholism malabsorption syndromes, or severely restricted nutrient intake caused by lack of a nutritionally balanced diet when the need for such therapy has been determined by a physician. (See part II. paragraph F.2. above—Safety and part II. paragraph F.7. above—Category I combinations.)

g. *Category II conditions under which vitamin E is not generally recognized as safe and effective or is misbranded.* The Panel recommends that the Category II conditions be eliminated from OTC vitamin E drug products effective 6 months after the date of publication of the final monograph in the FEDERAL REGISTER.

The Panel concludes that vitamin E is safe but there are no proven therapeutic indications for OTC drug use in man. Certain infants may require vitamin E but only under the direct care of a physician. Accordingly, no therapeutic claims of any kind are permitted for any OTC vitamin E drug preparation where vitamin E is the single active ingredient. Allowable combinations containing vitamin E and other vitamins are discussed elsewhere in this document. (See part II. paragraph F. above—Combination Policy.)

h. *Category III conditions for which the available data are insufficient to permit final classification at this time.* The Panel recommends that a period of 2 years be permitted for the completion of studies to support the movement of Category III conditions to Category I.

None.

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14. *Vitamin K.* The Panel's statement on vitamin K includes the following ingredient: phytonadione (phylloquinoe (vitamin K-1) and the menaquinones).

a. *Description.* At present, vitamin K-1 is the only form of vitamin K found in oral pharmaceutical preparations. Vitamin K-1 (2-methyl-3-phytyl-1,4-naphthoquinone) is also known as phylloquinone, 3-phytyl-menadione, phytomenadione, and phytonadione. It is the major form of vitamin K synthesized by plants and, therefore, it is the major dietary form of vitamin K for man. The formula for vitamin K-1 (phytonadione) is $C_{31}H_{46}O_2$ and the molecular weight is 450.7. Vitamin K-2 (menaquinone-7), originally found in fish meal, is a product of bacterial synthesis, as are all of the menaquinones with vitamin K activity, from menaquinone-6 through menaquinone-13. Menaquinone-4 is synthesized in animals and birds from menadione (2-methyl-1,4-naphthoquinone, vitamin K-3). Judging from the nature of vitamin K homologues stored in the liver, 40 to 50 percent of the human's requirement for vitamin K is met by plant sources and the remainder from microbiological biosynthesis (Ref. 1).

b. *Safety.* Synthetic water-soluble vitamin K analogues, e.g., menadiol tetrasodium diphosphate, are not available OTC. They are ineffective as antidotes to anticoagulant therapy (Ref. 2). In large amounts (5 to 30 mg daily) they have been claimed to have been responsible for hemolytic anemia, hyperbilirubinemia, kernicterus, and death in newborns, particularly prematures (Refs. 3 and 4). Menadione powder is irritating to the respiratory tract and to the skin, and a solution of it in alcohol is a vesicant.

c. *Effectiveness.* Clinically significant vitamin K deficiency because of dietary inadequacy rarely, if ever, occurs in the United States, except in newborn infants whose gastrointestinal tracts are sterile for the first few days after birth. The various pathological situations in which bleeding due to vitamin K deficiency may occur all require medical attention for diagnosis and management; therefore, labeling for OTC self-medication is inappropriate. Furthermore, vitamin K may represent a hazard for many patients on anticoagulant therapy.

The human requirement for vitamin K is not accurately known since so much of it is met through biosynthesis by intestinal micro-organisms, but a good estimate is around 1 μg/kg of body weight daily. Olson (Ref. 1) has calculated that "a normal mixed" diet for an adult in the U.S. will contain from 300 to 500 μg vitamin K daily.

The most commonly used technique for measuring the vitamin K content of foods is the chick bioassay, in which the prothrombin level of the blood of deficient chicks fed test diets is compared with a standard curve resulting from the feeding of known amounts of phylloquinone (Ref. 1). In man, in the absence of liver disease, the plasma prothrombin concentration is a measure of vitamin K adequacy.

Any disorder or therapeutic measure (e.g., chloestyramine (Ref. 5)) that hinders the delivery of bile to the small bowel reduces the absorption of vitamin K and can produce a reduction in plasma prothrombin concentration whfch can be prevented or corrected by parenteral vitamin K or by oral vitamin K with bile salts. Since the efficiency of absorption of vitamin K homologues from the intestine is

poor and variable, ranging from 10 to 70 percent (Ref. 1), vitamin K is generally administered parenterally for better control over plasma levels. Oral preparations are, however, on the market but available only on prescription by a physician. Malabsorption syndromes associated with sprue, pellagra, bowel shunts, regional ileitis, and ulcerative colitis may also cause a secondary vitamin K deficiency, as may prolonged therapy with intestinal antibiotics (e.g., neomycin) when used in combination with diets low in vitamin K.

Vitamin K deficiency is manifested by a prolonged clotting time caused by a lack of one or more of four coagulation factors normally produced in the liver, i.e. prothrombin (factor II), proconvertin (factor VII), Christmas factor (factor IX), and Stuart factor (factor X). Anti-coagulant therapy, when used in the treatment of a condition such as myocardial infarction, interferes with the action of one or more clotting factors. Synthetic water-soluble vitamin K analogues, e.g., menadiol tetrasodium diphosphate, are not effective as antidotes for anticoagulant therapy (Ref. 2) but are useful in the treatment of vitamin K deficiency.

Although low plasma prothrombin levels due to vitamin K deficiency cannot be said to be rare among newborn infants, individuals with fat malabsorption and individuals on long-term antibiotic therapy with plasma prothrombin levels sufficiently low to be responsible for bleeding are found much less commonly. In the management of all situations in which clinically significant vitamin K deficiency may develop, medical supervision is necessary.

d. *Conclusion.* The Panel has reviewed the scientific literature, the submitted data, and the marketing history of vitamin and mineral ingredients. Based upon the available data, the Panel concludes that vitamin K, owing to the potentiality for harmful effect, is not generally recognized as safe for use for the prevention or treatment of vitamin K-1 deficiency except under the supervision of a physician. (See Part III, paragraph A.14.f. below—Category II conditions.) Products containing vitamin K should be available only on prescription.

e. *Category I conditions under which vitamin K is generally recognized as safe and effective and not misbranded.* The Panel recommends that the Category I conditions be effective 30 days after the date of publication of the final monograph in the FEDERAL REGISTER.

None.

f. *Category II conditions under which vitamin K is not generally recognized as safe and effective or is misbranded.* The Panel recommends that the Category II conditions be eliminated from OTC vitamin K drug products effective 6 months after the date of publication of the final monograph in the FEDERAL REGISTER.

The Panel concludes that phytonadione should not be permitted on the OTC drug market until scientific testing supports its safety for OTC use.

Evaluation. Clinically significant vitamin K deficiency rarely, if ever, occurs in the U.S. because of dietary inadequacy, except in newborn infants. The various pathological situations in which bleeding due to vitamin K deficiency may occur require close medical supervision for diagnosis and treatment. The ready availability of OTC vitamin preparations containing vitamin K would present a hazard for many patients on anticoagulant therapy. Products containing vitamin K should be available only on prescription and not permitted on the OTC market.

g. *Category III conditions for which the available data are insufficient to permit final classification at this time.* The Panel recommends that a period of 2 years be permitted for the completion of studies to support the movement of Category III conditions to Category I.

None.

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IV. MINERALS

Minerals are commonly defined as those chemical elements or their salts which are noncombustible and inorganic, the substances remaining in the ash after combustion of natural materials at a high temperature. Certain individual elements at issue in this document are essential dietary ingredients (commonly known as essential minerals) in that they are required in the diet of animals and man. By convention, though not scientifically correct, certain essential nonmineral elements are included along with the essential minerals; these include chlorine, fluorine, and iodine. Although these are not actually minerals in themselves, but are often found combined in nature as part of mineral salts, they are included in nutrition among the "minerals." Nutritionists often divide the essential minerals into two groups. Macrominerals are those needed in relatively larger amounts in the diet (generally over 0.1 percent of the diet) such as calcium, phosphorous, magnesium, potassium, sodium, and chlorine. Microminerals are needed in trace quantities and are commonly known as trace ninerals; these include iron, zinc, manganese, copper, iodine, and fluorine. However, the mineral elements discussed in this document are considered in alphabetical order.

The dosages recommended in this document for minerals have been derived from the available scientific data. The Panel is also aware of the RDA (Ref. 1) and the dietary supplement regulations published in the FEDERAL REGISTER of October 19, 1976 (41 FR 45156). However, the Panel emphasizes that only drug considerations are applicable to the "OTC drug use" recommendations contained in this document.

It should also be noted that sulphur and cobalt are minerals which are required in the diet of all animals, but in monogastric animals only when combined as part of one or more organic compounds. Sulphur is a part of certain amino acids and vitamins, and cobalt is a part of the vitamin B-12 molecule. By tradition then, these are not counted among the essential minerals, since the inorganic form is generally inactive as a source of the amino acids or vitamins.

There are certain other mineral elements which have been shown to be required by certain experimental animals. These are silicon, tin, selenium, chromium, nickel, vanadium, molybdenum, and possibly others, but their need by humans either is not established or is considered to be so small that there is no need for their presence in OTC preparations.

It should also be noted that there are a number of additional minerals, such as aluminum, beryllium, barium, lithium, cadmium, lead, arsenic, and strontium, which do not appear to be dietary essentials and most of which can be toxic. They should not be present in biologically significant amounts in OTC minerals since there is no known use of them for this purpose.

REFERENCE

(1) "Recommended Dietary Allowances," 8th Ed., National Academy of Sciences, Washington, DC, 1974.

The Panel has classified the following mineral active ingredients as Category I for OTC drug use for the prevention and/or treatment of deficiency:

Calcium
- Calcium caseinate
- Calcium citrate
- Calcium glubionate
- Calcium gluconate
- Calcium lactate
- Calcium phosphate dibasic
- Calcium sulfate
- Precipitated calcium carbonate

Iron
- Ferrous sulfate, dried
- Ferrous succinate
- Ferrous lactate
- Ferrous fumarate
- Ferroglycine sulfate
- Ferrous glutamate
- Ferrous gluconate

Zinc
- Zinc Sulfate

The Panel has classified the following mineral active ingredients as Category II for OTC drug use for the prevention and/or treatment of deficiency:

Copper
- Cupric gluconate
- Cupric oxide
- Cupric sulfate

Fluoride
- Calcium fluoride
- Sodium fluoride

Iodine
- Calcium iodate
- Potassium iodide

Iron
- Ferric versenate
- Ferric citrate
- Ferrocholinate
- Ferric sulfate
- Ferric ammonium citrate

Magnesium
- Magnesium carbonate
- Magnesium chloride
- Magnesium gluconate
- Magnesium hydroxide
- Magnesium oxide
- Magnesium silicate
- Magnesium sulfate
- Magnesium trisilicate

Manganese
- Manganese chloride
- Manganese gluconate
- Manganous oxide

Phosphorus
- Calcium phosphate dibasic

Potassium
- Potassium chloride
- Potassium gluconate
- Potassium sulfate

Zinc
- Zinc hydroxide
- Zinc oxalate
- Zinc phytate
- Zinc sulfide

The Panel has classified the following mineral active ingredients as Category III for OTC drug use for the prevention of deficiency:

Iron
- Ferrous citrate
- Ferric ammonium phosphate
- Ferric phosphate
- Ferric pyrophosphate
- Ferrous tartrate
- Ferrous carbonate

Zinc
- Zinc carbonate
- Zinc chloride
- Zinc gluconate
- Zinc lactate
- Zinc oxide

1. *Calcium.* The Panel's statement on calcium includes the following ingredients: calcium caseinate, calcium citrate, calcium glubionate, calcium gluconate, calcium lactate, calcium phosphate dibasic, calcium sulfate, and precipitated calcium carbonate.

a. *Reference form.* Dosages recommended in this document for calcium are based on elemental calcium (Ca, molecular weight 40.1).

b. *Description.* Calcium, the most abundant cation and fifth most common element of the human body, not only serves as the principal component of skeletal tissue, imparting to it the structural integrity essential to support the increasing body size of the individual during growth, but also plays a vital role in a variety of physiological and biochemical processes. The calcium ion influences blood coagulation, neuromuscular excitability, cellular adhesiveness, nerve impulse transmission, maintenance and function of cell membranes, activation of enzyme reactions, and hormone secretion.

The average adult human contains 1,000 to 1,200 g calcium or 21 to 25 g/kg of fat-free body tissue. Over 99 percent of body calcium resides in the skeleton in the solid mineral phase of bone as a variant of poorly crystalline hydroxyapatite. The skeleton functions as a reservoir of insoluble complexed forms of calcium and is in dynamic equilibrium with physiochemically soluble forms of circulating calcium which is maintained at a remarkably constant level of 9.5 to 10.3 milligrams/deciliter (mg/dl) (or slightly higher when using atomic absorption spectroscopic analytical methods) with a diurnal plasma variation of ± 3 percent. Approximately 55 percent of circulating calcium is bound to proteins (primarily albumin). The majority (over 95 percent) of the nonprotein-bound calcium in blood is composed of the ionized calcium moiety, a physiologically important factor regulating membrane transport enzyme activity and hormonal secretion. Although the circulating calcium level in man is controlled primarily by parathyroid hormone, a variety of other harmones (i.e., thyroid, androgens, estrogens, cortisol), vitamins (i.e., vitamin D) and minerals (i.e., magnesium and inorganic phosphate) prevent the fluctuation of calcium over a wide range despite the insoluble skeletal reservoir and wide variations in calcium intake and output.

c. *Safety.* Calcium intakes ranging from 1,000 to 2,500 mg daily do not result in hypercalcemia in normal individuals. Ingestion of larger amounts, as may be necessary in ulcer patients consuming large amounts of milk and antacid products, chiefly calcium carbonate-containing products, may result in hypercalcemia and in repaid deterioration of renal function (Refs. 1, 2, and 3). An acquired or inherited vitamin D-sensitive hyperabsorption of calcium occurs in patients with sarcoidosis (Ref. 4) or in certain hypercalciuric individuals with renal calculi. In these subjects, hypercalcemia and/or hypercalciuria results from a vitamin D supplementation of diets which rarely affects normal individuals (Ref. 5). The symptoms of hypercalcemia are due to either a direct effect of elevated circulating calcium levels on cognative functions, cardiac rhythmicity, renal or gastrointestinal function, or indirect effect of diffuse metastatic calcification on critical organs such as kidney, heart, and blood vessels. Although individuals with slight degrees of hypercalcemia may, in fact, be asymptomatic, symptoms frequently noted initially are weakness, fatigue, malaise, dry mouth, vague muscle and skeletal aches, headache, and a metallic or bad taste. Weight loss, diarrhea, anorexia, nausea, and vomiting reflect the gastrointestinal response to hypercalcemia. Thirst, polyuria, nocturia, burning of eyes, conjunctivitis, generalized pruritis, diminished libido, pancreatitis, renal calculi, diminished heavy activity, photophobia, rhinorrhea, and hyperthermia in children have also been noted in the hypercalcemic state. Hemiplegia and mental impairment have been reported in children with hypercalcemia as have a variety of anatomical cardiac defects.

d. *Effectiveness.* A number of dietary surveys reveal that among western populations the mean calcium intake ranges from 500 to 1,200 mg calcium daily (Refs. 6 through 10). At all ages after 12 years, men consume more calcium than women and, at all ages, there are individual men and women who ingest two to four times the recommended allowances of calcium (Ref. 7). Many adult women ingest less than the recommended allowance of calcium. The absorptive efficiency of the intestine, however, is dependent on the amount of exposure to ultraviolet light (Ref. 11) and vitamin D intake, the sex and age of the individual, the food source, and the total calcium content of the source. Whereas, during periods of active skeletal growth, children may absorb up to 75 percent of ingested calcium, normal adults with daily intakes of 400 to 1,000 mg absorb 30 to 60 percent (Ref. 12). Dietary factors which increase calcium absorption include certain amino acids such as lysine and arginine, vitamin D, and lactose. Cocoa, soy beans, kale, spinach (or other high oxalate-containing foods), and foods with high phosphate content such as unpolished rice, hexaphosphoinositol in bran or wheatmeal

(Refs. 10, 13, and 14), decrease the intestinal absorptive efficiency for calcium. Other factors which decrease calcium absorption include the ingestion of alkali, decreased gastrointestinal transit time, stress, immobilization, thyroid hormone, and cortisol or any of its synthetic analogues. Antibiotics such as penicillin, neomycin, and chloramphenicol may actually enhance the absorption of calcium (Refs. 15 and 16).

The effect of inorganic phosphorus on calcium absorption is controversial. Earlier reports of an inhibition of calcium absorption induced by supplemental phosphate feeding (Ref. 17) conflict with later studies demonstrating no effect of dietary phosphorus increments on calcium absorption (Ref. 18). Calcium absorption is more efficient in males than in females. This may be explained by reports of stimulated calcium absorption when androgens are administered to females (Ref. 19). Absorption decreases as individuals age (Refs. 20 and 21). The adaptive efficiency of the intestine to fluctuations in calcium intake is one whereby, with decreasing calcium intake, the percent absorbed increases (Refs. 21 and 22). This intestinal adaptive efficiency appears to be blunted by the aging process (Ref. 21). Despite the recognized inverse relationship between calcium absorption and calcium intake, prolonged fasting paradoxically results in decreased absorption (Ref. 23), and absorption may actually increase as calcium intake rises with absorptive capacities of more than 1 g daily documented at intakes of 7.5 g (Ref. 24). Although it has been reported that calcium is significantly better absorbed when given as the lactate than as the gluconate salt (Ref. 25), it has also been observed that, in normal volunteers, no difference exists in the utilization of calcium from milk, or from gluconate, lactate, carbonate, or sulfate salts (refs. 26 through 28).

The full-term infant contains about 25 g calcium, about half of which is deposited during the last lunar month of pregnancy at a rate of approximately 300 mg daily. It has been demonstrated that the reproductive process in not impaired when the diet of pregnant women ranges between 700 to 1,100 mg daily (Refs. 29 and 30). More recent estimates place the calcium requirement of pregnant women at 2,000 mg daily (Ref. 31), although this has been contested (Ref. 32).

A newborn baby receives about 200 mg calcium daily while ingesting 650 ml of breast milk. By 8 months of age, the infant's daily calcium intake has increased to 350 mg (Ref. 33). Assuming a maintenance calcium requirement of 3 mg/kg of body weight and an efficiency of utilization of 30 percent, it has been estimated that a lactating mother will require from 1,000 to 2,000 mg calcium daily in order to insure an adequate calcium supply for the nursing infant and insure her skeletal balance of calcium (Ref. 34). The needs for the third trimester of pregnancy and normal lactation as recommended by the Joint FAO/WHO Expect Group on Calcium Requirements has been set at 1,200 mg daily (Ref. 8) although it was recognized that many women lactated adequately at lower intakes.

A premature infant needs about 90 to 120 mg/kg calcium and 60 to 90 mg/kg phosphorus daily, amounts which are easily provided by 100 g whole cow's milk (Ref. 35). An average 1-month-old infant weighing 4 kg will obtain 235 mg calcium daily from breast milk and at 3 months approximately 300 mg calcium daily, amounts sufficient to meet his or her skeletal demands (Ref. 36). Formula-fed children up to 1 year of age require no more than 600 mg calcium daily for adequate skeletal development and growth (Ref. 10). For children from 1 to 10 years on adequate viatmin D intakes, 800 mg calcium daily appears sufficient to insure normal skeletal growth (Ref. 10). Preadolescent growing children, however, may need two to four times as much calcium as does an adult (Ref. 10). Higher intakes of calcium in the order of 1,000 to 1,500 mg daily are recommended during preadolescence and puberty because of the demands of rapid skeletal growth. Intakes greater than this need not be advocated since maximal calcium retention occurs in children and young adults at this level of intake.

Although the majority of young and middle-aged adults are capable of maintaining a positive calcium balance on an average daily intake of 600 to 1,000 mg, higher intakes may be essential to maintain mineral and skeletal homeostasis in elderly individuals (Refs. 7 and 36).

The age-related needs for additional dietary calcium may result in part from the observations that absorption as well as the adaptive efficiency of the intestine to fluctuations in calcium intake decreases with age. Negative calcium balances observed in osteoporotic patients on low, but seemingly, adequate, calcium intakes have been variably ascribed to slow and noncompensatory adaptation to low calcium intakes, defective renal adaptation and relative hypercalciuria, and lactose intolerance resulting from intestinal lactase deficiency.

Evidence that calcium deprivation leads to osteoporosis in man stems primarily from controversial retrospective and epidemiological studies. Some reports reveal no significant difference in the incidence of "osteoporosis" between patients who patients who historically ingested less than 500 mg calcium daily and those with intakes greater than 1,500 mg daily (Refs. 37, 38, and 39). Others demonstrate a lower calcium intake in symptomatic "osteoporotic" indivduals than in age-matched normal control subjects (Refs. 41 through 47). Epidemiological and dietary survey studies may ultimately prove misleading, regardless of the conclusions derived, unless more specific emphasis is placed on evaluating dietary habits, the degree of mobilization, the daily intake of minerals other than calcium, the dietary intake of protein and vitamin D and the extent of sunlight exposure.

Modern diets which are characteristically rich in animal proteins and phosphorus, with low calcium/phosphorus ratios, may prove deleterious to bone since they may promote hypercalciuria and stimulate the release of parathyroid hormone with a resultant progressive decrease in bone mass (Refs. 48 through 51). Immobilization or the relative inactivity which often attends the infirmities of age promotes skeletal demineralization. Peculiar dietary habits may also lead to increased urinary calcium loss and a negative calcium balance despite an adequate intake. Although calcium intakes may in fact be adequate in geriatric populations, an associated vitamin D deficiency may prevent maximal absorption of the ingested calcium. It has been determined that long-term calcium supplements (2 to 3 years of 700 to 800 mg daily) lead to detectable increments in skeletal mass in elderly females with long histories of subnormal calcium intake (Ref. 52).

e. *Conclusion.* The Panel has reviewed the scientific literature, the submitted data, and the marketing history of vitamin and mineral ingredients. Based upon the available data, the Panel concludes that calcium, in the dosage and forms identified under Category I conditions below, is safe and effective for the prevention of calcium deficiency when the need for such therapy has been determined by a physician.

f. *Category I conditions under which calcium is generally recognized as safe and effective and is not misbranded.* The Panel recommends that the Category I conditions be effective 30 days after the date of publication of the final monograph in the FEDERAL REGISTER.

Acceptable sources of calcium are calcium caseinate, calcium citrate, calcium glubionate, calcium gluconate, calcium lactate, calciumphosphate dibasic, calcium sulfate, and precipitated calcium carbonate. Dosage must be based on elemental calcium (Ca, molecular weight 40.1).

(1) *Dosage—For prevention of deficiency.* For adults, children 1 to under

10 years of age, and children 12 years of age and older, the oral dosage is 400 to 800 mg daily. For preadolescent and pubescent children 10 to under 12 years of age and for pregnant and lactating women, the oral dosage is 600 to 1,200 mg daily. For elderly adults over 51 years of age, the oral dosage is 500 to 1,000 mg daily. For infants 6 months to under 1 year of age, the oral dosage is 300 to 600 mg daily. For infants under 6 months of age, the oral dosage is 200 to 400 mg daily.

(2) *Labeling.* The Panel recommends the following Category I labeling:

Indication—For prevention of deficiency. "For use in the prevention of calcium deficiency when the need for such therapy has been determined by a physician."

g. *Category II conditions under which calcium is not generally recognized as safe and effective or is misbranded.* The Panel recommends that the Category II conditions be eliminated from OTC calcium drug products effective 6 months after the date of publication of the final monograph in the FEDERAL REGISTER.

None.

h. *Category III conditions for which the available data are insuffcient to permit final classification at this time.* The Panel recommends that a period of 2 years be permitted for the completion of studies to support the movement of Category III conditions to Category I.

None.

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2. *Copper.* The Panel's statement on copper includes the following ingredients: cupric gluconate, cupric oxide, and cupric sulfate.

a. *Description.* Copper is an essential trace element for humans. The adult body contains about 75 to 150 mg copper (Ref. 1). Plasma copper levels are about 100 μg/100 ml. Over 90 percent of plasma copper is in the form of ceruloplasmin, an alpha$_2$-globulin essential for the utilization of iron in hemoglobin synthesis. The rest is loosely bound to albumin or amino acids (Refs. 2 and 3). Copper is a constitutent of many enzymes, including cytochrome oxidase, monoamine oxidase, tyrosinase, and superoxide dismutase and is important for a variety of metabolic functions, including energy metabolism and the normal development of bone, connective tissue, and the central nervous system (Refs. 3 and 4).

Copper is currently sold OTC as part of vitamin-mineral preparations or by itself. It is primarily in the form of copper sulfate or copper gluconate (sometimes "chelated" with amino acids), and amounts are generally 2 mg or less per dose.

b. *Safety.* Excessive accumulation of copper in the liver and other tissues in Wilson's disease, a rare genetic disease also known as hepatolenticular degeneration, results from a defect in the handling of copper by the body and is not related to excessive copper consumption (Refs. 3, 4, and 5). Elevated plasma copper and ceruloplasmin levels are found in pregnant women, in users of oral contraceptives and other estrogen-containing preparations, and in individuals with various diseases, such as portal and biliary cirrhosis, thyrotoxicosis, leukemia, and certain malignancies and infections, but in these cases the changes occur regardless of the copper level in the diet (Refs. 1, 3, 4, and 5).

Monogastric mammals, such as rats and pigs, can tolerate fairly large chronic intakes of copper (200 times the normal intake), and generally show symptoms of copper poisoning only after the acute ingestion of very large amounts (Ref. 6). However, the maximum dose of copper, consumed chronically or acutely, which is safe for humans is not accurately known. The Joint FAO/WHO Expert Committee of Food Additives has estimated that 0.5 mg/kg daily is a safe level of copper intake (Ref. 7).

Signs of acute toxicity have been reported after the ingestion of a single dose of as little as 5 to 32 mg copper (Ref. 8). Wyllie (Ref. 8) described a poisoning at a cocktail party in which these amounts of copper were found in the cocktails, but it is possible that substances other than copper may have been responsible for the toxicity. This report alone provides insufficient evidence to conclude that this low level of copper is toxic.

After the rapid ingestion of copper in mg amounts (in most cases, the exact amount can only be roughly estimated), symptoms of copper intoxication, such as nausea, vomiting, diarrhea, headache, and dizziness, may occur (Refs. 8 through 11). In severe cases, after the ingestion of gram quantities of copper (usually copper salts), there may be tachycardia, hypotension, coma, methemoglobinemia, hemolytic anemia, jaundice, uremia, and even death (Refs. 12 and 13). Acute symptoms of copper intoxication have also been reported after the topical application of copper sulfate to the wounds of a seriously burned patient (Ref. 13).

Verified cases of chronic copper poisoning in humans have rarely been reported in the literature (Refs. 14 and 15). However, there has been one case reported of suspected chronic copper poisoning in a 15-month-old child whose family's hot water system contained 79 ug copper/100 ml, a concentration much higher than that found in other households in the area (Ref. 16).

c. *Effectiveness*—(1) *Absorption and excretion.* With usual diets, about 30 percent of the copper in foods is absorbed (Refs. 4 and 5). Absorption takes place by active transport primarily in the stomach and upper small intestine (Ref. 3). Copper in foods may become linked to amino acids, proteins, phytates, other trace elements, or other substances, leading to variable effects on copper absorption (Refs. 3 and 5). Small, stable complexes may actually be absorbed more readily than the free copper ion of copper salts such as cupric sulfate (Refs. 4 and 5). Several elements, including calcium, cadmium, mercury, silver, zinc, and molybdenum, may compete with copper for absorption or otherwise antagonize copper metabolism (Refs. 3 and 4). Ascorbic acid has been shown in animal studies to interfere with copper absorption (Ref. 3). Studies in rats have shown that intrapyloric administration of very large quantities of copper results in the passive absorption of about 10 percent of the dose (Ref. 17).

Bile is the major route of copper excretion, although a small amount of copper is excreted in the urine (Refs. 2 and 3). Sweat and menstrual losses are usually negligible, but individuals living in a hot climate may lose significant amounts of copper in sweat (Refs. 5 and 18).

(2) *Dietary intake and requirement.* Copper is found widespread in foods. Especially good dietary sources of copper are nuts, liver, some shellfish, kidney, raisins, and dried legumes. Cow's milk is a particulary poor source of copper (Refs. 1 and 19). Typical U.S. diets contain about 2 to 5 mg copper daily (Ref. 20), although an individual consuming foods high in copper (Ref. 19) could easily obtain more. Variable amounts of copper in water supplies may also contribute to the copper intake (Ref. 21).

Recommended daily copper intakes have been suggested in several studies. Requirements for infants and children have been estimated at 0.05 to 0.1 mg/kg of body weight daily (Ref. 1). In a study of boys aged 3 to 6 years, it was concluded that 0.053 to 0.085 mg copper/kg body weight was required daily (Ref. 22). In another study, preadolescent girls had a requirement of at least 1.3 mg copper daily in order to maintain a copper balance (Ref. 23). In most metabolic studies of adults, 2 mg copper daily was adequate to maintain a copper balance (Refs. 5 and 20).

However, Butler and Daniel (Ref. 18), who performed metabolic balance studies on young women, have suggested that the estimated requirement of 2 mg may be inadequate to cover the needs of some persons, particularly those with large sweat losses. Also, Klevay (Ref. 24) has hypothesized that our diets may be deficient in copper relative to zinc and that this imbalance may contribute to hypercholesterolemia and coronary heart disease.

(3) *Copper deficiency in humans.* Copper deficiency is rare in humans but there have been a number of case reports observed in unusual situations (Ref. 25), e.g., premature infants fed low-copper milk formulas (Refs. 26 and 27), severely malnourished infants rehabilitated on milk diets (Ref. 28), an infant with chronic malabsorption (Ref. 29), and infants (Refs. 25 and 27) and adults (Refs. 30 and 31) on long-term total parenteral nutrition following bowel surgery. Deficiency symptoms include a hypochromic anemia, neutropenia (low levels of neutrophils, a type of white blood cell), and skeletal abnormalities in infants. Copper deficiency was alleviated in these cases

with oral or parenteral copper supplementation at levels comparable to the U.S. RDA.

Menkes's steely-hair syndrome (formerly called "kinky-hair syndrome") is an inborn error of metabolism occurring in one out of about 35,000 live births (Ref. 32). The disease becomes clinically evident in the first few months of life and is characterized by growth retardation, neutrological damage, convulstions, bone changes, problems with temperature regulation, peculiar hair (like steel wool) and an early death (usually by 3 years of age) (Refs. 32 and 33). Low levels of copper in the blood and tissues of infants with steely-hair syndrome appear to result from impaired intestinal absorption of copper (Refs. 32 and 33). Copper may be absorbed in sufficient amounts when oral doses of copper (as cupric sulfate) are administered at about ten times the normal infant requirement (0.52 mg/kg daily, compared with 0.05 mg/kg daily) (Ref. 33). However, parenteral administration of copper given intramuscularly, intravenously, and even subcutaneously, is more effective and is certainly the preferred route of administration (Refs. 34, 35, and 36). Proper diagnosis and treatment of this disease require a physician.

d. *Conclusion.* The Panel has reviewed the scientific literature, the submitted data, and the marketing history of vitamin and mineral ingredients. Based on the available data, the Panel concludes that copper is not appropriate for the OTC drug market for the prevention or treatment of copper deficiency since copper deficiency in man is rare and because of the potential for copper toxicity at relatively low levels of intake.

e. *Category I conditions under which copper is generally recognized as safe and effective and is not misbranded.* The Panel recommends that the Category I conditions be effective 30 days after the date of publication of the final monograph in the FEDERAL REGISTER.

None.

f. *Category II conditions under which copper is not generally recognized as safe and effective or is misbranded.* The Panel recommends that the Category II conditions be eliminated from OTC copper drug products effective 6 months after the date of publication of the final monograph in the FEDERAL REGISTER.

The Panel concludes that there is no demonstrated need or justification for cupric gluconate, cupric oxide, and cupric sulfate in OTC drug preparations for the prevention of treatment of deficiency because of the potential for copper toxicity at relatively low levels of intake and the absence of any demonstrated need for OTC copper preparations to prevent or treat a deficiency. Therefore, no OTC drug use of copper is recommended since conditions which indicate the need for therapeutic use of copper require the close supervision of a physician.

g. *Category III conditions for which the available data are insufficient to permit final classification at this time.* The Panel recommends that a period of 2 years be permitted for the completion of studies to support the movement of Category III conditions to Category I.

None.

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3. *Fluoride.* The Panel's statement on fluoride includes the following in-

gredients: calicum fluoride and sodium fluoride.

a. *Description.* Although considerable information exists regarding fluoride metabolism in a variety of animal species, there are limited data on the fate of ingested fluoride in man. In certain endemic areas the fluoride content of drinking water approximates 4.0 to 5.8 ppm (Ref. 1).Ordinary drinking water, which often contains up to 1 ppm, contributes approximately 1.0 to 1.5 to the daily fluoride intake. The average daily U.S. diet also contains 0.25 to 0.30 mg fluorine (Ref. 2), although specific foods such as tea, baking powders, wines, fresh mackeral, dries salmon, or unwashed apples sprayed with fluoride-containing insecticides may contain up to 6.3 mg/liter (wines) or 2.7 mg/100 g (fresh mackeral) (Ref. 2). Fluoride is widely distributed in nature, and food contents usually reflect both soil and atmospheric concentrations of fluoride. Specific in this regard is the use of different forms of fertilizer, with fluoride contents ranging from 0.01 to 9.88 percent (Ref. 3).

The gastrointestinal tract is the major site of fluoride absorption in man, although fluorine is absorbed via the lungs following inhalation of industrial atmospheric contaminants as may occur in cryolite workers, steel and metal workers where fluorospan is used as a flux, chemical workers using hydrofluoric acids, workers in brick factories using fluorine-rich clay and those employed in the manufacture of phosphate compounds. Hydrogen fluoride is minimally absorbed by the skin although the resulting burn is of much greater consequence than the minute amount of fluoride absorbed. The degree of absorption of fluoride correlates with its solubility. Relatively soluble compounds such as sodium fluoride are well absorbed by the gastrointestinal tract, whereas relatively insoluble forms such as cryolite (Na_3AlF_6) and the fluoride found in bone meal (fluoroapatite) are poorly absorbed (Refs. 4 and 5).

Radioactive fluoride absorption studies in human subjects reveal that the isotope enters the blood extremely rapidly when given by mouth (Refs. 6 and 7). The greatest urinary fluoride concentration after the oral ingestion of a single dose of sodium fluoride occurs within 2 hours (Refs. 8 and 9). The absorption of fluoride from vitamin-containing fluoride preparations containing 0.1 mg fluoride is also quite rapid with increments of blood-fluoride concentrations from 0.15 ppm to 0.26 ppm noted 1 hour after the ingestion of a tablet containing a vitamin-fluoride combination (Ref. 10). The fluoride content of plasma of humans ingesting communal water with fluoride contents of 0.15 to 2.5 ppm is relatively constant at 0.12 to 0.15 ppm (Ref. 11). Once absorbed, renal excretion and skeletal mineral sequestration are the principal mechanisms which regulate circulating fluoride levels.

The percentage of ingested fluoride that appears in the urine amounts to 50 to 65 percent of the daily intake (Refs. 12, 13, and 14). It appears that when humans ingest small amounts of fluoride (i.e., 1 ppm) for a prolonged period, the daily urinary excretion is a greater fraction of the intake. Labile skeletal fluoride reserves are excreted more rapidly by adults than children; also, the more rapid metabolic activity of developing bone in children liberates more of the sequestered fluoride and, as such, maintains elevated blood and urine fluoride concentrations over a much longer time interval (Ref. 15).

b. *Safety.* A lethal dose of fluoride (2.5 to 5 g) produces signs of violent gastrointestinal irritation, shock, and death within 2 to 4 hours. The safety factor assuming the ingestion of a quart of water daily at 1 ppm fluoride concentration (i.e., 1 mg fluoride) is at least 2,500-fold (Ref. 16). Crippling fluorosis occurs when humans ingest or inhale 20 to 80 mg fluoride or more for 10 to 20 years, and enamel hyperplasia noted in children within the first 8 years of life with graded severity when the drinking water contains 2 to 5 ppm fluoride or more. There are reports of retinopathy and others describing optic neuritis and macular edema after daily doses of 30 mg fluoride for 6 weeks. Atopic dermatitis, urticaria, pruitis, and edema have also been reported to occur in patients using fluoride-containing vitamins and toothpastes (Ref. 16, 17, and 18).

c. *Effectiveness.* Skeletal deposition of fluoride is a continuing process in which 25 to 50 percent of the ingested fluoride is deposited daily. The concentration of fluoride in bones and teeth depends on the total daily intake and length of exposure, with skeletal levels reportedly increasing with age (Ref. 19). Studies in humans 26 to 90 years of age who have drunk water containing 0.1 to 4.0 ppm fluoride for at least 10 years reveal no significant histological changes in soft tissue and bones (Refs. 20 and 21). The concentration of fluoride in the skeleton increases in an essentially linear fashion with an increase in fluoride content of drinking water up to 4 ppm (Refs. 20 and 21). Fluoride is desposited in bone by simply ionic exchange with the hydroxyl groups of hydroxyapatite (Ref. 22). The skeletal deposition of fluoride is reversible. Skeletal mobilization is slow but predictable with a biological halftime (i.e., the period required to mobilize and remove from the body half of the skeletal fluoride) of 1 to 2 years (Ref. 12). Although ingestion of large doses of fluoride (i.e., up to 16.2 ppm) induces a variety of pathological changes in man such as mottled enamel and crippling bone disease (Ref. 23), the ingestion of water containing fluoride up to 8 ppm reportedly produces no deleterious bone changes other than dental mottling (Ref. 24) and may in fact retard the rate of bone loss which normally attends senescence (Refs. 1, 14, and 24) and dental caries (Ref. 25).

d. *Conclusion.* The Panel has reviewed the scientific literature, the submitted data, and the marketing history of vitamin and mineral ingredients. Based upon the available data, the Panel concludes that there is no justification for an OTC drug preparation containing fluoride for the prevention or treatment of deficiency.

e. *Category I conditions under which fluoride is generally recognized as safe and effective and is not misbranded.* The Panel recommends that the Category I conditions be effective 30 days after the date of publication of the final monograph in the FEDERAL REGISTER.

None.

f. *Category II conditions under which fluoride is not generally recognized as safe and effective or is misbranded.* The Panel recommends that the Category II conditions be eliminated from OTC fluoride drug products effective 6 months after the date of publication of the final monograph in the FEDERAL REGISTER.

The Panel concludes that calcium fluoride and sodium fluoride for the prevention or treatment of fluoride deficiency are not justified as an OTC vitamin or mineral drug preparation since the small amounts needed for fluoride balance are easily provided in the diet.

g. *Category III conditions for which the available data are insufficient to permit final classification at this time.* The Panel recommends that a period of 2 years be permitted for the completion of studies to support the movement of Category III conditions to Category I.

None.

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4. *Iodine.* The Panel's statement on iodine includes the following ingredients: calcium iodate and potassium iodide.

a. *Description.* Elemental iodine as contained in the above ingredients will be referred to as iodine in this document. Although iodine is a scarce element, it is widely distributed and concentrated in a variety of food sources. Iodine in the plasma is concentrated in the thyroid, salivary, mammary, and gastric glands and in the kidney. It is essential for the proper synthesis of thyroid hormone and a deficiency or excess of this element may alter thyroid function.

b. *Safety*—(1) *Chronic toxicity.* The long-term ingestion of large doses of iodine (40 mg to several grams daily over a period of months to years) may alter thyroid function and produce symptoms of iodism in some individuals (Refs. 1 and 2).

When exogenous iodine intake is increased, the thyroid takes up the excess but does not metabolize it. This protective mechanism is operative until the amount ingested exceeds 2 mg. Thereafter, the thyroidal iodine uptake is diminished. This protective effect prevents the accumulation of so much iodine that thyroid hormone sythnesis is inhibited. It is for these reasons that iodine-induced goiter, hypothyroidism, and hyperthyroidism (Jod-Basedow disease) occur rarely and almost always in individuals with underlying thyroid abnormalities (Refs. 1 and 2). Pregnant women ingesting several grams of iodine daily may bear infants with a goiter that can cause respiratory distress (Ref. 1).

The chronic ingestion of large amounts of iodine, as discussed above, can produce iodism in some individuals. This syndrome has a variable presentation but may include a metallic taste, rhinorrhea, headache, an acne-form skin lesion, parotitis, and pulmonary edema (Refs. 2, 3, and 4). Minor side effects occurred in 11 percent of 2,404 patients with chronic obstructive pulmonary disease who received oral potassium iodide chronically (Ref. 1).

(2) *Acute toxicity.* The acute toxicity of iodine in humans is poorly documented. Relatively large daily doses (200 mg to 4 g iodide as potassium iodide) administered over 4 months produced no symptoms of hyperthyroidism or toxicity (Ref. 1). The acute toxicity of iodine in animals has been reviewed elsewhere (Ref. 1). Rarely, angioedema, serum sickness, and hemorrhagic skin lesions occur in sensitive individuals (Refs. 1 and 3).

c. *Effectiveness.* Iodine is an essential nutrient which is required for the synthesis of thyroid hormone.

Iodine requirements, as determined by epidemiological data and metabolic balance studies, are probably between 100 to 200 μg daily (Refs. 4 through 7). The requirements vary widely among indivuduals and are influenced by factors such as age, differences in urinary clearance, sex, and the ingestion of foods such as cabbage, peaches, and almonds containing goitrogenic substances. Goiter is generally prevented by the injestion of 50 to 75 μg (1 μg/kg) daily in adults (Refs. 5 and 6). Children and pregnant and lactating females require larger amounts (Refs. 4 and 5).

Dietary sources of iodine include water, vegetables, meat, eggs, and dairy products, although the amount present in these substances ultimately depends on the iodine content of the soil as well as that of animal feeds. Iodized salt (76 μg/g), seafoods (fish and seaweed) and some breads are particularly rich sources of iodine (Ref. 8). The American dietary intake of iodine is highly variable, but is estimated to range from 240 to 740 μg daily (Ref. 9). The average American consumes something more than 300μg daily, well in excess of those amounts recognized as necessary for adequate nutrition (Ref. 1).

Dietary iodine as the iodide is rapidly absorbed by normal persons in the fasting state. Free and bound iodide and iodates are converted largely to iodide in the gastrointestinal tract before they are absorbed. Some iodide is absorbed from the stomach, but most is absorbed from the small intestine. Absorption of iodide in the nonfasting individual is virtually complete in 3 hours (Ref. 4). Soybean products interfere with the reabsorption of thyroxine so that chronic ingestion of such products can induce depletion and goiter (Ref. 10). No substances are known to alter the absorption of inorganic iodide (Ref. 10).

Since there are no renal mechanisms for the conservation of iodine, when dietary intake is inadequate, deficiency will ultimately result.

A diet deficient in iodine is the most common cause of simple goiter, an enlargement of the thyroid gland involving an increase in the size and number of epithelial cells. Endemic goiter occurs in populations living in mountainous and inland areas where soils have been leached of iodine and the dietary intake of seafoods is minimal. Those states in the Great Lakes region and in the Pacific northwest are the major endemic areas in the United States.

Although the incidence of goiter in the United States has decreased markedly since the introduction of iodized

salt (Ref. 6), several recent surveys indicate that approximately 5 percent of the population in Michigan and Texas have goiters (Refs. 11, 12, and 13), with a higher frequency among females of the childbearing age. It is important to emphasize that these cases of goiter are not necessarily related to iodine deficiency, since their occurrence is not correlated with indices of iodine under-nutrition as indicated, for example, by the daily urinary excretion of iodine (Ref. 14). There are reasons to believe that factors other than iodine deficiency may be important in the induction of simple goiter. Iodine deficiency does not produce goiter in 100 percent of patients. Iodine replacement does not eradicate goiter completely. Also, within a given endemic area, the incidence of goiter does not correlate with iodine intake. Postulated goitrogenic factors include genetically determined deficiencies in enzymes responsible for the synthesis of thyroid hormones, the ingestion of dietary goitrogens, and infectious agents.

Data from the Ten State Nutrition Survey for 1968-1970 published in 1972 by the U.S. DHEW showed that only a small number of individuals in the population showed evidence of iodine deficiency (Ref. 14). There was no correlation between this deficiency and the prevalance of goiter.

d. *Conclusion.* The Panel has reviewed the scientific literature, the submitted data, and the marketing history of vitamin and mineral ingredients. Based upon the available data, the Panel concludes that there is no rationale for the inclusion of iodine in OTC drug products for the prevention or treatment of iodine deficiency.

e. *Category I conditions under which iodine is generally recognized as safe and effective and is not misbranded.* The Panel recommends that the Category I conditions be effective 30 days after the date of publication of the final monograph in the FEDERAL REGISTER.

None.

f. *Category II conditions under which iodine is not generally recognized as safe and effective or is misbranded.* The Panel recommends that the Category II conditions be eliminated from OTC iodine drug products effective 6 months after the date of publication of the final monograph in the FEDERAL REGISTER.

The Panel concludes that there is not rationale for the inclusion of calcium iodate or potassium iodide as a source of elemental iodine in OTC drug products for the prevention or treatment of iodine deficiency. Recent evidence for the increased consumption of iodine taken together with the decreased incidence of goiter in endemic areas indicate that adequate amounts are available to the general population. Additionally, the excessive ingestion of iodine is not without risk, and treatment with iodine when required should be closely supervised by a physician.

g. *Category III conditions for which the available data are insufficient to permit final classification at this time.* The Panel recommends that a period of 2 years be permitted for the completion of studies to support the movement of Category III conditions to Category I.

None.

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5. *Iron.* The Panel's statement on iron includes the following ingredients: Ferric ammonium citrate; ferric ammonium phosphate; ferric citrate; ferric phosphate; ferric pyrophosphate; ferric sulfate; ferric versenate; ferrocholinate; ferroglycine sulfate; ferrous carbonate; ferrous citrate, ferrous fumarate; ferrous glutamate; ferrous gluconate; ferrous lactate; ferrous succinate; ferrous sulfate, dried; and ferrous tartrate.

a. *Reference form.* Dosages recommended in this document for iron are based on elemental iron (Fe, molecular weight 55.8).

b. *Description.* The term iron used in this document refers to elemental iron. Iron is a component of the heme molecule and, as such, plays a vital role in biologic processes involving oxygen and electron transport. The total body iron of a normal adult male is approximately 4 g. Most of the iron (2.5 g) is incorporated into the hemoglobin of red blood cells and a significant protion (1.0 g) is stored in the reticuloendothelial system (bone marow, spleen, liver). The remainder is found in myoglobin and respiratory enzymes (Ref. 1).

Iron stores are maintained through a balance of absorption and elimination. Iron absorbed from food goes to storage sites and the iron released from aging red cells is recycled. In the adult male and postmenopausal female, daily obligatory losses of iron are balanced by iron absorption from food. Each day, iron in the amount of 0.5 to 1.0 mg is lost from the body through exfoliation of gastrointestinal and dermal cells, biliary secretions, sweat, gastrointestinal blood loss, and urinary excretion (Refs. 2, 3, and 4). Women of childbearing age lose additional iron through menstrual bleeding.

Because the amount lost each day is so limited, absorption plays a major role in regulating iron balance (Ref. 5).

The average American diet contains 6 mg iron per 1,000 kilocalories (kcal) providing 10 to 20 mg daily (Refs. 6 through 9). Even though the availability of iron from foods is highly variable and accurate absorption data are difficult to obtain, it has been estimated that iron-replete individuals absorb 5 to 10 percent or the equivalent of 0.5 to 2.0 mg iron from food each day (Ref. 6). Iron-depleted individuals absorb two to three times more (Refs. 8 and 10).

Iron is principally absorbed in the duodenum and upper jejunum through a complex, poorly understood process. The amount of iron which is absorbed increases with the dose, but the fraction of the dose which is absorbed decreases. Innumerable factors affect the absorption of iron, including the food source and the status of the iron stores. In general, iron from vegetables is more poorly absorbed than that from animals (heme iron) and individuals with low stores absorb a greater amount of iron than those who are iron replete. Accelerated erythropoiesis also enhances iron absorption, even in the absence of depleted iron stores (Ref. 11).

Ascorbic acid increases the absorption of food iron by reducing ferric iron to the more soluble ferrous state and through formation of a soluble iron-ascorbate chelate. Doses greater than 200 mg may increase the absorption of iron salts by 25 to 50 percent (Ref. 12). However, in view of the fact that recommended Category I iron doses without vitamin C will adequately prevent iron deficiency, there is no rationale for adding large amounts of vitamin C to approved iron preparations. Small doses of vitamin C do not significantly increase iron absorption.

There are various degrees of iron undernutrition. Initially, tissue iron stores are partially or totally depleted. Thereafter, serum iron is diminished and red cell production is impaired. Eventually, severe iron deficiency results in an anemia characterized by small red blood cells deficient in hemoglobin.

The prevalence of iron deficiency is difficult to extrapolate from the medical literature because most of the data is based only on the presence of overt animia. Also, because iron deficiency without anemia is more dificult to establish, it is frequently overlooked in epidemiologic studies. Therefore, the propensity of any given population for iron deficiency is best assessed on the basis of what is known about iron balance.

(1) *Menstruating females.* In this group, menstrual losses must be added to the basal iron losses. Several investigators have established that the average menstrual blood loss is approximately 40 ml or the equivalent of 0.7 mg iron daily (Refs. 10 and 13). The 90th percentile for menstrual iron loss has been estimated to be 1.35 mg daily and the 95th percentile, has been estimated to be 1.75 mg daily (Ref. 9). If basal iron losses (0.5 to 1.0 mg) are added to these figures, this population would have to absorb a total of 1.2 to 2.75 mg iron daily to maintain adequate body iron stores. A dietary intake of 2,500 calories would provide a sufficient amount of iron for most women (10 percent absorption of 15 mg dietary iron, providing 1.5 mg absorbed iron). Beaton et al. (Ref. 7) have demonstrated that a daily dietary iron intake of 11 to 12 mg or more prevented iron deficiency, as judged by serum iron, total iron binding capacity, and iron saturation. However, it is apparent that iron balance in these individuals is at best precarious, as demonstrated by the studies of Scott and Pritchard (Ref. 14) which showed the absence of iron stores in the bone marrow in 24 percent of college women. Another 42 percent had greatly diminished iron stores. The incidence of iron deficiency anemia may be as high as 10 percent in this population (Refs. 8, 10, and 15). In view of the high prevalence of iron deficiency in this population, the variable absorption of iron from food, the borderline caloric intake in this group, and the possibility of excessive iron loss secondary to unrecognized menorrhagia, it seems reasonable to provide 10 to 30 mg of exogenous (extradietary) iron daily (1 to 3 mg absorbed) for women of child-bearing age to supplement the dietary intake and preserve iron stores. This is a liberal figure because it does not take into account any increased iron absorption which may result from negative iron balance.

(2) *Lactating females.* An additional 0.5 to 1.0 mg iron is lost daily through lactation, an amount approximately equivalent to daily menstrual losses (Refs. 9 and 16). Because lactating women are usually amenorrheic, iron requirements for this group are approximately the same as those for menstruating females. Therefore, 10 to 30 mg of exogenous (extradietary) iron should be available to this population as well.

(3) *Pregnant females.* In pregnancy, iron requirements are greatly increased because iron is transferred to the growing fetus and placenta during the latter half of pregnancy. Also, blood loss at delivery and the expansion of blood volume that occurs during pregnancy contribute to increased iron requirements. When the iron savings from 9 or more months of amenorrhea are taken into consideration, the net increase in iron requirement will average 500 mg for the entire time period (Ref. 8). The resulting deficit is highly variable and may range from 0 to 750 mg iron (Ref. 8). The estimated daily requirements for absorbed iron range from 2 to 5 mg (mean 3.5 mg) (Refs. 6, 7, and 17). Even through iron absorption is increased in pregnancy (30 percent during the second trimester; 40 percent during the third trimester), it is unlikely that dietary sources of iron will be sufficient for this population. This inadequacy is further supported by the apparent decreased caloric and iron intake of pregant women as compared to their nonpregnant counterparts (Refs. 9, 18, and 19). The incidence of iron deficiency anemia in this population varies from 10 to 20 percent, in communities with adequate levels of nutrition, to 50 percent in areas of poor diets (Refs. 6 and 17). Iron depletion without anemia may be much more common (Ref. 8). Chanarin and Rothman (Ref. 20) demonstrated that a daily dose of 30 mg iron was sufficient to maintain hemoglobin levels throughout pregnancy, as did Iyengar and Apte (Ref. 21). In contrast, DeLeeuw, Lowenstein, and Hsieh (Ref. 22) found that 39 mg iron was insufficient to achieve an optimal hemoglobin mass and to maintain iron stores in 50 percent of their subjects. A daily dose of 78 mg was effective. On the basis of the high prevalence of iron deficiency in this group of individuals, iron balance studies, and therapeutic trials, the Panel recommends a daily dose of 30 to 60 mg iron be made available to this population to maintain iron stores and prevent iron deficiency.

(4) *Infants and children (6 months to 5 years of age).* Iron nutriture in infancy is at best marginal, and iron deficiency is the most prevalent nutritional deficiency in infants. This is a consequence of the increased iron requirements arising from growth, a tripling of the blood volume during this period, and the low iron content of the diet. Human milk and cow's milk contain very little iron. Iron in egg yolk and iron from iron pyrophosphate in fortified cereals are inadequately available (Refs. 23 and 24).

The prevalence of iron deficiency anemia in the 6 months to 5 year age group is high in all areas of the U.S. and varies with the socioeconomic status and age of the population studied (Refs. 24 through 28). Preliminary results of the Hanes survey show an overall prevalence of anemia (hemoglobin less than 11 g percent) to be 6.4 percent (range of 5.07 to 17.62 percent) in the 1- to 5-year age group (Ref. 29). Anemia was more prevalent in Blacks and in children from families earning incomes below the poverty level. The high prevalence (13 to 22 percent) of an iron saturation index below 15 percent and the finding that dietary intakes were below the standard in 95 percent of this population suggest that the anemia may arise from iron deficiency. When the data are broken down by age, it is apparent that iron deficiency is much more prevalent in the first years of life. Owen, Lubin, and Garry (Ref. 25) surveyed a cross-sectional sample of children 1 to 6 years of age and found the overall incidence of anemia (hemoglobin less than 10 g percent) to be 5 percent. However, 39 and 45 percent of a group of children, 12 to 23 months of

age, from upper middle and lower middle class families, respectively, had transferrin saturations of less than 15 percent. Several studies of economically deprived children indicate that the incidence of anemia is very high (59 to 68 percent) (Ref. 26). Although the prevalence of anemia is lower in children 3 to 5 years of age, it is also a significant problem. Incidences ranging from 2.8 percent to 12 percent have been reported (Refs. 24 and 29).

Iron requirements for infants have been estimated by two methods. The first is based upon calculations of the net total body iron which must be realized during the first year of life. The second method is based on the daily intake of iron which produces the highest hemoglobin levels. The Committee on Nutrition of the American Academy of Pediatrics based its recommended iron intake of 1 mg/kg daily, to a maximum of 15 mg daily per infant, on the results of the second method (Ref. 23).

In view of the occurrence of iron deficiency in this population and the sporadic use of iron-fortified foods, the Panel recommends that an iron preparation containing a daily dose of 10 to 15 mg be made available for use in children 6 months to 5 years of age.

c. *Safety.* Because iron absorption is limited by a protective mucosal block, chronic intoxication from amounts found in food or medicines is not likely to occur in normal individuals. A primary consideration in making medicinal iron available in an OTC preparation is whether prolonged or excessive iron intake will result in iron overload. Disorders of iron load appear to be rare (Ref. 30) and are characterized by an accumulation of iron in the reticuloendothelial system or in the parenchymal cells of various organs. Although there is some debate with regard to terminology, most authorities used the term "hemosiderosis" to describe the presence of iron accumulation without tissue damage and "hemochromtosis" to describe fibrosis and organ damage resulting from excessive iron deposition (Refs. 30, 31, and 32).

Primary or idiopathic hemochromatosis is thought by most authorities to be a disease characterized by an excessive absorption of dietary iron caused by an inherited inborn error of metabolism. When definite causative factors for iron overlaod can be identified, the term "secondary hemosiderosis" or "hemochromatosis" is used. The latter can be caused by the prolonged ingestion of excessive iron or by conditions which increase the absorption of iron. Alcoholics with cirrhosis may have a secondary hemosiderosis. The high iron content of some alcoholic beverages and the increased iron absorption associated with alcoholic liver disease contribute to the iron overload observed in these individuals (Ref. 31 and 32). Iron overload is also associated with porta-caval shunts, chronic pancreatitis, and a variety of hematological disorders characterized by an increased and/or ineffective erythropoiesis (Refs. 31 and 32). Repeated transfusions and, very rarely, the prolonged or excessive intake of medicinal iron may be associated with hemosiderosis or hemochromatosis (Refs. 31 and 33 through 37).

Acute iron intoxication resulting from the accidental ingestion of large amounts of iron by children between the ages of 2 to 4 years appears to be a greater health problem than does chronic iron intoxication. In the U.S., iron and vitamins are the fourth most frequently ingested toxic substances in children under the age of five (Ref. 38). It has been estimated that one child dies each month from an overdose of elemental iron (Ref. 39). A 32-month survey or iron intoxication reports received by the National Clearing House for Poison Control Centers revealed that 74 percent of all iron intoxications occurred in the 1- to 2-year-old age group. Only 8 percent occurred in the population greater than 5 years of age (Ref. 40).

The ingestion of large doses overwhelms the mucosal block which normally exists for iron. Initially, symptoms can be related to the direct corrosive action of large doses of iron on the gastrointestinal tract (vomiting, diarrhea, melena, dehydration). The severe shock, which may or may not follow, may be due to elevated serum levels of ferritin or free iron. Metabolic acidosis and central nervous system depression are frequently observed in severe cases (Ref. 41 and 42).

All iron products are potentially toxic. Reduced (elemental) iron is said to have a safety margin 100-fold greater than iron salts (Ref. 41). However, in micronized form, it is absorbed as well as the ferrous salts and should be considered potentially toxic.

The ingestion of more than 150 mg/kg is considered serious by some (Ref. 41). The estimated "average" lethal dose for children is 200 to 250 mg/kg iron. This amount would approximate 2 to 4 g elemental iron in the 6 months to 5-year-old age group (Ref. 43).

Oral iron in a total daily dose of 200 mg may cause nausea, abdominal cramping, constipation, and diarrhea in 5 to 15 percent of patients. Several controlled trials reviewed by Fairbanks, Fahey, and Beutler (Ref. 44) have demonstrated that there is no significant difference in the incidence of gastrointestinal intolerance caused by various iron salts when administered in bioequivalent doses. Such side effects are uncommon if the total daily dose is 100 mg or less.

d. *Effectiveness.* Any iron preparation which is absorbed 80 percent as well as a ferrous sulfate solution by the method of Brise and Hallberg (Ref. 45) is considered effective.

Solutions of some ferrous salts are well-absorbed, as demonstrated by the studies of Brise and Hallberg (Ref. 46). It will be assumed that nonenteric coated tablets of the same salts will also be well absorbed if they pass the dissolution test described below. Dissolution tests may not correlate well with bioavailability. However, the practical limitations of all methods currently available to study iron absorption in a rigorous, meaningful way do not warrant that such tests be required for preparations for which there is reasonable evidence of effectiveness.

Absorption studies will be required for enteric-coated and sustained-release preparations of Category I iron salts, as well as for any product containing iron salts or combinations not listed in Category I or II (See Part IV, paragraph A.5.h. below—Category III conditions.) A dissolution test will be sufficient if it can be demonstrated that results correlate with absorbability as measured by the method of Brise and Hallberg (Ref. 45) or any comparable test.

A rise in hemoglobin in response to iron therapy in individuals with well-defined iron deficiency anemia has been used to document the effectiveness of a variety of iron products. However, because the doses recommended for OTC use are inadequate to treat iron deficiency anemia, this method would be inappropriate to document effectiveness in this group of products.

Dissolution Test. Since iron is most efficiently absorbed in the duodenum and jejunum, in vitro studies of the dissolution rate of all products should show a release of a significant percentage (80 percent) of their elemental iron content after 120 minutes in actual or simulated digestive fluids (60 minutes in gastric fluid and 60 minutes in intestinal fluid). The method described by Middleton, Nagy, and Morrison, or a comparable method, should be used (Refs. 44 and 47).

e. *Conclusion.* The Panel has reviewed the scientific literature, the submitted data, and the marketing history of vitamin and mineral ingredients. Based upon the available data, the Panel concludes that iron, in the dosages and forms identified under Category I conditions below, is safe and effective for the prevention of iron deficiency when the need for such therapy has been determined by a physician.

f. *Category I conditions under which iron is generally recognized as safe and effective and is not misbranded.*

The Panel recommends that the Category I conditions be effective 30 days after the date of publication of the final monograph in the FEDERAL REGISTER.

Acceptable sources of iron are ferroglycine sulfate; ferrous lactate; ferrous fumarate; ferrous glutamate; ferrous gluconate; ferrous succinate; and ferrous sulfate, dried. Dosage must be based on elemental iron (Fe, molecular weight 55.8). The iron content of a product must be labeled in terms of elemental iron.

(1) *Dosage—For prevention of deficiency.* For menstruating and lactating women, the oral dosage is 10 to 30 mg daily. For pregnant women, the oral dosage is 30 to 60 mg daily. For children 6 months to under 5 years of age, the oral dosage is 10 to 15 mg daily. For infants under 6 months of age, the Panel recommends the advice and supervision of a physician. For combination products other than for use in pregnancy, the oral dosage for adults and children 5 years of age and older is 10 to 20 mg daily.

(2) *Labeling.* The Panel recommends the following Category I labeling:

(i) *Indication—For prevention of deficiency.* "For use in the prevention of iron deficiency when the need for such therapy has been determined by a physician."

(ii) *Warning. "Caution:* The treatment of any anemic condition should be under the advice and supervision of a physician."

g. *Category II conditions under which certain iron compounds are not generally recognized as safe and effective or are misbranded.* The Panel recommends that the Category II conditions be eliminated from OTC iron drug products effective 6 months after the date of publication of the final monograph in the FEDERAL REGISTER.

The OTC drug use of certain iron salts, complexes, and combinations or use in certain target groups listed below is unsupported by scientific data, and in some instances, by sound theoretical reasoning.

(1) The following iron salts or complexes are poorly soluble and absorbed when compared to the well-absorbed standard, ferrous sulfate (Ref. 46):

(i) Ferric versenate.

(ii) Ferric citrate.

(iii) Ferrocholinate.

(iv) Ferric sulfate.

(v) Ferric ammonium citrate.

(2) Iron in combination with any of the following: Magnesium trisilicate, cobalt, copper, cyanocobalamin, intrinsic factor, liver stomach concentrate, molybdenum.

A number of substances have been combined with iron salts for the purposes of increasing absorption, minimizing gastrointestinal intolerance, potentiating erythropoietic activity, or preventing oxidation. Some of these are discussed briefly as follows:

(i) *Magnesium trisilicate* retards iron absorption, presumably by absorption of iron to the insoluble particles in the antacid preparation (Ref. 48). (ii) *Cobalt.* (Ref. 49) Large doses (60 to 150 mg) of cobaltous chloride have a nonspecific erythropoietic effect in various types of anemia unresponsive to other hematinics. There is no evidence that cobalt iron combinations produce a more rapid hematologic response than iron alone in iron-deficient patients. Further, the administration of these doses for prolonged periods of time is associated with anorexia, nausea, vomiting, and, less frequently, with more severe problems such as rash, flushing, tinnitus, deafness, and thyroid hyperplasia. Smaller doses have negligible erythropoietic effects (Refs. 44 and 49).

(iii) *Miscellaneous hematinics (copper, cyanocobalamin, intrinsic factor, liver stomach concentrate, and molybdenum).* Although all of these substances may play a role in erythropoiesis under certain circumstances, it has not been demonstrated that any of them will increase the hematologic response to iron (Ref. 44).

(iv) *Surface active agents.* Polysorbate 20 (400 mg), dioctyl sodium sulfosuccinate (150 mg), sodium laurel sulfate (200 mg), cholic acid (146 mg), and dehydrocholic acid (37 mg) do not significantly increase the absorption of iron (Ref. 50).

(3) *Adult males and postmenopausal females.* In this population, sufficient body stores of iron are theoretically maintained because daily obligatory losses of iron are balanced by iron absorption from food. Thus, unless there are unusual sources of iron loss (e.g., excessive gastrointestinal blood loss), dietary iron is generally sufficient to maintain iron nutrition in this population.

Recent nutritional surveys have raised the possibility of iron deficiency in the adult male population. Although the mean dietary intake for all adult males, aged 18 to 44, was above 10 mg, 41 percent of Blacks and 15 percent of Whites in the low-income group had intakes below the standard (10 mg). Twenty-five percent of Blacks and 15 percent of Whites with incomes above poverty level also had intakes below the standard (Ref. 51). Although 6.15 percent of males in the low-income group and 3.5 percent of males with incomes above poverty level had hemoglobin levels below 14 g/100 ml (Ref. 52), less than 2 percent had evidence of iron deficiency as measured by the iron saturation index (less than 15 percent) (Ref. 53). The Ten State Nutrition Survey did not measure dietary intakes in the population studied, but noted an unexpectedly high incidence of "low" (less than 14 g/100 ml) serum hemoglobins in this population. In the low-income-ratio States, about 20 percent of Whites, 40 percent of Blacks, and 15 percent of Spanish American adult males between 17 and 59 years of age had low serum hemoglobins. In the high-income-ratio States, about 11 percent of Whites, 30 percent of Blacks, and 20 percent of Spanish Americans had low hemoglobin levels (Ref. 54). When FAO/WHO criteria for low serum hemoglobin (less than 13 g/100 ml) are applied to these data, the incidence is reduced by approximately one-half. There was no correlation between the serum hemoglobin and serum iron or transferrin saturation in this group of males (Ref. 55). Although a high incidence of "deficient" transferrin saturaton was noted, the standard used (less than 20 percent) was much higher than the value generally accepted as indicative of iron deficiency (less than 15 of 16 percent) (Refs. 16 and 56). In view of insufficient evidence for iron deficiency in this population, there is no recommendation for an OTC iron preparation for this group.

h. *Category III conditions for which the available data are insufficient to permit final classification at this time.* The Panel recommends that a period of 2 years be permitted for the completion of studies to support the movement of Category III conditions to Category I except as specifically noted below for certain target populations.

(1) The following are questionable sources of elemental iron for OTC vitamin and mineral drug products because of insufficient data demonstrating effectiveness. If it can be shown by the method of Brise and Hallberg (Ref. 45) that these sources are absorbed at least 80 percent as well as the reference standard ferrous sulfate, dried, any of these iron preparations would then be acceptable as a source of elemental iron.

(i) Ferrous citrate.

(ii) Ferric ammonium phosphate.

(iii) Ferric phosphate.

(iv) Ferric pyrophosphate.

(v) Ferrous tartrate.

(vi) Ferrous carbonate.

(2) Category I salts of iron in combination with therapeutic laxative doses of dioctyl sodium sulfosuccinate. Dioctyl sodium sulfosuccinate in combination with iron must be tested in placebo-controlled, double-blind studies to show that it improves the tolerance of the vitamin/mineral preparation without impairing its effectiveness.

(3) All category I products for men and women over 60 years of age in oral doses of 10 to 20 mg daily. The evidence for iron deficiency in a substantial portion of the geriatric population is equivocal.

Several U.S. nutritional surveys indicate that dietary iron intake may be lower than 10 mg in a significant portion of the population over the age of 59 (Refs. 18, 19, and 57). This is presumably due to the reduced caloric intake in this group (Refs. 9 and 58). In the Ten State Survey, approximately 60 to 70 percent of females over 60 years of age and 37 to 45 percent of males over 60 years of age had iron intakes of less than 10 mg (Ref. 59). These findings were generally consistent with other nutritional surveys (Refs. 18 and 57).

In the same population, approximately 20 percent of males and 6 percent of females had "low" serum hemoglobin levels (less than 14 g/100 ml for males and less than 12 g/100 ml for females) (Ref. 60). The transferrin saturation indices for persons with "low" hemoglobin levels cannot be determined from the Ten State Nutrition data. However, 50 percent of those individuals with "deficient" hemoglobin levels (less than 10 g/100 ml for females and less than 12 g/100 ml for males) had deficient transferrin saturations (less than 15 percent for females and less than 20 percent for males). The prevalance of "deficient" hemoglobin levels was generally much lower (0 to 5 percent) in this population (Ref. 60). There was also evidence for iron deficiency, i.e., deficient transferrin saturations, in approximately 5 percent of women and 15 percent of men who had "adequate" serum hemoglobin concentrations (Ref. 61). The findings of the Ten State Survey suggest that the unsatisfactory hemoglobin levels are related to inadequate dietary iron intake, but they are not conclusive.

The presence of iron deficiency in the geriatric population is also supported by a British study of 475 people over the age of 65 living at home, which found the prevalence of iron deficiency with and without anemia to be 19 percent for women and 15 percent for men. In the population studied, there was a significant association between iron deficiency and the presence of gastrointestinal lesions capable of causing blood loss or a history of chronic salicylate ingestion (Ref. 62).

The results of the Ten State Nutritional Survey were not confirmed by the preliminary Hanes report which found the overall prevalance of "low" serum hemoglobins in this population to be 8.82 percent. The overall prevalence of low transferrin saturation was 2.76 percent. Furthermore, although Blacks aged 60 years and over had the highest prevalance of low hemoglobins for any age group regardless of income level (23 to 30 percent), only 0.8 percent had low values for percent transferrin saturation. Thus, there was no indication that the low hemoglobin levels observed were primarily related to iron deficiency (Ref. 63).

On the basis of suggestive evidence for iron in this population, a preparation containing 10 to 20 mg iron may be marketed. A prevalence of 10 percent iron deficiency, defined as a percent transferrin saturation of less than 15 percent, must be demonstrated in this population within 5 years.

(4) No claims for improved gastrointestinal tolerance will be permitted until substantiated, using a double-blind, crossover study which compares bioequivalent doses of the iron preparation in question with a Category I iron preparation. The doses studied must be comparable to those recommended in this document for Category I iron preparation.

(5) All Category I products in doses of 10 to 20 mg for adolescent males (aged 12 to 17 years). The estimated iron requirements for adolescent males is 1 to 2 mg based upon a basal loss of 0.8 mg daily and a 0.6 mg daily requirement for growth and expansion of blood volume. Until recently, there have been few studies of iron nutrition in this group. The Ten State Nutrition Survey found that 16.8 percent of Whites, 30.6 percent of Blacks, and 14.3 percent of Spanish American Boys between the ages of 13 and 16 surveyed in the low-income-ratio States had serum hemoglobins of less than 12 gram percent (Ref. 64). The corresponding figures for boys surveyed in the high-income-ratio States were 9.5 percent, 25.2 percent, and 21.9 percent (Ref. 65). There was a positive correlation between serum hemoglobin and transferrin saturation in this population. However, the standard for deficient transferrin saturation was higher than that generally accepted as indicative of iron deficiency. Preliminary results of the Hanes survey show that the mean dietary iron intake for this population is 70 percent below the standard (18 mg daily) (Ref. 66). The prevalence of anemia for boys (7.9 percent) was much higher than for girls of the same age (1.9) percent, an unexpected finding which agrees with those of the Ten State Nutrition Survey (Ref. 67). Also, the percentage of low hemoglobin values were four to six times higher in Blacks than in Whites regardless of income (Ref. 68). Using the same standards as the Ten State Nutrition Survey, 7.66 percent had a "low" transferrin saturation, i.e., less than 20 percent. Although more studies are needed, preliminary data suggest that iron balance in adolescent males may be precarious. On this basis, an OTC iron preparation containing 10 to 20 mg to prevent iron deficiency is placed in Category III for 5 years. Iron nutrition studies which show that a high prevalence of anemia correlates with an iron saturation of less than 15 percent or studies which demonstrate a 10 percent prevalence of iron deficiency with or without anemia in accordance with FAO/WHO standards will be sufficient to move this preparation to Category I.

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6. *Magnesium.* The Panel's statement on magnesium includes the following ingredients: Magnesium carbonate, magnesium chloride, magnesium gluconate, magnesium hydroxide, magnesium oxide, magnesium silicate,

magnesium sulfate, and magnesium trisilicate.

a. *Description.* Elemental magnesium as found in the above magnesium preparations will be referred to as magnesium in this document. Magnesium is the fourth most plentiful cation in the body. The body contains 20 to 28 g or approximately 2,000 meq magnesium, 55 percent of which is present in bone combined with calcium and phosphorus and 27 percent in muscle. The remainder (18 percent) is distributed elsewhere in nonmuscular soft tissues and body fluids. In plasma, 55 percent exists as free magnesium. The remainder is complexed (13 percent) and protein bound (32 percent) (Refs. 1 and 2).

b. *Safety.* Since the kidney is capable of excreting 40 to 60 meq magnesium daily, hypermagnesemia rarely occurs except in persons with renal failure (Ref. 2). Central nervous system depression, anesthesia, and flaccid paralysis may occur when serum levels exceeds 8 meq/liter (96 mg/liter). In addition, profound depression of the central nervous system respiration, and of the heart may follow the parenteral administration of magnesium sulfate for the treatment of eclampsia.

c. *Effectiveness.* Magnesium is an important activator or cofactor for many enzyme systems, particularly those responsible for the energy transformation of phosphate bonds. It also plays a role in protein synthesis and in maintaining electrical potentials in the neuromuscular system.

On the basis of metabolic balance studies, magnesium requirements may be met by 0.30 to 0.35 meq/kg daily (250 to 300 mg daily for a 70 kg man) (Ref. 1). Dietary sources include cereals, nuts, seafoods, peas, beans, corn, and soybeans. Seelig (Ref. 3) reviewed the literature and concluded that occidental diets provide an average intake of 250 to 300 mg daily (10 meq or 120 mg/1,000 kcal). The range is between 150 to 480 mg magnesium daily.

Magnesium is probably absorbed in the small bowel, although absorption of magnesium from rectal enemas indicates that absorption can also occur in the colon (Ref. 1). Approximately 44 percent of magnesium is absorbed when the dietary intake is in the normal range of 250 to 300 mg (21 to 25 meq) daily. However, the extent of absorption is profoundly influenced by the nature of the diet, the dose of magnesium, and the intestinal transit time. Phosphate and calcium may hinder magnesium absorption. The latter apparently competes for a common absorptive pathway (Ref. 4). In a study of 13 subjects given magnesium orally, those receiving 22.8 mg (1.9 meq) daily absorbed 75.8 percent, while those receiving 240 mg (20 meq) daily absorbed 43.3 percent. Subjects receiving 564 mg (47 meq) daily absorbed only 23.7 percent (Ref. 1). Thus, the fraction absorbed decreases as the dose increases, although the absolute amount absorbed increases.

The kidney is the major organ of elimination. Intravenous studies have demonstrated that little endogenous magnesium is lost through the fecal route under normal circumstances (Ref. 1). The striking ability of the body to conserve magnesium has been demonstrated by deprivation experiments. Urinary excretion of magnesium falls to less than 12 mg (1 meq) daily within 4 to 6 days of magnesium restriction (Refs. 1 and 5).

Because magnesium is present in many foods, is absorbed efficiently, and is conserved by the kidneys, deficiency of this element in the normal population is essentially nonexistent.

Symptomatic deficiency in man is usually associated with a serum magnesium level that is 10 to 30 percent of normal (normal range is 1.5 to 2.5 meq/liter or 18 to 30 mg/liter). It is rarely caused by dietary deficiency alone but may occur as a complication of certain conditions as in alcoholism with malnutrition or the prolonged administration of parenteral fluids, which are usually low in magnesium. With the exception of a rare, inherited renal magnesium-wasting syndrome (Ref. 5), deficiency almost always occurs in association with factors that decrease magnesium absorption (malabsorption syndromes, steatorrhea, the concurrent administration of calcium) or increase magnesium elimination (diuretics, alcohol, diarrhea, nasogastric suction, parathyroid disorders, malignant osteolytic disease, kidney disease, hyperaldosteronism, diabetic ketoacidosis, excess vitamin D, thyrotoxicosis, and perhaps kwashiorkor) (Refs. 1, 5, and 6).

Clinically, magnesium deficiency is characterized by neuromuscular, behavioral, and cardiac disturbances, such as tetany, convulsions, ataxia, tremors, depression, irritability, and psychosis. Treatment is almost always by intramuscular or intravenous injection (Ref. 2) because oral doses above 2 g (140 meq) regularly produce an osmotic diarrhea. Also, as noted earlier, the fraction absorbed decreases following large oral doses of magnesium. Only a few cases of hypomagnesemia responding to oral magnesium supplements have been cited in the literature (Refs. 5, 7, 8, and 9).

d. *Conclusion.* The Panel has reviewed the scientific literature, the submitted data, and the marketing history of vitamin and mineral ingredients. Based on the available data, the Panel concludes that magnesium is not justified for the prevention or treatment of magnesium deficiency as an OTC mineral drug.

e. *Category I conditions under which magnesium is generally recognized as safe and effective and is not misbranded.* The Panel recommends that the Category I conditions be effective 30 days after the date of publication of the final monograph in the FEDERAL REGISTER.

None.

f. *Category II conditions under which magnesium is not generally recognized as safe and effective or is misbranded.* The Panel recommends that the category II conditions be eliminated from OTC magnesium drug products effective 6 months after the date of publication of the final monograph in the FEDERAL REGISTER.

The Panel concludes that there is no rationale for the inclusion of elemental magnesium in the form of magnesium carbonate, magnesium chloride, magnesium gluconate, magnesium hydroxide, magnesium oxide, magnesium silicate, magnesium sulfate, and magnesium trisilicate in OTC drug products for the prevention or treatment of magnesium deficiency. Such a deficiency due solely to inadequate dietary intake is essentially nonexistent. When magnesium depletion occurs in association with disease, treatment by replacement is usually required by the parenteral route.

g. *Category III conditions for which the available data are insufficient to permit final classification at this time.* The Panel recommends that a period of 2 years be permitted for the completion of studies to support the movement of Category III conditions to Category I.

None.

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7. *Manganese.* The Panel's statement on manganese includes the following ingredients: Manganese chloride, manganese gluconate, and manganous oxide.

a. *Description.* Manganese occurs in nature chiefly in the form of its oxides. Hydrated manganous salts are pink in color, anhydrous manganous salts are usually white, manganates are green, and permanganates form solutions which are characteristically deep purple violet. Manganese is frequently present in mineral supplements and in hematopoietic preparations, but its value in such products has yet to be demonstrated (Ref. 1).

b. *Safety.* The homeostatic mechanism for regulating the concentration of manganese in the body is very precise. Manganese is absorbed from the small intestine and is then transported via the blood in the trivalent form bound to a beta$_1$-globulin, transmanganin. Whole blood contains 1.5 to 3 μg/100 ml manganese equally divided between plasma and the red blood cells. Manganese is excreted in the bile; this constitutes the principal mechanism for regulating the amounts of manganese in the tissues. With a high manganese intake, the element is also excreted in the pancreatic juice. The amount excreted in the urine is very small. About 12 to 20 mg manganese are present in the body of a 70 kg man, but not all of this amount exists in the dynamic pool of available manganese. High levels of manganese occur in bone, liver, kidney, pancreas, and the pituitary, whereas the concentration in the skeletal muscle is very low. The manganese in bone cannot be mobilized to meet a need. The stores of managanese, in the order of their importance, are found in the liver, skin, and skeletal muscle. There is not a special store in the newborn (Ref. 2).

Chronic manganism in man has been a major industrial hygiene problem in the manganese-ore processing industry. The disease is characterized by a nonspecific, dust-related, lung disease and a progressive central nervous system affliction similar to the symptoms of Parkinson's disease (Refs. 3 and 4). Although manganese entered the body by inhalation, a considerable amount of this manganese eventually passed through the gastrointestinal tract and was absorbed (Ref. 5). Kawamura et al. (Ref. 6) reported severe manganese poisoning in 16 of 25 individuals exposed to drinking water containing 3 to 10 ppm manganese. Two deaths were reported, but the period of exposure was not specified.

c. *Effectiveness.* Manganese is an essential element for higher animals and man. Manganese deficiency in animals results in the impairment of growth, reproduction, glucose tolerance, blood clotting, proper skeletal formation, and function of the central nervous system (Ref. 4). Manganese is known to be an integral part of several enzymes, notably pyruvate carboxylase, which play important roles in mammalian metabolism. These roles involve mucopolysaccharide synthesis, sugar metabolism, and protecting the cell from the effects of destructive oxygen radicals (Ref. 2). Overt and unequivocal deficiency of manganese in man is not known, suggesting that the average dietary intake of 2.5 to 7 mg daily meets the requirement (Ref. 7). Most human foods contain measurable amounts of manganese. Cereal products, leafy fresh vegetables, nuts, and dried fruits are the richest sources (Ref. 8).

A role for manganese has been postulated in disease conditions, such as atherosclerosis (Ref. 8), severe liver disorders (Ref. 9), lupus erythematosus (L. E.) (Ref. 8), "the hydralazine (poisoning) syndrome" (Ref. 8), extrapyramidal disease (Ref. 10), and alcaptonuria (Ref. 11), but no satisfactory explanation which would be a basis for manganese therapy exists.

Hartman, Matrone, and Wise (Ref. 12) hypothesized that manganese interfered with iron absorption. Thomson and Valberg (Ref. 13) reported that both iron and manganese were absorbed to a greater extent when the other was not present in a solution used to perfuse the duodenum of rats. Pollack et al. (Ref. 14) observed incresed manganese absorption in iron deficiency. The latter observations suggested that iron and manganese have a metabolic pathway in common. Diez-Ewald, Weintraub, and Crosby (Ref. 15) also reported increased manganese absorption concomitantly with increased iron absorption in iron deficiency. However, feeding high levels of manganese (14,000 ppm) caused blood loss from the gastrointestinal tract. Moreover, the work by Borg and Cotzias (Ref. 16) suggests that manganese may also interfere with iron metabolism by replacing iron in hemoglobin. Mena et al. (Ref. 5) suggested that iron deficiency anemia played a role in an individual's susceptibility to manganese toxicity.

Although the antagonism of iron metabolism by manganese was often only achieved at high manganese concentration, the source of iron that was used in these studies was often a highly biologically available form of iron, not representative of all forms of iron usually in one's diet, and often was present in the diet at levels in excess of the requirement. There is no doubt that manganese imbalance, albeit at high levels, can resut in an alteration in iron metabolism. Whether levels of manganese two to ten times the median adult intake (10 to 50 mg daily) taken by man over a long period would contribute to the iron undernutrition due to low dietary iron intake is not known.

Chronic manganese poisoning, with severe central nervous system effects, appears long after exposure to manganese and is not necesarily associated with high tissue levels of manganese. A diagnosis of manganism is very difficult, if not impossible, in the absence of known exposure to high levels of manganese. No information is at hand regarding the risk to man of relatively high dietary intakes of manganese over a lifetime.

d. *Conclusion.* the Panel has reviewed the scientific literature, the submitted data, and the marketing history of vitamin and mineral ingredients. Based upon the available data, the Panel concludes that because of the potential for manganese toxicity, and in the absence of any demonstrated need for OTC drug preparations of manganese to prevent a deficiency, manganese is not generally recognized as safe or effective therapy for any disease condition.

e. *Category I conditions under which manganese is generally recognized as safe and effective and is not misbranded.* The Panel recommends that the Category I conditions be effective 30 days after the date of publication of the final monograph in the FEDERAL REGISTER.

None.

f. *Category II conditions under which manganese is not generally recognized as safe and effective or is misbranded.* The Panel recommends that the Category II conditions be eliminated from OTC manganese drug products effective 6 months after the date of publication of the final monograph in the FEDERAL REGISTER.

The Panel concludes that, because of the potential for manganese toxicity and the absence of any demonstrated need for OTC drug preparations of manganese chloride, manganese gluconate, and manganous oxide for the prevention or treatment of deficiency, manganese is not generally recognized as safe or effective OTC therapy for any disease condition.

g. *Category III conditions for which the available data are insufficient to permit final classification at this time.* The Panel recommends that a period of 2 years be permitted for the completion of studies to support the movement of Category III conditions to Category I.

None.

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8. *Phosphorus.* the Panel's statement on phosphorus includes the following ingredient: calcium phosphate dibasic.

a. *Description.* The average daily phosphorus intake of adults in the U.S. is estimated at 0.8 to 1.5 g daily (Refs. 1, 2, and 3). The primary source of calcium in the American diet is milk. Other major sources of phosphorus include poultry, fish, and meat. Nonnutritious soft drinks containing excess phosphorus in the form of phosphoric acid also serve as sources for children and adults alike. The relatively greater availability of phosphate-containing foodstuffs has resulted in a calcium/phosphate dietary ratio much lower than that recommended to maintain the integrity of skeletal tissue (Ref. 4). This matter is ot some concern since diets with low calcium/phosphorous ration have led to progressive bone loss in rats (Ref. 5), dogs (Ref. 6), and horses (Ref. 7).

The efficiency of phosphate absorption is a function of both the dietary intake and the food source (Ref. 1). Sixty to 70 percent is absorbed on a normal intake and maximal absorption (up to 90 percent) achieved on very low intakes (Ref. 8). Most, if not all, phosphorus is absorbed as free phosphates and various inorganic esters are hydrolyzed by specific intestinal phosphatases prior to absorption. The phosphate in organic phosphate esters such as phytic acid of cereals and seeds are not available to man since the human intestine lacks the enzyme, phytase, essential for hydrolysis of the organic esters. Organic phosphate ester compounds may also interfere with calcium absorption since they form insoluble calcium salts within the intestinal lumen (Ref. 9). In animals, certain substances, i.e., unsaturated fatty acids, iron, and aluminum, intefere with intestinal phosphate absorption (Refs. 10, 11, and 12). Vitamin D increases intestinal phosphate absorptionin certain animal species (Ref. 13). A direct effect of vitamin D or its biologically active metabolites on phosphate absorption in man is still to be adequately defined. There is no known effective physiological mechanism regulating the intestinal absorption of phosphorus in man; the control of phosphate economy is achieved primarily by variations in dietary intake and renal excretion (Ref. 14). Fecal phosphorus represents both unabsorbed phosphorus and that secreted into the gastrointestinal tract. In man, with phosphorus intakes of approximately 1 to 1.5 g daily, the endogenous secretion of phosphate into the intestinal lumen is 3 mg/kg daily (Ref. 8). Dietary phosphorus is absorbed to a greater extent than calcium and consequently the renal excretion of phosphorus is much greater than that of calcium (Ref. 14).

With normal renal function, urinary phosphorus usually amounts of variation in phosphate clearance occurs with the usual pattern, that of a matutinal increase in urinary phosphorus-creatinine ratios. this circadian rhythm is related to physical activity with the nadir appearing a few hours after the end of sleep. The loss of diurnal variation in adrenal insufficiency states and the documented inverse correlation between phosphate excretion and plasma cortisol levels suggest that this rhythm is also controlled by the adrenal glands (Refs. 15, 16, and 17).

In man, the tubular reabsorption of phosphate cleared by the glomeruli is normally 85 to 95 percent (Ref. 14). This process is rate-limited with an upper limit of maximum tubular reabsorptive capacity of 4 to 8 milligrams/minute (mg/min). The tubular resorption of phosphate is increased by cortisol (physiological levels) and growth hormone, and decreased by digoxin, estrogen, parathyroid hormone, and pharmacological levels of cortisol or structurally related synthetic analogues (Refs. 14 through 18). The renal tubular reabsorption of filtered phosphorus is also decreased by elevations in serum calcium (Ref. 19).

b. *Safety.* Since the kidney is capable of excreting 600 to 900 mg phosphorus daily, hyperphosphatemia is rare in the absence of chronic renal disease and then only when the glomerular filtration rate falls below 20 milliliters/minute (Ref. 14). Hyperphosphatemia is also characteristic of disorders of parathyroid secretion and metabolism such as hypoparathyroidism and pseudohypoparathyroidism (Ref. 20) and can be accentuated by phosphate feeding. There are no specific signs or symptoms of hyperphosphatemia per se, although the hypocalcemia often associated with the hyperphosphatemia can result in enhanced neuroexcitability, tetany, and convulsions (Ref. 20). Chronic phosphate feeding induces secondary hyperparathyroidism and soft tissue calcification in dogs (Ref. 21), and may stimulate secondary hyperparathyroidism in man (Ref. 22).

c. *Effectiveness.* Of the 11 to 14 g phosphate per kg fat-free tissue in the normal adult, 85 percent is in the skeleton. The remainder is distributed between tissue and membrane components of skeletal muscle, skin, nervous tissue, and other organs. Whereas most of the phosphorus in soft tissue and cell membranes is in the form of organic esters, almost all of the phosphorus in bone is contained in the mineral phase as inorganic orthophosphate and small amounts of inorganic pyrophosphate. The regulation of plasma phosphate is not as readily explained as that of plasma calcium, since not only is the circulating phosphate in equilibrium with skeletal and cellular inorganic phosphate, but also with a large number of organic compounds which result from cellular metabolism. The phosphate ion is essential for the metabolism of carbohydrate, lipids, and protein via the intermediation of a multitude of enzyme systems and the metabolic potential of so-called "high energy phosphate" compounds. Phosphate also functions to modify acid-base equilibrium in plasma and within cells, and also plays

a fundamental role in modifying the development and maturation of bone, in the renal excretion of hydrogen ions, and in modifying the effect of the B-vitamins. In the human adult, serum inorganic phosphate ranges between 2.5 to 4.4 mg/dl, with a mean of 3.5 mg/dl. Dietary phosphate, stage of growth and age, time of day, hormonal interplay, and renal function all contribute to the variability of the fasting serum phosphate concentration.

Eighty-eight percent of the plasma phosphate is unfilterable, some of which is complexed with mono or divalent cations such as sodium^{+}, calcium^{++}, and magnesium^{++}. At normal Blood pH, 85 percent of the ultrafilterable phosphate is in the form of HPO_4^{-2}, the remainder existing mainly as $H_2PO_4^{-}$.

The concentratin of plasma phosphate varies with age. In prepubertal children, the main values for circulating phosphate approximates 5 to 6 mg/dl. Normal adult human values are gradually approached by the third decade after which plasma phosphate decreases progressively between ages 20 and 40 years and begins to rise in females in the postmenopausal period.

With the exception of young infants, the recommended allowance of phosphorus daily is the same as that of calcium, although the calcium/phosphorus ratio of diets ingested through the world today is reportedly less than 0.75 (Refs. 4, 23, and 24). The calcium/phosphorus ratio of cow's milk is 1.3/1 as compared with a calcium/phosphorus ratio of 2/1 in breast milk (Ref. 23). A high phosphate/calcium ratio may contribute to the syndrome of idiopathic hypocalcemia and tetany of infants on formula feeding.

Phosphorus depletion in man, a syndrome characterized by weakness, anorexia, malaise, and skeletal aches can occur during prolonged and excessive intake of nonabsorbable antacids. Specific abnormalities such as hemolytic anemia, granulocyte dysfunction, and erythrocyte glycolysis also result from phosphate depletion (Refs. 25, 26, and 27). The syndrome has been experimentally produced in man and is readily reversed when the medication is discontinued and sufficient amounts of dietary phosphorus are consumed (Refs. 28 and 29). Its frequency in the very large population of individuals ingesting antacids is unknown, but is probably rare based on the infrequency of published reports of this complication. Recognition and appropriate therapy require medical supervision, particularly when adjustments in drug therapy for peptic ulcer are involved.

d. *Conclusion.* The Panel has reviewed the scientific literature, the submitted data, and the marketing history of vitamin and mineral ingredients. Based upon the available data, the Panel concludes that phosphorus for the prevention or treatment of phosphorus deficiency is not justified as an OTC mineral drug preparation.

e. *Category I conditions under which phosphorus is generally recognized as safe and effective and is not misbranded.* The Panel recommends that the Category I conditions be effective 30 days after the date of publication of the final monograph in the FEDERAL REGISTER.

None.

f. *Category II conditions under which phosphorus is not generally recognized as safe and effective or is misbranded.* The Panel recommends that the Category II conditions be eliminated from OTC phosphorus drug products effective 6 months after the date of publication of the final monograph in the FEDERAL REGISTER.

The Panel concludes that there is no rationale for the inclusion of calcium phosphate dibasic in OTC drug preparations for the prevention or treatment of deficiency since phosphate deficiency is virtually nonexistent.

g. *Category III conditions for which the available data are insufficient to permit final classification at this time.* The Panel recommends that a period of 2 years be permitted for the completion of studies to support the movement of Category III conditions to Cateory I.

None.

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9. *Potassium.* The Panel's statement on potassium includes the following ingredients: potassium chloride, potassium gluconate, and potassium sulfate.

a. *Description.* Potassium is the principal intracellular cation. The average 70 kg adult body contains approximately 3,500 meq (140 g) potassium. Of this total, 65 meq (2.6 g) occurs in the extracellular fluid. The remainder occurs primarily in the muscle (3,000 meq or 120 g), liver (200 meq or 8 g), and red cell mass (235 meq or 10 g) (Refs. 1 and 2). In healthy individuals, better than 90 percent of the daily input of potassium is excreted in the urine. The residue appears in the sweat and feces. Elimination through sweat is significant only in the tropics where potassium levels approach those of sodium. Although potassium loss in the feces can be significant, amounting to 5 to 10 meq daily (200 to 400 mg daily) in healthy individuals, the kidney serves as the main organ for potassium elimination. Filtered potassium is virtually completely reabsorbed in the proximal convoluted tubule. The majority of urinary potassium is accounted for by active secretion in the distal tubule in exchange for sodium under the influence of aldosterone.

b. *Safety.* Hyperkalemia (plasma levels in excess of 4 meq/liter) may be caused by acute or chronic renal failure, shock, massive tissue injury, severe metabolic or respiratory acidosis, adrenal insufficiency, accelerated catabolic state, and gastrointestinal hemorrhage. Although it is capable of causing severe muscle weakness and pain, hyperkalemia's chief danger is cardiac arrest. Typical electrocardiographic changes include prolongation of the PR interval, peaking of the T waves, and prolongation of the QRS complex.

Under normal circumstances, hyperkalemia is an uncommon event because the kidney is able to excrete large potassium loads. Daily amounts of potassium in excess of 5 meq/kg (500 meq) have been ingested chronically in divided doses without evidence of intoxication. On the other hand, even the normal kidney has a limited capacity for handling large single doses of potassium. Doses of 1.0 meq/kg or 40 mg/kg may increase the serum potassium by as much as 1 meq/liter and doses of 2 to 2.5 meq or 80 to 100 mg/kg may produce serum potassium levels of 6 to 8 meq/liter (Ref. 3).

Since the kidney is the principal organ of elimination, patients with renal failure are predisposed to hyperkalemia. Although patients with chronic severe uremia (blood urea nitrogen greater than 100 mg percent) are frequently able to eliminate the usual daily intake of potassium as evidenced by normal or slightly elevated serum potassium, their ability to excrete an acute load of this ion is clearly abnormal. Three hours following a dose of 1 meq/kg, 4 to 39 percent of the potassium appears in the urine in contrast to 49 to 100 percent in normal subjects. Also, the serum concentration may increase by 1.5 to 3.5 meq/liter resulting in cardiac toxicity (Ref. 3).

The consumption of potassium in the form of concentrated salts has been shown to cause irritation and even destruction of tissues in the gastrointestinal tract.

Enteric coated tablets of potassium chloride containing approximately 8 meq have been associated with a number of cases of intestinal ulceration and obstruction (Ref. 4).

c. *Effectiveness.* Potassium is absorbed efficiently in the jejunum and ileum when the concentration exceeds 5 to 6 meq/ml (200 to 300 mg). In humans, absorption is not influenced by the presence of sodium or the direction of movement of water (Ref. 5).

The normal diet provides 50 to 150 meq potassium daily (Refs. 1 and 6). Food tables show that animal and vegetable foods contain significant quantities of potassium making it difficult to design a calorically adequate diet which is low in potassium (Ref. 1).

The serum potassium concentation is frequently a poor indicator of total body stores. Hypokalemia (plasma levels less than 3.5 meq/liter) is generaly consistent with total body potassium depletion. However, the latter may frequently be accompanied by a normal or even high serum potassium concentration, e.g., in end-stage uremia and in diabetic ketoacidosis. The presence or absence of signs and symptoms of hypokalemia, however, is related to serum potassium concentration (Ref. 7). These include lethargy, irritability, decreased deep tendon reflexes, tetany, paresthesias, muscle weakness, paralytic ileus, and electrocardiographic changes which include depression of the ST segment, prolongation of the QRS complex, and U waves. Hypokalemia also increases the sensitivity of the myocardium to the toxic effects of digitalis.

A renal conservation mechanism for potassium has been demonstrated in deprivation states which is relatively inefficient and certainly not absolute (Refs. 1 and 3). Renal absorption during potassium deprivation is sluggish. On diets of 15 to 20 meq (600 to 800 mg) potassium daily the 24-hour urine potassium of normal subjects decreases to 20 to 25 meq (800 to 1,000 mg) after 1 week and to 10 to 15 meq daily (400 to 600 mg) in 2 weeks. A total body potassium deficit of 8 to 10 percent (250 to 300 meq or 10 to 12 g) occurs prior to the attainment of equilibrium. Following prolonged, severe potassium deprivation, the 24-hour urine potassium may reach levels as low as 3 to 5 meq/liter (120 to 200 mg/liter). A low sodium diet enhances the ability of the kidney to conserve potassium (Ref. 3) and high sodium intake stimulates potassium excretion.

Hypokalemia is generaly associated with conditions in which there are substantial extrarenal or excessive renal losses of potassium. It is rarely caused by decreased intake alone. Several review articles on hypokalemia (Refs. 1, 2, 8, 9, and 10) discuss its association with one or more of the following conditions: (1) Decreased intake together with obligatory potassium losses in anorexic and comatose patients, and in alcoholics (low serum potassium observed in 10 of 30 alcoholics in one study) (Ref. 11);

(2) Excessive gastrointestinal losses due to emesis, laxative abuse, diarrhea, prolonged nasogastric suction, and fistulas. Diarrhea is the major cause of hypokalemia in children (Ref. 12);

(3) Excessive renal losses as a result of diuretics, renal tubular acidosis, metabolic alkalosis, excessive adrenal corticosteroids, surgery, consumption of significant quantities of licorice (greater than 100 g daily); and

(4) Redistribution of serum potassium due to alkalosis or the administration of insulin with or without glucose.

Potassium depletion is rarely associated with dietary insufficiency except, perhaps, in the alcoholic. Indeed, even with the provocation of diuretic therapy, dietary sources of potassium are generally sufficient to cover the increased loss (Refs. 9 and 10) so that potassium supplementation is not routinely indicated. When potassium supplementation is indicated, a dose of 40 to 100 meq (1.6 to 4.0 g) potassium daily readily corrects the hypokalemia in adults (Ref. 10). Since laboratory tests are required to establish the diagnosis of hypokalemia and to assess the effectiveness of therapy, OTC drug use of potassium is unwarranted.

d. *Conclusion.* The Panel has reviewed the scientific literature, the submitted data, and the marketing history of vitamin and mineral ingredients. Based upon the available data, the Panel concludes that potassium for the prevention or treatment of potassium deficiency is not justified as an OTC mineral drug preparation.

e. *Category I conditions under which potassium is generally recognized as safe and effective and is not misbranded.* The Panel recommends that the Category I conditions be effective 30

days after the date of publication of the final monograph in the FEDERAL REGISTER.

None.

f. *Category II conditions under which potassium is not generally recognized as safe and effective or is misbranded.* The Panel recommends that the Category II conditions be eliminated from OTC potassium drug products effective 6 months after the date of publication of the final monograph in the FEDERAL REGISTER.

The Panel concludes that, in general, dietary sources provide more than adequate amounts of potassium. Although potassium depletion may be a frequent complication of diuretic use and alcoholism, the need for supplementation in these situations should be assessed by a physician. Routine supplementation with small amounts of potassium is not indicated. For these reasons there is no justification for the inclusion of potassium chloride, potassium gluconate, or potassium sulfate in any OTC drug preparation for the prevention or treatment of potassium deficiency.

g. *Category III conditions for which the available data are insufficient to permit final classification at this time.* The Panel recommends that a period of 2 years be permitted for the completion of studies to support the movement of Category III conditions to Category I.

None.

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10. *Zinc.* The Panel's statement on zinc includes the following ingredients: zinc carbonate, zinc chloride, zinc gluconate, zinc hydroxide, zinc lactate, zinc oxalate, zinc oxide, zinc phytate, zinc sulfate, and zinc sulfide.

a. *Reference form.* Dosages recommended in this document for zinc are based on elemental zinc (Zn, molecular weight 65.4).

b. *Description.* Zinc is a part of at least 18 enzymes and enzyme cofactors, including alkaline phosphatase and alcohol dehydrogenase (Ref. 1). It is involved in protein synthesis and nucleic acid synthesis (Ref. 2). The mobilization of vitamin A from the liver into the plasma requires zinc (Ref. 3).

Zinc is distributed in bone (20 percent), muscle (63 percent), blood (2 percent), and other organs (Ref. 4), totaling about 2.2 g in the body (Refs. 4 and 5). Zinc is excreted from the body via the feces, urine, and skin (Refs. 6, 7, and 8). The pancreatic contribution to fecal excretion is estimated to be about 1.5 mg daily in adults (Ref. 7). Urinary losses of zinc average 0.5 mg daily. As much as 1 mg zinc/liter sweat may be lost (Ref. 8). In hot and arid climates, this rate of loss could be a significant drain on the body economy. Dermal losses under normal conditions may average 2.8 mg daily (Ref. 9). Total menstrual loss of zinc is only 0.3 to 0.6 mg per menses (Ref. 10). A daily turnover of 6 mg zinc can be calculated from radioisotope studies (Refs. 11 and 12).

c. *Safety.* In humans, daily therapeutic doses of zinc have been used ranging from 33 to 44 mg elemental zinc, i.e., from 3.3 to 4.4 times the RDA for children (Ref. 13), to 150 mg elemental zinc or 10 times the RDA for adults (Refs. 14 through 21). The only side effects reported for time periods of up to 6 months were occasional mild nausea and mild diarrhea. The most careful studies of possible subtle side effects were by Greaves and Skillen (Ref. 16) and Czerwinski (Ref. 18), who reported no evidence for hematological, hepatic, or renal toxicity as assessed by a number of biochemical parameters in patients treated with zinc sulfate (10 times the RDA) for 4 to 6 months.

(1) *Acute zinc toxicity.* Zinc sulfate is sometimes used as an emetic, as vomiting occurs after the ingestion of 1 to 2 g zinc sulfate, i.e., 225 to 450 mg elemental zinc (Ref. 22). Other symptoms of zinc toxicity are fever, nausea, stomach cramps, and diarrhea in 3 to 12 hours following ingestion (Ref. 23).

Death has been reported after consumption of 6 g zinc as zinc sulfate in an adult woman. Complications included hemorrhagic pancreatitis and severe renal damage (Ref. 24). Intervention of hemodialysis (Ref. 25) or chelation therapy (Ref. 26) probably prevented death in two other cases. In the former, an unknown quantity of metallic zinc was dissolved in hydrocholoric acid and swallowed by an adult male alcoholic. This resulted in diarrhea, weakness, vomiting, severe epigastric pain, jaundice, and severe renal failure of greater than 4 days duration, then partial renal failure for an additional 15 days. In the second case, 4 g metallic zinc on day 1 and 8 g on day 2 were consumed by a 16-year-old boy. Mental and muscular incoordination were reported. Many cases of acute toxicity occur after food or drink is prepared or stored in galvanized vessels (Ref. 23).

The severely toxic zinc levels in the above cases appear to be about 400 times the Recommended Dietary allowances of 15 mg zinc established by the Food and Nutrition Board, NAS/NRC (Ref. 27).

(2) *Chronic zinc toxicity.* A review of studies by Van Reen (Ref. 23), Bremner (Ref. 28), and Calhoun, Smith, and Becker (Ref. 29) indicates that in rats, zinc is toxic when present in the diet at 0.5 to 1.0 percent levels over many weeks. This represents 100 to 200 times normal requirements.

Many of the toxic effects of zinc result from its interaction with other essential elements, primarily copper, iron, and calcium (Refs. 23, 28, and 29). The mineral imbalance caused by excessive levels of zinc results in both direct and indirect disturbances in the absorption and metabolism of these minerals.

Whether long-term superoptimal levels of zinc consumption are hazardous or not has been the subject of recent reports (Refs. 30 and 31). Based on epidemiological evidence supported by preliminary animal experiments, Klevay (Ref. 31) proposes the hypothesis that a high ratio of zinc to copper intake predisposes to coronary heart disease, perhaps by a metabolic effect on cholesterol metabolism.

d. *Effectiveness.* The relative availability of various zinc salts has been studied by the chick growth assay technique. Zinc oxide, carbonate, chloride, and zinc metal were as available as zinc sulfate, even though their solubilities in water are quite different (Refs. 32 and 33). Zinc sulfide was not nutritionally available. No such studies have been reported in humans. Food generally decreases the availability of zinc salts. The ultimate absorption of zinc is determined by the inter-

action of many factors. It is known that phytate (inositol hexaphosphate) is abundant in grains, nuts, and legumes. High phytate consumption by animals or humans results in an increased zinc requirement to maintain balance (Refs. 34, 35, and 36). Calcium in the presence of phytate lowers the availability of zinc (Ref. 37). Other dietary components can complex zinc to form insoluble or unabsorbable ligands. Reinhold, Ismail-Beigi, and Faradji (Ref. 38) have recently shown fiber to be as important as phytate in this respect. Whole grain foods are rich in both. Phosphate salts given at the same time as zinc sulfate can reduce its absorption, and phosphate in the form of milk does so to a greater extent (Ref. 39). Pecoud, Donzel, and Schelling (Ref. 39) measured serum zinc levels as an indication of relative absorption. A 25-mg zinc dose gave about one-half the response of a 50-mg dose, providing the subject was fasting. Taking zinc sulfate with milk, cheese, brown bread, or coffee reduced serum zinc response by at least 43 percent. Meat had no effect.

Research on human requirements for zinc from Western diets recently has been reviewed (Refs. 40 and 41). Although experimental design and assay techniques vary widely, in no instance is negative balance observed in adults when greater than 18 mg dietary zinc is consumed daily (Ref. 41). Negative balance occurs at an intake of 5 to 6 mg daily (Ref. 41). It appears that zinc sufficiency is achieved at an intake of 8 to 10 mg daily (Ref. 41). There are no balance studies of adolescents, lactating women, or the elderly. In pregnancy, positive zinc balance may require 26 to 29 mg daily (Ref. 9). It is yet unexplained why infants consuming breast milk have a negative zinc balance, losing more than 1 percent total body zinc daily (Ref. 42). The loss may be even greater if the mother's milk is low in zinc. Animal studies show that maternal dietary zinc deficiency resulted in zinc deficiency of the offspring due to lowered zinc content of the milk (Ref. 43). Zinc availability in the postweaning diet may be critical in reversing this trend. Unfortunately no data are available.

A recent study of the zinc content of typical meals served in a hospital showed a range of 7 to 16 mg zinc daily. The average was 11.3 mg zinc daily (Ref. 44). Higher zinc content was associated with the higher protein diet, reflecting the fact that foods highest in zinc are meat, eggs, milk products, and shellfish. The more vegetarian diet found in North China supplies an estimated 9.5 mg zinc daily (Ref. 45). Assuming that 20 to 30 percent of dietary zinc is absorbed, Sandstead reviewed data which indicate that many groups of people in the United States are consuming diets marginal to deficient in zinc (Ref. 40).

Discussion of zinc deficiency in the U.S. necessitates review of techniques for assessing zinc deficiency. Currently metabolic balance studies, isotope turnover studies, plasma zinc levels, urinary zinc excretion, hair zinc content, and taste acuity are being used. No technique has been demonstrated to provide direct evidence of zinc deficiency. The critical test remains a definitive response to oral supplementation with zinc under controlled conditions (Ref. 41).

Evidence that marginal zinc deficiency does occur is presented in the work of Henkin and Bradley, (Ref. 46), Henkin et al. (Ref. 47) and Schechter et al. (Ref. 48), who find that a decrease in taste/smell acuity may be corrected by zinc administration. Hambidge et al. (Ref. 49) reported that of 10 children living in the Denver area and having low hair zinc concentration, 7 had poor appetites, 8 had heights below the tenth percentile (Harvard growth charts), and 5 of 6 showed lowered taste acuity. After 1 to 3 months of daily dietary zinc supplementation (1 to 2 mg/kg zinc sulfate), taste acuity returned to normal and hair zinc increased in 5 of the 10 children. The children were drawn from a group of 338 upper- and middle-class Caucasians.

Hallbook and Lanner (Ref. 19) treated leg ulcer patients with zinc. One group had initial serum zinc levels of less than 110 μg percent and the other had initial levels greater than 110 μg percent. Those with low serum zinc had slower healing, and this defect was corrected by 600 mg zinc sulfate daily. Pories et al. (Ref. 15) also found shortened healing time in surgical patients when zinc sulfate was given orally. It appears that zinc supplements do not accelerate wound healing unless there has been previous depletion of this element.

Abnormally high urinary zinc levels are observed in alcoholics (Ref. 50), and such patients are a higher risk population for zinc deficiency. Fasting obese patients have up to 10-fold increases in urinary zinc but no change in plasma levels and a cumulative loss of 10 to 15 percent of total body zinc. High urine zinc levels are seen in renal disease, diabetes, liver disease, porphyria, proteinuria, trauma, and kwashiorkor (Refs. 51 and 52).

Zinc depletion has been associated with the use of various drugs, including histidine (Ref. 53), penicillamine (Ref. 54), phenytoin (Ref. 55), thiamazole (Ref. 56), and thiazides (Ref. 57).

Human dietary zinc deficiency has been documented in the Middle East (Refs. 57 through 64). Dwarfs with extreme iron deficiency anemia and retarded sexual development responded to treatment with zinc sulphate by growth and sexualfunctioning. Studies by Ronaghy et al. (Refs. 65 and 66) suggest that less severe zinc deficiency might contribute to short stature with delayed puberty. Clinical deficiency states are associated with low levels of zinc in hair as well as plasma zinc (Ref. 67).

Zinc deficiency may occur in association with other diseases. Caggiano et al. (Ref. 68) reported a case of zinc deficiency occurring secondary to intestinal malabsorption, recurrent infection, and hypogammaglobulinemia. Again, retarded growth and hypogonadism were seen, both responsive to zinc supplementation.

Zinc deficiency might be expected in many other types of generalized malabsorption. The low plasma zinc levels and reduced taste acuity observed in celiac sprue and regional enteritis (Refs. 69 and 70) imply possible deficiency in these diseases. One severe case of deficiency in regional enteritis, responsive to zinc therapy, was reported by Sandstead (Ref. 40).

Clinical and biochemical indications of zinc deficiency are found to accompany sickle cell disease. In controlled studies of patients with sickle cell anemia complicated by leg ulcers, those treated with zinc sulfate had a healing rate that was three times faster than the placebo group (Ref. 14). Prasad et al. (Ref. 20) observed hypogonadism and growth retardation in a group of 36 patients with sickle cell anemia. Those treated with oral zinc sulfate responded by weight gain and in some cases by growth and sexual development. Plasma zinc in sickle cell disease is below normal (Refs. 20 and 71) as is erythrocyte and hair zinc. Urinary zinc excretion is elevated, probably associated with increased hemolysis in this disease.

Moynahan (Ref. 13) reported in 1974 that in infants suffering from acrodermatitis enteropathica, treatment with zinc led to complete clearance of skin lesions and restored normal bowel function. Malabsorption is thought to be one of the defects in zinc metabolism leading to zinc deficiency in this disease (Ref. 72). The effectiveness of zinc treatment has been confirmed by others (Refs. 73 through 77).

In patients with acrodermatitis enteropathica who became pregnant, there were, out of the seven pregnancies reported, one abortion and two major congenital malformations (Ref. 78). The malformations were similar to those seen in the offspring of zinc-deficient rats. Zinc deficiency in animals need only be transient to have teratogenic effects on the fetus. Burch, Hahn, and Sullivan review a wealth of additional circumstantial evidence which strongly suggests that zinc deficiency in pregnant humans

may result in congenital anomalies (Ref. 7).

Cohen, Schechter, and Henkin reported that in 19 patients with second and third degree burns, 84 percent showed decreased taste acuity (Ref. 79). Of these, the serum zinc was decreased and urinary zinc was elevated compared to 150 controls. Carr and Wilkinson (Ref. 80) also found persistent, highly elevated urinary zinc in severely burned children. A substantial decrease in tissue zinc following thermal injury has been reported (Ref. 81).

Recently, in a controlled study, 220 mg zinc sulfate given three times daily improved joint pain and stiffness in a group of patients with rheumatoid arthritis (Ref. 21). This promising observation requires confirmation with further attention to the zinc status of patients and the long-term effects of therapy.

Use of zinc in the management of conditions such as acrodermatitis enteropathica, sickle cell disease, and rheumatoid arthritis requires the direct supervision of a physician. Zinc is therefore not appropriate for OTC use.

e. *Conclusion.* The Panel has reviewed the scientific literature, the submitted data, and the marketing history of vitamin and mineral ingredients. Based on the available data, the Panel concludes that zinc sulfate, in the dosage identified under Category I conditions below, is the only acceptable source of elemental zinc which is safe and effective for the prevention of zinc deficiency when the need for such therapy has been determined by a physician.

f. *Category I conditions under which zinc is generally recognized as safe and effective and is not misbranded.* The Panel recommends that the Category I conditions be effective 30 days after the date of publication of the final monograph in the FEDERAL REGISTER.

Zinc sulfate is the only zinc source which may be used as a Category I source of zinc. Dosage must be based on elemental zinc (Zn, molecular weight 65.4).

(1) *Dosage—For prevention of deficiency.* For adults and children 1 year of age and older, the oral dosage is 10 to 25 mg daily. For pregnant and lactating women, the oral dosage is 25 mg daily. For children under 1 year of age, the Panel recommends the advice and supervision of a physician.

(2) *Labeling.* The Panel recommends the following Category I labeling:

Indication—For prevention of deficiency. "For use in the prevention of zinc deficiency when the need for such therapy has been determined by a physician."

g. *Category II conditions under which zinc is not generally recognized as safe and effective or is misbranded.* The Panel recommends that the Category II conditions be eliminated from OTC zinc drug products effective 6 months after the date of publication of the final monograph in the FEDERAL REGISTER.

The Panel concludes that the effectiveness of zinc hydroxide, zinc oxalate, zinc phytate, and zinc sulfide is not supported by the scientific evidence because absorption of these salts is not substantiated. Zinc depletion associated with sickle cell anemia, acrodermatitis enteropathica, celiac disease, and other gastrointestinal disorders should be diagnosed and managed directly under a physician's continuing care, and OTC zinc preparations for those purposes are not safe and appropriate. Similarly, self-medication with zinc for leg ulcers or rheumatoid arthritis should not be attempted, despite preliminary reports suggesting that zinc may be useful in treating those conditions. Leg ulcers and rheumatoid arthritis require diagnosis and management by a physician, not OTC management.

h. *Category III conditions for which the available data are insufficient to permit final classification at this time.* The Panel recommends that a period of 2 years be permitted for the completion of studies to support the movement of Category III conditions to Category I.

There are insufficient data to establish the safety or effectiveness of zinc carbonate, zinc chloride, zinc gluconate, zinc lactate, and zinc oxide.

Data to demonstrate bioavailability or isotope absorption tests are required to show serum zinc elevation greater than 80 percent of that of zinc sulfate as a single ingredient and when combined with vitamins and minerals.

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The Food and Drug Administratin has determined that this document does not contain an agency action covered by 21 CFR 25.1(b) and consideration by the agency of the need for preparing an environmental impact statement is not required.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201, 502, 505, 701, 52 Stat. 1040-1042 as amended, 1050-1053 as amended, 1055-1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 321, 352, 355, 371)), and the Administrative Procedure Act (secs. 4, 5, and 10, 60 Stat. 238 and 243 as amended (5 U.S.C. 553, 554, 702, 703, 704)), and under authority delegated to him (21 CFR 5.1), the Commissioner proposes that Subchapter D of Chapter I of Title 21 of the Code of Federal Regulations be amended by adding new Part 345, to read as follows:

PART 345—VITAMIN AND MINERAL DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

Subpart A—General Provisions

Sec.
345.1 Scope.
345.3 Definitions.

Subpart B—Active Ingredients

345.10 Vitamins.
345.12 Minerals.
345.20 Permitted combinations of active ingredients.

Subpart C—[Reserved]

Subpart D—Labeling

345.50 Labeling of vitamin drug products.
345.70 Labeling of mineral drug products.
345.78 Labeling of permitted combinations of active ingredients.
345.80 Professional labeling.

AUTHORITY: Secs. 201, 502, 505, 701, 52 Stat. 1040-1042 as amended, 1050-1053 as amended, 1055-1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 321, 352, 355, 371); (5 U.S.C. 553, 554, 702, 703, 704).

Subpart A—General Provisions

§ 345.1 Scope.

An over-the-counter vitamin and mineral drug product in a form suitable for oral administration is generally recognized as safe and effective and is not misbranded if it meets each of the conditions in this Part 345 in addition to each of the general conditions established in § 330.1 of this chapter.

§ 345.3 Definitions.

(a) *Vitamin drug.* An agent which is essential in small amounts for the maintenance of normal metabolic functions but is not synthesized within the body and, therefore, must be furnished from exogenous sources and that is labeled for use in the prevention or treatment of a deficiency when the need for such therapy has been determined by a physican.

(b) *Mineral Drug.* An agent, or its salts, which is noncombustible and inorganic and remains in the "ash" after combustion of natural materials at a high temperature and that is labeled for use in the prevention or treatment of a deficiency when the need for such therapy has been determined by a physican.

Subpart B—Active Ingredients

§ 345.10 Vitamin active ingredients.

The active ingredients of the product consist on one or more of the following when used within the dosage for each ingredient identified in § 345.50(d):

(a) *Vitamin C.* Acceptable sources of vitamin C activity are ascorbic acid, ascorbyl palmitate, calcium ascorbate, niacinamide ascorbate (for use only in combinations requiring both niacin and vitamin C), and sodium ascorbate: *Provided,* That the dosage identified in § 345.50(d)(1) or (2) is based on the *L*-ascorbic acid equivalent ($C_6H_8O_6$, molecular weight 176.2).

(b) *Vitamin B-12.* Cyanocobalamin is only acceptable source of vitamin B-12 activity: *Provided,* That the dosage identified in § 345.50(d)(3) is based on the cyanocobalamin equivalent ($C_{63}H_{88}CoN_{14}O_{14}P$, molecular weight 1355.4).

(c) *Folacin.* Folic acid is the only acceptable source of folacin activity: *Provided,* That the dosage identified in § 345.50(d)(4) is based on the pteroyl mono-*L*-glutamic acid equivalent ($C_{19}H_{19}N_7O_6$, molecular weight 441.4).

(d) *Niacin.* Accpetable sources of niacin activity are niacinamide and niacinamide ascorbate: *Provided,* That the dosage identified in § 345.50(d)(5) or (6) is based on the niacinamide equivalent ($C_6H_6N_2O$, molecular weight 122.1).

(e) *Pantothenic acid.* Accpetable sources of pantothenic acid activity are calcium pantothenate, dexpanthenol, and panthenol: *Provided,* That the dosage identified in § 345.50(d)(7) is based on the *D*-pantothenic acid equivalent ($C_9H_{17}NO_5$, molecular weight 219.2): *And provided,* That pantothenic acid is not used as a single active ingredient drug product but may be used only in combinations identified in § 345.20(a)(1), (2), (3), (4), (5), (6), (7), (b)(1), (2), and (3).

(f) *Vitamin B-6.* Pyridoxine hydrochloride is the only acceptable source of vitamin B-6 activity: *Provided,* That the dosage identified in § 345.50(d)(8) or (9) is based on the pyridoxine hyrochloride equivalent ($C_8H_{12}ClNO_3$, molecular 205.6).

(g) *Riboflavin.* Acceptable sources of riboflavin activity are riboflavin and riboflavin-5-phosphate sodium: *Provided,* That the dosage identified in § 345.50(d)(10) or (11) is based on the riboflavin equivalent ($C_{17}H_{20}N_4O_6$, molecular weight 376.4).

(h) *Thiamine.* Acceptable sources of thiamine activity are thiamine hydrochloride and thiamine mononitrate: *Provided,* That the dosage identified in § 345.50(d)(12) or (13) is based on the thiamine chloride hydrochloride equivalent ($C_{12}H_{17}ClN_4OS.HCl$, molecular weight 337.3).

(i) *Vitamin A.* Acceptable sources of vitamin A activity are vitamin A, vitamin A acetate, and vitamin A palmitate: *Provided,* That the dosage identified in §345.50(d)(14) or (15) is based on the retinol equivalent expressed in international units ($C_{20}H_{30}O$, molecular weight 286.4 and 0.3 microgram retinol is equivalent to 1.0 international unit).

(j) *Vitamin D.* Acceptable sources of vitamin D activity are cholecalciferol and ergocalciferol: *Provided,* That the dosage identified in § 345.50(d)(16) is based on either the cholecalciferol equivalent ($C_{27}H_{44}O$, molecular weight 384.6) expressed in international units or the ergocalciferol equivalent ($C_{28}H_{44}O$, molecular weight 396.6) expressed in international units (0.025 microgram vitamin D is equivalent to 1.0 international unit).

(k) *Vitamin E.* Acceptable sources of vitamin E activity are tocophersolan, alpha-tocopheryl acetate, alpha-tocopheryl acid succinate, and vitamin E: *Provided,* That the dosage identified in § 345.50(d)(17) is based on the *dl*-alpha-tocopheryl acetate equivalent expressed in international units ($C_{31}H_{52}O_3$, molecular weight 472.7 and 1 milligram *dl*-alpha-tocopheryl acetate is equivalent to 1.0 international unit): *And provided,* That vitamin E is not used as a single active ingredient drug product but may be used only in combinations identified in § 345.20(a)(1), (5), (6), (7), and (b)(1).

§ 345.12 Minerals.

The active ingredients of the product consist of one or more of the following when used within the dosage for each ingredient identified in § 345.70(d):

(a) *Calcium.* Acceptable sources of calcium are calcium caseinate, calcium citrate, calcium glubionate, calcium gluconate, calcium lactate, calcium phospahte dibasic, calcium sulfate, and precipitated calcium carbonate: *Provided* That the dosage identified in § 345.70(d)(1) is based on elemental calcium (Ca, molecular weight 40.1).

(b) *Iron.* Acceptable sources of iron are ferroglycine sulfate; ferrous fumarate; ferrous glutamate; ferrous gluconate; ferrous succinate; and ferrous lactate; and ferrous sulfate, dried: *Provided,* That the dosage identified in § 345.70(d)(2) is based on elemental iron (Fe molecular weight 55.8). The iron content of a product must be labeled in terms of elemental iron.

(c) *Zinc.* Zinc sulfate is the only acceptable source of zinc: *Provided,* That the dosage identified in § 345.70(d)(3) is based on elemental zinc (Zn, molecular weight 65.4).

§ 345.20 Permitted combinations of active ingredients.

The combination product may consist of any of the following:

(a) *Combinations for prevention of deficiency.* (1) All Category I vitamin ingredients identified in § 345.10 may be combined within the recommended dosage ranges for the prevention of deficiency identified in § 345.50(d). This combination may additionally contain pantothenic acid identified in § 345.10(e) within the dosage range identified in § 345.50(d)(7) and/or vitamin E identified in § 345.10(k) within the dosage identified in § 345.50(d)(17).

(2) All Category I B-vitamin ingredients identified in § 345.10 (b), (c), (d), (f), (g), and (h) may be combined within the recommended dosage ranges for the prevention of deficiency identified in § 345.50(d). This combination may additionally contain pantothenic acid identified in § 345.10(e) within the dosage range identified in § 345.50(d)(7).

(3) All Category I B-vitamin ingredients identified in § 345.10 (b), (c), (d), (f), (g), and (h) may be combined with vitamin C identified in § 345.10(a) all within the recommended dosage ranges for the prevention of deficiency identified in § 345.50(d). This combination may additionally contain pantothenic acid identified in § 345.10(e) within the dosage range identified in § 345.50(d)(7).

(4) Any combination identified in subparagraphs (1), (2), or (3) of this paragraph may be combined with iron identified in § 345.12(b) within the dosage range for prevention of deficiency identified in § 345.70(d)(2): *Provided*, That the combination is labeled for the prevention of vitamin and iron deficiencies.

(5) Any combination identified in subparagraph (1) of this paragraph may be combined with zinc identified in § 345.12(c) within the dosage range identified in § 345.70(d)(3). This combination may additionally contain iron identified in § 345.12(b) within the dosage range identified in § 345.70(d)(2) and/or calcium identified in § 345.12(a) within the dosage range identified in § 345.70(d)(1): *Provided*, That the combination is labeled for the prevention of vitamin and zinc (iron and/or calcium) deficiencies.

(6) Any combination identified in subparagraph (1) of this paragraph may be combined with calcium identified in § 345.12(a) within the dosage range identified in § 345.70(d)(1). This combination may additionally contain iron identified in § 345.12(b) within the dossage level identified in § 345.70(d)(2) and/or zinc identified in § 345.12(c) within the dosage range identified in § 345.70(d)(3): *Provided*, That the combination is labeled for the prevention of vitamin and calcium (iron and/or zinc) deficiencies.

(7) All Category I vitamin ingredients identified in § 345.10 may be combined with zinc identified in § 345.12(c) for prevention of deficiency in persons who use alcohol to excess, provided all ingredients are present at dosage levels for treatment of deficiency identified in § 345.50(d) or at the maximum dosage level for prevention of deficiency identified in § 345.50(d) or § 345.70(d) when dosage levels for treatment of deficiency have not been specified. This combination may additionally contain pantothenic acid identified in § 345.10(e) within the dosage range identified in § 345.50(d)(7) and/or vitamin E identified in § 345.10(k) within the dosage identified in § 345.50(d)(17).

(8) Any combination for prevention of deficiency in pregnant women is permitted: *Provided*, That all Category I vitamin ingredients identified in § 345.10 are combined with iron identified in § 345.12(b): *And provided*, that all ingredients are present within the dosage range for prevention of deficiency in pregnant women identified in § 345.50(d), or within the prevention dosage range if no pregnancy dosage range has been specified. This combination may additionally contain zinc identified in § 345.12(c) and/or calcium identified in § 345.12(a) within the dosage range for prevention of deficiency in pregnant women identified in § 345.70(d), or within the prevention dosage range if no pregnancy dosage range has been specified.

(b) *Combinations for the treatment of deficiency.* (1) All Category I vitamin ingredients identified in § 345.10 (a), (d), (f), (g), (h), and (i) within the dosage ranges identified in § 345.50(d) for the treatment of deficiency may be combined with all Category I vitamin ingredients identified in § 345.10 (b), (c) and (j) which have no established dosage range for the treatment of deficiency: *Provided*, That these ingredients are present at the maximum dosage level identified in § 345.50(d) for the prevention of deficiency. This combination may additionally contain pantothenic acid identified in § 345.10(e) within the dosage range identified in § 345.50(d)(7) and/or vitamin E identified in § 345.10(k) within the dosage range identified in § 345.50(d)(17) and provided that the combination is labeled for the treatment of deficiency.

(2) All Category I B-vitamin ingredients identified in § 345.10 (d), (f), (g), and (h) within the dosage ranges identified in § 345.50(d) for the treatment of deficiency may be combined with all Category I B-vitamin ingredients identified in § 345.10 (b) and (c) which have no established dosage range for the treatment of deficiency: *Provided*, That these ingredients are present at the maximum dosage level identified in § 345.50(d) for the prevention of deficiency. This combination may additionally contain pantothenic acid identified in § 345.10(e) within the dosage range identified in § 345.50(d)(7): *Provided*, That the combination is labeled for the treatment of deficiency.

(3) All Category I B-vitamin ingredients identified in § 345.10 (d), (f), (g), and (h) within the recommended dosage ranges identified in § 345.50(d) for the treatment of deficiency may be combined with vitamin C identified in § 345.10(a) within the dosage range identified in § 345.50(d)(2) and with all Category I B-vitamin ingredients identified in § 345.10 (b) and (c) which have no established dosage range for the treatment of deficiency: *Provided*, That these ingredients are present at the maximum dosage level identified in § 345.50(d) for the prevention of the deficiency. This combination may additionally contain pantothenic acid identified in § 345.10(e) within the dosage range identified in § 345.50(d)(7): *Provided*, That the combination is labeled for the treatment of deficiency.

Subpart C—[Reserved]

Subpart D—Labeling

§ 345.50 Labeling of vitamin drug products.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as a "vitamin."

(b) *Indications.* The labeling of the product contains a statement of the indications under the heading "Indications" that is limited to one or more of the following phrases:

(1) *For products containing vitamin C identified in § 345.50(d)(1) for prevention of deficiency.* "For use in the prevention of vitamin C deficiency when the need for such therapy has been determined by a physician."

(2) *For products containing vitamin C identified in § 345.50(d)(2) for treatment of deficiency.* "For use in the treatment of vitamin C deficiency when the need for such therapy has been determined by a physician."

(3) *For products containing vitamin B–12 identified in § 345.50(d)(3) for prevention of dietary deficiency.* "For use in the prevention of vitamin B–12 dietary deficiency when the need for such therapy has been determined by a physician."

(4) *For products containing folacin identified in § 345.50(d)(4) for prevention of deficiency.* "For use in the prevention of folic acid deficiency when the need for such therapy has been determined by a physician."

(5) *For products containing niacin identified in § 345.50(d)(5) for prevention of deficiency.* "For use in the prevention of niacin deficiency when the need for such therapy has been determined by a physician."

(6) *For products containing niacin identified in § 345.50(d)(6) for treatment of deficiency.* "For use in the treatment of niacin deficiency when the need for such therapy has been determined by a physician."

(7) *For products containing vitamin B–6 identified in § 345.50(d)(8) for prevention of deficiency.* "For use in the prevention of vitamin B–6 deficiency when the need for such therapy has been determined by a physician."

(8) *For products containing vitamin B-6 identified in § 345.50(d)(9) for treatment of deficiency.* "For use in the treatment of vitamin B-6 deficiency when the need for such therapy has been determined by a physician."

(9) *For products containing riboflavin identified in § 345.50(d)(10) for prevention of deficiency.* "For use in the prevention of riboflavin deficiency when the need for such therapy has been determined by a physician."

(10) *For products containing riboflavin identified in § 345.50(d)(11) for treatment of deficiency.* "For use in the treatment of riboflavin deficiency when the need for such therapy has been determined by a physician."

(11) *For products containing thiamine in § 345.50(d)(12) for prevention of deficiency.* "For use in the prevention of thiamine deficiency when the need for such therapy has been determined by a physician."

(12) *For products containing thiamine identified in § 345.50(d)(13) for treatment of deficiency.* "For use in the treatment of thiamine deficiency when the need for such therapy has been determined by a physician."

(13) *For products containing vitamin A identified in § 345.50(d)(14) for prevention of deficiency.* "For use in the prevention of vitamin A deficiency when the need for such therapy has been determined by a physician."

(14) *For products containing vitamin A identified in § 345.50(d)(15) for treatment of deficiency.* "For use in the treatment of vitamin A deficiency when the need for such therapy has been determined by a physician."

(15) *For products containing vitamin D identified in § 345.50(d)(16) for prevention of deficiency.* "For use in the prevention of vitamin D deficiency when the need for such therapy has been determined by a physician."

(c) *Warnings.* The labeling of the product contains the following warnings under the heading "Warnings":

(1) *For products containing vitamin C identified in § 345.50(d)(1) and (2)—(i) For products containing 0.2 meq (5 mg) or higher of sodium per unit of dose.* The sodium content must be stated per dosage unit (e.g., tablet, teaspoonful) when some or all of the source of vitamin C is sodium ascorbate if the sodium content is 0.2 meq (5 mg) or higher.

(ii) *For products containing more than 5 meq (125 mg) sodium per unit of dose.* "Do not take this product if you are on a sodium-restricted diet except under the advice and supervision of a physician."

(iii) *For products containing vitamin C identified in § 345.50(d)(2) for the treatment of deficiency.* (*a*) "Patients with gout and/or a tendency to form kidney stones may be at increased risk when taking more than the recommended dose.'

(*d*) "Diabetics taking more than 500 milligrams vitamin C daily may obtain false readings in their urinary glucose test."

(2) *For products containing vitamin B-12 identified in § 345.50(d)(3) as the only active ingredient. "Caution:* This preparation is for the prevention of vitamin B-12 dietary deficiency and cannot be safely used for the treatment of vitamin B-12 dietary deficiency."

(3) *For combination products for the prevention or treatment of multiple deficiencies which contain a prevention dose of vitamin B-12 identified in § 345.50(d)(3).* "This product cannot be safely used for the treatment of vitamin B-12 deficiency."

(4) *For products containing 1 milligram folacin per unit of dose identified in § 345.50(d)(4)*—(i) *"Caution:* The use of folic acid for treatment of anemia without the direction of a physician may be dangerous."

(ii) "Do not exceed the recommended daily dosage."

(5) *For combination products for the prevention or treatment of multiple deficiencies which contain a prevention dose of 1 milligram folacin per unit of dose identified in § 345.50(d)(4).* "This product cannot be safely used for the treatment of folic acid deficiency."

(6) *For products containing vitamin B-6 identified in § 345.50(d)(8) and (9). "Caution:* Do not take this product if you have Parkinsonism and are currently taking l-dopa except under the advice and supervision of a physician."

(7) *For products containing riboflavin identified in § 345.50(d)(11).* "Do not exceed the recommended dosage except under the advice and supervision of a physician."

(8) *For products containing vitamin A identified in § 345.50(d)(15). "Do not exceed the recommended dosage except under the advice and supervision of a physician. Excessive dosages may cause harm."*

(9) *For products containing vitamin D identified in § 345.50(d)(16).* "Do not take this product if you have a history of kidney stones except under the advice and supervision of a physician."

(d) *Directions.* The labeling of the product contains the following statements under the heading "Directions" followed by "or as directed by a physician":

(1) *For products containing vitamin C identified in § 345.10(a) for prevention of deficiency.* For adults and children 1 year of age and older, the oral dosage is 50 to 100 milligrams daily. For children under 1 year of age, there is no recommended dosage except under the advice and supervision of a physician.

(2) *For products containing vitamin C identified in § 345.10(a) for treatment of deficiency.* For adults and children 1 year of age and older, the oral dosage is 300 to 500 milligram daily. For children under 1 year of age, there is no recommended dosage except under the advice and supervision of a physician.

(3) *For products containing vitamin B-12 identified in § 345.10(b) for prevention of dietary deficiency.* For adults and children 1 year of age and older, the oral dosage is 3 to 10 micrograms daily. For children under 1 year of age, there is no recommended dosage except under the advice and supervision of a physician.

(4) *For products containing folacin identified in § 345.10(c) for prevention of deficiency.* For adults and children 1 year of age and older, the oral dosage is 0.1 to 0.4 milligram daily. For pregnant and lactating women, the oral dosage is 1.0 milligram daily. For those persons who use alcohol to excess, the oral dosage is 1.0 milligram daily. For children under 1 year of age, there is no recommended dosage except under the advice and supervision of a physician.

(5) *For products containing niacin identified in § 345.10(d) for prevention of deficiency.* For adults and children 1 year of age and older, the oral dosage is 10 to 20 milligrams daily. For children under 1 year of age, there is no recommended dosage except under the advice and supervision of a physician.

(6) *For products containing niacin identified in § 345.10(d) for treatment of deficiency.* For adults and children 1 year of age and older, the oral dosage is 25 to 50 milligrams daily. For children under 1 year of age, there is no recommended dosage except under the advice and supervision of a physician.

(7) *For products containing pantothenic acid identified in § 345.10(e) provided that pantothenic acid is not used as a single ingredient product but may be used in combinations identified in § 345.20(a)(1), (2), (3), (4), (5), (6), (7), (b)(1), (2), and (3):* For adults and children 1 year of age and older, the oral dosage is 5 to 20 milligrams daily. For children under 1 year of age, there is no recommended dosage except under the advice and supervision of a physician.

(8) *For products containing vitamin B-6 identified in § 345.10(f) for the prevention of deficiency.* For adults and children 1 year of age and older, the oral dosage is 1.5 to 2.5 milligrams daily. For children under 1 year of age, there is no recommended dosage except under the advice and supervision of a physician.

(9) *For products containing vitamin B-6 identified in § 345.10(f) for the*

treatment of deficiency. For adults and children 1 year of age and older, the oral dosage is 7.5 to 25 milligrams daily. For children under 1 year of age, there is no recommended dosage except under the advice and supervision of a physician.

(10) *For products containing riboflavin identified in § 345.10(g) for the prevention of deficiency.* For adults and children 1 year of age and older, the oral dosage is 1 to 2 milligrams daily. For children under 1 year of age, there is no recommended dosage except under the advice and supervision of a physician.

(11) *For products containing riboflavin identified in § 345.10(g) for the treatment of deficiency.* For adults and children 1 year of age and older, the oral dosage is 5 to 25 milligrams daily. For children under 1 year of age, there is no recommended dosage except under the advice and supervision of a physician.

(12) *For products containing thiamine identified in § 345.10(h) for the prevention of deficiency.* For adults and children 1 year of age and older, the oral dosage is 1 to 2 milligrams daily. For children under 1 year of age, there is no recommended dosage except under the advice and supervision of a physician.

(13) *For products containing thiamine identified in § 345.10(h) for the treatment of deficiency.* For adults and children 1 year of age and older, the oral dosage is 5 to 25 milligrams daily. For children under 1 year of age, there is no recommended dosage except under the advice and supervision of a physician.

(14) *For products containing vitamin A identified in § 345.10(i) for the prevention of deficiency.* For adults and children 1 year of age and older, the oral dosage is 1,250 to 2,500 international units daily. For children under 1 year of age, there is no recommended dosage except under the advice and supervision of a physician.

(15) *For products containing vitamin A identified in § 345.10(i) for the treatment of deficiency.* For adults and children 1 year of age and older, the oral dosage is 5,000 to 10,000 international units daily. For children under 1 year of age, there is no recommended dosage except under the advice and supervision of a physician.

(16) *For products containing vitamin D identified in § 345.10(j) for the prevention of deficiency.* For children under 18 years of age, the oral dosage is 400 international units daily. For adults 18 years of age and older, the oral dosage is 200 international units daily.

(17) *For products containing vitamin E identified in § 345.10(k), provided that vitamin E is not used as a single ingredient but may be used in combinations identified in § 345.20(a)(1), (5), (6), (7), and (b)(1).* For adults and children 1 year of age and older, the oral dosage is 30 international units daily. For children under 1 year of age, there is no recommended dosage except under the advice and supervision of a physician.

§ 345.70 Labeling of mineral drug products.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as a "mineral."

(b) *Indications.* The labeling of the product contains a statement of the indications under the heading "Indications" that is limited to one or more of the following phrases:

(1) *For products containing calcium identified in § 345.12(a).* "For use in the prevention of calcium deficiency when the need for such therapy has been determined by a physician."

(2) *For products containing iron identified in § 345.12(b).* "For use in the prevention of iron deficiency when the need for such therapy has been determined by a physician."

(3) *For products containing zinc identified in § 345.12(c).* "For use in the prevention of zinc deficiency when the need for such therapy has been determined by a physician."

(c) *Warnings.* The labeling of the product contains the following warnings under the heading "Warnings":

For products containing iron identified in § 345.12(b). "Caution: The treatment of any anemic condition should be under the advice and supervision of a physician."

(d) *Directions.* The labeling of the product contains the following statements under the heading "Directions" followed by "or as directed by a physician":

(1) *For products containing calcium identified in § 345.12(a) for prevention of deficiency.* For adults, children 1 to under 10 years of age, and children 12 years of age and older, the oral dosage is 400 to 800 milligrams daily. For preadolescent and pubescent children 10 to under 12 years of age and for pregnant and lactating women, the oral dosage is 600 to 1,200 milligrams daily. For elderly adults over 51 years of age, the oral dosage is 500 to 1,000 milligrams daily. For infnats 6 months to under 1 year of age, the oral dosage is 300 to 600 milligrams daily. For infants under 6 months of age, the oral dosage is 200 to 400 milligrams daily.

(2) *For products containing iron identified in § 345.12(b) for prevention of deficiency.* For menstruating and lactating women, the oral dosage is 10 to 30 milligrams daily. For pregnant women, the oral dosage is 30 to 60 milligrams daily. For children 6 months to under 5 years of age, the oral dosage is 10 to 15 milligrams daily. For infants under 6 months of age, there is no recommended dosage except under the advice and supervision of a physician. For combination products other than for use in pregnancy, the oral dosage for adults and children 5 years of age and older, is 10 to 20 milligrams daily.

(3) *For products containing zinc identified in § 345.12(c) for prevention of deficiency.* For adults and children 1 year of age and older, the oral dosage is 10 to 25 milligrams daily. For pregnant and lactating women, the oral dosage is 25 milligrams daily. For children under 1 year of age, there is no recommended dosage except under the advice and supervision of a physician.

§ 345.78 Labeling of permitted combinations of active ingredients.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any and identifies the product as either a "multiple vitamin" or a "multiple vitamin with minerals."

(b) *Indications.* The labeling of the product contains a statement of the indications under the heading "Indications" that is limited to one or more of the following phrases:

(1) *For combinations containing only vitamins identified in § 345.20(a)(1), (2), and (3) for prevention of deficiency.* "For the prevention of deficiencies of vitamins named on the label when the need for such therapy has been determined by a physician."

(2) *For combinations containing vitamins and minerals identified in § 345.20(a)(4), (5), and (6) for prevention of deficiency.* "For the prevention of deficiencies of vitamins and minerals named on the label when the need for such therapy has been determined by a physican."

(3) *For combinations identified in § 345.20(a)(7) for prevention of deficiency.* "Useful as an aid in the prevention of deficiency of vitamins named on the label and zinc in persons using alcohol to excess when the need for such therapy has been determined by a physican."

(4) *For combinations identified in § 345.20(a)(8) for prevention of deficiency.* "For the prevention of deficiencies of vitamins named on the label and iron in pregnant women when the need for such therapy has been determined by a physican."

(5) *For combinations containing only vitamins identified in § 345.20(b)(1), (2), and (3) for treatment of deficiency.* "For the treatment of deficiencies of vitamins named on the label when the need for such therapy has been determined by a physician."

§ 345.80 Professional labeling.

The lebeling of the product provided to health professionals contains the following information:

(a) *For products containing vitamin C identified in § 345.10(a).* (1) "When diabetics ingest large quantities (greater than 500 milligrams daily) of vitamin C, the following false results may occur when testing for glycosuria: (i) false-negatives for glucose oxidase enzyme strip-tests and (ii) false-positives for tests based on copper reduction."

(2) "The ingestion of daily doses of 1,000 milligrams or more vitamin C may result in harmful effects due to hyperoxaluria and to increased urinary acidity and uric acid excretion; oxalate and uric acid crystalization may occur in the kidney or bladder, especially in patients prone to renal stone formation. Additional risk factors include consumption of foods containing high levels or exalate, and small intestinal disease states, e.g., resectioning, evidencing increased urinary oxalate. Persons consuming these excessive amounts of vitamin C should be under a physican's supervision."

(3) "No exogenous vitamin C should be ingested for 48 to 72 hours prior to conducting amine-dependent stool occult blood tests, to prevent a false-negative test resulting from a high fecal excretion of ascorbic acid."

(b) *For products containing vitamin B-6 identified in § 345.10(f).* "Increased pytidoxine hyrochloride doses are required in vitamin B-6 dependency syndromes (pytidoxine-responsive-anemia, seizures, familial xanthurenic aciduria, cystationiuria). Supplemental levels of pyridoxine hydrochlordie are required when patients take (during receipt of) drugs or chemicals which bind and inactivate pyridoxine hydrochloride (isonicotinic acid hydrazide, cycloserine, hydralazine, penicillamine, and semicarbazide)."

(c) *For products containing riboflavin identified in § 345.10(g).* "Certain individuals may require increased levels of reboflavin, such as individuals with biliary obstruction, individuals or oral contraceptives, and individuals consuming large quanities of alcohol."

Interested persons are invited to submit their comments in writing (preferably in quadruplicate and identified with the Hearing Clerk docket number found in brackets in the heading of this document) regarding this proposal on or before June 14, 1979. Such comments should be addressed to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, and may be accompanied by a memorandum or brief in support thereof. Additional comments replying to any comments so filed may also be submitted on or before July 16, 1979. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

In accordance with Executive Order 12044, the economic effects of this proposal have been carefully analyzed, and it had been determined that the proposed rulemaking does not involve major economic consequences as defined by that order. A copy of the regulatory analysis assessment supporting this determination is on file with the Hearing Clerk, Food and Drug Administration.

Dated: March 1, 1979.

SHERWIN GARDNER,
Acting Commissioner of Food and Drugs.

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federal register

FRIDAY, MARCH 16, 1979

PART III



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

■

ACIDIFIED FOODS AND LOW-ACID CANNED FOODS IN HERMETICALLY SEALED CONTAINERS

Emergency Permit Control and Current Good Manufacturing Practice

[4110-03-M]

Title 21—Food and Drugs

CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

SUBCHAPTER B—FOOD FOR HUMAN CONSUMPTION

[Docket No. 75N-0332]

PART 108—EMERGENCY PERMIT CONTROL

Acidified Foods

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This document prescribes the specific enforcement provisions for exemption from, or compliance with, the emergency permit control system of the Federal Food, Drug, and Cosmetic Act for the production of acidified foods. The primary public health problem with these foods is the possible formation of botulinal toxin, and this regulation will ensure safe manufacturing, processing, and packing procedures.

DATES: Effective May 15, 1979, except for: (1) § 108.25(c)(1) (21 CFR 108.25(c)(1)), concerning registration, which is effective July 16, 1979; (2) § 108.25(c)(2), concerning process filing, which is effective 60 days after registration and before packing any new product; and (3) § 108.25(f), concerning personnel training, which is effective September 16, 1980. Objections by April 16, 1979.

ADDRESS: Written objections to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Melvin R. Johnston, Bureau of Foods (HFF-414), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C St. SW., Washington, DC 20204, 202-245-1514.

SUPPLEMENTARY INFORMATION: In the FEDERAL REGISTER of July 23, 1976 (41 FR 30442), the Commissioner of Food and Drugs proposed to establish a new regulation (21 CFR 90.22 before the recodification published in the FEDERAL REGISTER of March 15, 1977 (42 FR 14302)) subjecting pickled, fermented, and acidified foods to regulation under section 404, the emergency permit control provisions of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 344). The proposal set forth requirements intended to ensure safe manufacturing, processing, and packing procedures for these foods and to permit the Food and Drug Administration (FDA) to verify that the procedures are being followed. Failure of any establishment to comply with the requirements would constitute a prima facie basis for immediate application of section 404 of the act to that establishment under the procedures established in Part 108 (21 CFR Part 108 (formerly 21 CFR Part 90)), Subpart A.

The agency provided a period of 60 days for the filing of comments on the proposal. In response to a request by three trade associations and by the Spanish Ministry of Trade, the Commissioner further extended the comment period to November 20, 1976 (see the FEDERAL REGISTER of September 22, 1976 (41 FR 41436)). Elsewhere in the July 23, 1976 issue of the FEDERAL REGISTER, the Commissioner proposed to establish current good manufacturing practice regulations for preparing pickled, fermented, and acidified foods (41 FR 30457) and to revise the current good manufacturing regulations for low-acid canned foods (41 FR 30444).

The National Canners Association (now the National Food Processors Association (NFPA)) filed extensive comments on the proposed revocation of the exemption from the definition of low-acid foods for tomatoes, pears, and pineapple having a pH of less than 4.7 and figs having a pH of 4.9 or below. After the comment period closed, NFPA requested that the comment period be reopened to allow that association to develop and submit data to determine the final pH of certain products and/or classes of products that it felt should be exempted from the regulation. The comment period was reopened until October 3, 1977, by notice published in the FEDERAL REGISTER of July 29, 1977 (42 FR 38608).

Nineteen letters, each containing one or more comments, were received from industry, trade associations, State and Federal government agencies, and members of Congress.

Eight of the comments pertain to the proposed revision of the good manufacturing practice regulations for thermally processed low-acid foods packaged in hermetically sealed containers (Part 113 (21 CFR Part 113)) and the proposed good manufacturing practice regulation for pickled, fermented, and acidified foods (Part 114 (21 CFR Part 114)). Those comments and the Commissioner's responses are found in the final orders on those proposals, published elsewhere in this issue of the FEDERAL REGISTER. The remaining comments, summarized, and the Commissioner's responses to them follow:

1. One comment questioned the inclusion of fermented foods in the regulation because, the comment noted, the agency gave no examples in which any proven improper fermentation procedure caused that kind of food to be a health hazard.

The Commissioner has reexamined the basis for the decision to include pickled and fermented foods within this order. No instances of illness as the result of contamination of commercially processed fermented foods with *Clostridium botulinum* have been reported in the United States. In addition, the Commissioner has contacted health authorities in Canada, Japan, the United Kingdom, and other members of the European Economic Community concerning this problem (the correspondence is on file in the office of the Hearing Clerk, FDA). No cases of botulism caused by commercially processed fermented foods have been reported in those countries. In the absence of known illnesses or deaths from commercially prepared fermented foods, the Commissioner has concluded that the regulation should apply only to acidified foods. Because pickled foods include those pickled by fermentation or by acidification, the Commissioner has dropped the word "pickled" from the title but advises that pickled foods prepared by acidification are considered acidified foods and are subject to this order. Moreover, in the event that illness due to commercially prepared fermented foods does occur, the Commissioner will reconsider this decision. The final regulation reflects this change.

The function of these regulations is to protect the public from the danger of botulism poisoning associated with acidified foods. Accordingly, the Commissioner considers it appropriate to consider precisely what foods are subject to this regulation. Among the principal factors that control the gowth of *C. botulinum* in food are pH, water activity, and storage conditions. As the Commissioner notes in the document in this issue of the FEDERAL REGISTER concerning current good manufacturing practice regulations for low-acid canned foods, *C. botulinum* will not grow in food that has a pH of 4.6 or below. Similarly, evidence shows that food with a water activity value that is 0.85 or below also will not permit *C. botulinum* to grow. This regulation and the current good manufacturing practice regulations for acidified foods, published elsewhere in this issue of the FEDERAL REGISTER, are intended to ensure that naturally low-acid foods, which use acidification as the means of protecting against *C. botulinum* growth, are properly acidified. Accordingly, all foods that are intended to be acidified to a finished equilibrium pH of 4.6 or below and

that have a water activity greater than 0.85 are subject to this regulation and the current good manufacturing practice regulations (21 CFR Part 114) which the Commissioner is also promulgating.

2. Four comments questioned the Commissioner's authority under section 404 of the act to impose emergency permit control restrictions for pickled, fermented, and acidified foods. One comment maintained that the Commissioner's authority to impose emergency permit control restrictions under section 404 is limited to situations in which a potential for contaminating a class of food with microorganisms is sufficiently great to warrant extraordinary processing restrictions as a preventive measure. The comment argued that pickled, fermented, and acidified foods are not such a class of foods.

A second comment stated that under section 404 of the act the Commissioner can impose emergency permit control upon a company or an industry only when the following conditions are met: (1) The Secretary (or delegate) has conducted an investigation of a class of food; (2) that investigation reveals an emergency situation, that is, a clear and present danger to the public health because that class of food is contaminated with microorganisms; (3) the danger cannot adequately be determined after the food has entered interstate commerce; and (4) the Secretary then, and in that case only, issues temporary regulations imposing emergency permit control on the affected industry. Therefore, the comment argued, the Commissioner can impose an emergency permit control only in rare instances of an emergency nature, only after investigation, only on a temporary basis, and only when other sections of the act are inadequate to protect the public. The comment also alleged that FDA has not conducted any investigation and is not faced with an emergency for which other sections of the act are inadequate to protect the public; to support this allegation, the comment pointed out that there have been no cases of botulism from commercially produced pickles.

Another comment contended that the adulteration and misbranding provisions of the act, and the regulations promulgated under those sections, are more than adequate to deal with the problems discussed in the proposal. Finally, one comment stated that the Commissioner does not have the authority under the act to require "(1) registration of food processing plants; (2) establishment and filing of 'scheduled processes'; (3) maintenance of records of equipment calibration and testing; (4) specific food manufacturing processes; (5) product coding; (6) maintenance of processing and production records; (7) setting aside and reworking certain batches of product; and (8) sending supervisory personnel to approved schools."

The Commissioner notes that this regulation brings acidified foods within the scope of the emergency permit control section of the act and the regulations. It establishes criteria that a manufacturer of those foods must satisfy to maintain an exemption from the factory permit requirement. The criteria are the same as those established for thermally processed low-acid canned foods in Part 108. Briefly, the regulation requires every commercial processor engaged in processing or packing acidified foods to (1) register and file its processing method with FDA; (2) process the foods in accordance with the filed process; (3) provide FDA with information to determine the adequacy of the processing; (4) report to FDA any spoilage, process deviations, or contamination that may have health significance, when any part of affected lots has reached the channels of interstate commerce; (5) develop for use by it and the distributors of its products a recall procedure that includes product coding and FDA notification; (6) prepare, retain, and review specific records and make them available to FDA upon written demand; and (7) operate only under the supervision of persons who have attended FDA-approved schools for appropriate food processing.

Arguments that the Commissioner lacks authority to regulate food in the manner described in Part 108 were raised and rejected when the Commissioner first established this procedure to regulate low-acid canned foods (see the FEDERAL REGISTER of May 14, 1973 (38 FR 12716) and January 29, 1974 (39 FR 3750)). To recapitulate, the Commissioner has reviewed the legislative history of the act and concludes that section 404 of the act gives the Commissioner the authority to establish the system set out in Part 108 for dealing with the threat of botulism in acidified foods. The act is remedial and should be construed in a manner consistent with its overriding public health protection function. The legislative history of the emergency permit control system shows that Congress intended to develop a regulatory scheme to protect the public from virulent foodborne diseases that cannot be controlled by routine inspection procedures. Botulism was the principal disease cited. Congress authorized a rulemaking procedure to enable FDA to develop the facts for determining whether a specific class of food should be subject to the emergency permit control system, unless that food is manufactured in accordance with the strict requirements which the agency can prescribe. Furthermore, the requirements can be more stringent than the current good manufacturing practices of the industry involved, and FDA can tailor current good manufacturing practice regulations for any specific industry that poses a problem.

On the basis of experience in regulating the low-acid canned food industry, the Commissioner concludes that the requirements set forth in this regulation are appropriate and necessary for (1) adequate monitoring of the acidification of food and (2) expeditious revocation of the exemption from the requirement for a temporary emergency permit to manufacture acidified foods. These two factors are necessary to protect the public from botulinal food poisoning. Based on the evidence adduced thus far, the Commissioner believes that there is every reason to subject acidified foods to the requirements of Part 108.

As comments noted, the term "pickled foods" encompasses both acidified and fermented foods. As discussed earlier in this preamble, the Commissioner has concluded that the regulation should be applicable only to acidified foods. In the preamble to the proposal, the Commissioner described two specific instances of botulinal food poisoning caused by commercially processed acidified foods in the United States, in which eight people became ill. Material on file concerning the other incidents described in the earlier preamble shows that the processors of pickled and acidified foods appear to lack an awareness of the importance of proper technical processing of these foods. Thus, numerous cases of botulism have occurred in commercially produced acidified foods, the class of foods defined in new Part 114 (21 CFR Part 114). Furthermore, since publication of the proposal there have been other reported outbreaks of botulinal poisoning attributable to improper acidification of commercially processed foods. The Oklahoma State epidemiologists and experts at the Center for Disease Control in Atlanta, Georgia, identified seven persons with clinical symptoms of botulism which was attributed to the consumption of commercially canned acidified sweet cherry peppers in a restaurant in Oklahoma in April 1976. The Food and Drug Administration agreed that the illnesses were caused by the canned cherry peppers, and it classified the recall of the incriminated product as a Class I recall. An outbreak of 45 cases of botulism was recorded as the result of consumption of improperly acidified and processed food in a restaurant in Michigan in 1977. As of October 27, 1977, a total of 29 foreign shippers had been identified as not controlling the pH of acidified low-acid canned foods. Therefore,

the Commissioner finds ample data to support the promulgation of this regulation as it concerns acidified canned foods. Copies of the pertinent data are on file with the Hearing Clerk, FDA.

3. One comment contended that the two botulism poisoning episodes associated with commercially prepared pickled and acidified foods mentioned in the preamble to the proposed regulation are clearly an insufficient basis for evoking the extraordinary powers of section 404 of the act. The comment further argued that the reported cases of botulism associated with pickled, home-canned products cited in the preamble are irrelevant to the proposed restrictions on commercial processing.

The Commissioner rejects the comment. The potential hazard due to botulism from pickled and acidified foods is just as great as, if not greater than, the hazard of botulism associated with low-acid canned foods. The deaths and other poisoning cases described in paragraph 2 of this preamble and in the preamble to the notice of proposed rulemaking are evidence to support the rule. In the Commissioner's opinion, the data on home-canned foods are relevant because they demonstrate a considerable potential for producing unsafe food if the producer fails to maintain proper critical factors.

4. One comment requested the Commissioner to delay implementing the proposed regulations until a public hearing is held.

The Commissioner advises that a hearing is inappropriate at this time. The regulation is being promulgated under section 701(e) of the act (21 U.S.C. 371(e)), under which interested parties have 30 days to file objections to the final order and supporting data under § 12.22 (21 CFR 12.22). The Commissioner will evaluate any objections and data received and will decide whether the objections raise genuine and substantial factual issues whose resolutions require a hearing. A hearing will be held and the regulation delayed only if legally adequate objections are filed.

5. One comment attacked the regulation as it applies to imported food. The comment argued that the regulation discriminates against imported food and foreign processors and favors domestic food and domestic processors. The comment also questioned whether section 801 of the act (21 U.S.C. 381) permits the Commissioner to prevent importation of food that fails to comply with section 404 of the act. The comment argued that, to the extent used to prevent importation of acidified food, the regulation constitutes a nontariff trade barrier that violates the General Agreement on Tariff and Trade, a problem exemplified by the requirement for registration and the process filing before importing.

The Commissioner disagrees. The comment shows a misunderstanding of the application of the regulation and section 801 of the act. First, the Commissioner has found a number of imported, commercially processed foods that have been improperly acidified. From April 1975 to October 1976, the Commissioner also identified 31 foreign processors that failed to control the pH of their products at levels sufficient to protect the public health. For these reasons, and for the reasons described in paragraph 1 of this preamble, the commissioner concludes that there are sufficient grounds for imposing the requirements of section 404 of the act on imported acidified foods. Therefore, all foreign and domestic processors of acidified foods shall register and file their scheduled processes with FDA before their foods can be imported to this country. Because the agency is applying the regulation uniformly to all acidified foods and processors of acidified foods, both foreign and domestic, the commissioner finds no basis for contending that the regulation constitutes a trade barrier.

When FDA determines, after investigation, that a domestic manufacturer, processor, or packer of an acidified food has not met or does not meet the mandates of this regulation or other provisions of Part 108, the agency may have to require that party to obtain and hold an emergency permit. In that case, FDA will issue an order to the manufacturer, processor or packer under § 108.5 (21 CFR 108.5), explaining that the party must hold a permit before it can introduce food, or deliver food for introduction, into interstate commerce. Until the agency issues a permit, the manufacturer, processor, or packer may not introduce, or deliver for introduction, into interstate commerce any such food manufactured, processed, or packed by it, except as provided by the rigid provisions of § 108.19 (21 CFR 108.19). Similary, when the Commissioner determines, after investigation, that the foreign processor of an imported acidified food, or the imported food itself, does not meet the requirements of this regulation or of new Part 114, the Commissioner will request the Secretary of the Treasury to refuse admission of that food into the United States, under section 801 of the act.

Acidified food that has been manufactured, processed, or packed under conditions that fail to comply with the requirements established by this regulation and by Part 114 has been processed under inadequate, i.e., insanitary conditions. Therefore, prohibiting the importation of this potentially adulterated and unsafe food is appropriate because the introduction or delivery for introduction of adulterated food or foods in violation of section 404 of the act is a prohibited act under section 301 of the act (21 U.S.C. 331). The Commissioner did not intend to discriminate against importers, and to make it clear that both domestic and foreign processors have the same time to register and file their processes with FDA before thay offer their products to consumers, the Commissioner has reworded § 108.25(c)(1) and (2) to give both domestic and foreign processors 120 days after the effective date of this regulation to register with FDA and 60 days after registration to file their processes. These requirements are the same for importers of low-acid canned foods.

6. One comment suggested that proposed § 108.25(c)(2)(i) be revised to permit processors to establish processes that exceed the safety requirements established under Part 114.

The Commissioner agrees and has so changed this provision, which is now § 108.25(c)(3)(i).

7. Two comments requested that § 108.25(f) be changed to exempt from further schooling all persons certified before March 16, 1979 as having attended a school approved by the Commissioner for giving instruction in retort operations, processing system operations, aseptic processing and packaging systems operations, and container closure inspections.

The Commissioner agrees and has reworded this provision to allow persons certified before the publication of this final regulation to be exempt from the schooling requirement. However, the Commissioner notes that a course including more details on acidification of foods is advisable for persons involved in the processing of such foods to ensure that they are knowledgeable in this process.

8. The State of California requested the Commissioner to rule that compliance with State regulations which California intends to promulgate on pickled, fermented, and acidified foods constitutes compliance with § 108.25.

The Commissioner cannot grant such a request until a State has promulgated, and the agency has reviewed, such regulations. But the Commissioner has added a new paragraph (i) to § 108.25 to enable California, or any other State that regulates the commercial processing of acidified foods, to promulgate regulations that coordinate with those of FDA. When the Commissioner finds that a State has promulgated effective regulations specifying at least the requirements of Part 114 for the regulation of the commercial processing of acidified foods, the agency will issue a notice stating that compliance with the State regula-

tions constitutes compliance with Part 114.

9. One comment requested that, if a processor has filed information with FDA on forms FD-2541, 2541a, 2541b, or 2541c as required under § 108.35 (for low-acid canned foods), there should be no need for that processor to submit new form FD-2962.

The Commissioner agrees and has substituted forms FD-2541 and 2541c for the proposed form FD-2962. Any processor that has registered its establishments on form FD-2541 and filed its processes on forms FD-2541a, b, or c, need not reregister or refile its processes. Processors must file new processes or changes in processes, however, on form FD-2541c.

10. Some comments questioned whether commercial processor that operate pilot plants, producing samples of acidified foods for market or consumer testing, need file their processes with FDA.

The Commissioner points out that foods produced in these plants must be processed in accordance with good manufacturing practices so that they do not present the potential public health hazard that this regulation is being promulgated to prevent. To protect the public adequately, the Commissioner concludes that pilot plant processes must be filed with FDA in the same manner as those for any other commercially prepared acidified food. An identical regulation (§ 108.35 (21 CFR 108.35)) applies to sampling and testing operations making low-acid canned foods.

11. One comment claimed that the added cost of the paperwork involved in this regulation would eliminate many small part-time producers in the United States. The comment further contended that the regulation would virtually eliminate all imports of specialty canned and bottled foods, thereby eliminating the jobs of small food importers.

The Commissioner doubts that this will be the case. Many of the products and processors, both domestic and imported, are currently subject to § 108.35 (21 CFR 108.35) for low-acid canned foods and have been for several years. In certain cases losses have occurred, but they did so because the producer did not have a safe product. The minimal cost of the paperwork is a small price to pay to ensure that food is safe for the American consumer.

Therefore, under the Federal Food, Drug, and Comestic Act (secs. 402, 404, 701(e), 52 Stat. 1046-1047 as amended, 1048, 70 Stat. 919 (21 U.S.C. 342, 344, 371(e))) and under authority delegated to the Commissioner (21 CFR 5.1), Chapter I of Title 21 is amended in Part 108 by adding to Subpart B a new § 108.25 as follows:

§ 108.25 Acidified foods.

(a) Inadequate or improper manufacture, processing, or packing of acidified foods may result in the distribution in interstate commerce of processed foods that may be injurious to health. The harmful nature of such foods cannot be adequately determined after these foods have entered into interstate commerce. The Commissioner of Food and Drugs therefore finds that, to protect the public health, it may be necessary to require any commericial processor, in any establishment engaged in the manufacture, processing, or packing of acidified foods, to obtain and hold a temporary emergency permit provided for under section 404 of the Federal Food, Drug, and Cosmetic Act. Such a permit may be required whenever the Commissioner finds, after investigation, that the commercial processor has failed to fulfill all the requirements of this section, including registration and filing of process information, and the mandatory portions of §§ 114.10, 114.80(a) (1) and (2), and (b), 114.83, 114.89, and 114.100 (b), (c), and (d) of this chapter as they relate to acidified foods. These requirements are intended to ensure safe manufacturing, processing, and packing processes and to permit the Food and Drug Administration to verify that these processes are being followed. Failure to meet these requirements shall constitute a prima facie basis for the immediate application of the emergency permit control provisions of section 404 of the act to that establishment, under the procedures established in Subpart A of this part.

(b) The definitions in § 114.3 of this chapter are applicable when those terms are used in this section.

(c) (1) *Registration.* A commercial processor, when first engaging in the manufacture, processing, or packing of acidified foods in any State, as defined in section 201(a)(1) of the act, shall, not later than 10 days after first so engaging, register and file with the Food and Drug Administration on Form FD-2541 (food canning establishment registration) information including, but not limited to, the name of the establishment, principal place of business, the location of each establishment in which that processing is carried on, the processing method in terms of acidity and pH control, and a list of foods so processed in each establishment. These forms are available from the Food and Drug Administration, Bureau of Foods, Industry Guidance Branch (HFF-342), 200 C St. SW., Washington, DC 20204, or at any Food and Drug Administration district office. The completed form shall be submitted to the Food and Drug Administration, Bureau of Foods, Industry Guidance Branch (HFF-342), 200 C St. SW., Washington, DC 20204. Commercial processors presently so engaged shall register within 120 days after the effective date of this regulation. Foreign processors shall register within 120 days after the effective date of this regulation or before any offering of foods for import into the United States, whichever is later. Commercial processors duly registered under this section shall notify the Food and Drug Administration not later than 90 days after the commercial processor ceases or discontinues the manufacture, processing, or packing of the foods in any establishment, except that this notification shall not be required for temporary cessations due to the seasonal character of an establishment's production or by temporary conditions including, but not limited to, labor disputes, fire, or acts of God.

(2) *Process filing.* A commercial processor engaged in the processing of acidified foods shall, not later than 60 days after registration, and before packing any new product, provide the Food and Drug Administration information on the scheduled processes including, as necessary, conditions for heat processing and control of pH, salt, sugar, and preservative levels and source and date of the establishment of the process, for each acidified food in each container size. Filing of this information does not constitute approval of the information by the Food and Drug Administration, and information concerning processes and other data so filed shall be regarded as trade secrets within the meaning of 21 U.S.C. 331(j) and 18 U.S.C. 1905. This information shall be submitted on form FD-2541c (food canning establishment and process filing for other than still retort and agitating processes). Forms are available from the Food and Drug Administration, Bureau of Foods, Industry Guidance Branch (HFF-342), 200 C St. SW., Washington, D.C. 20204, or at Food and Drug Administration district office. The completed form shall be submitted to the Food and Drug Administration, Bureau of Foods, Industry Guidance Branch (HFF-342), 200 C St. SW., Washington, D.C. 20204.

(3) *Process adherence and information*—(i) *Scheduling.* A commercial processor engaged in processing acidified foods in any registered establishment shall process each food in conformity with at least the scheduled processes filed under paragraph (c)(2) of this section.

(ii) *Process and pH information availability.* When requested by the Food and Drug Administration in writing, a commercial processor engaged in the processing of acidified foods shall provide the Food and Drug Administration with any process and proce-

dure information that the Food and Drug Administration deems necessary to determine the adequacy of the process. Furnishing of this information does not constitute approval by the Food and Drug Administration of the content of the information filed, and the information concerning processes and other data so furnished shall be considered trade secrets within the meaning of 21 U.S.C. 331(j) and 18 U.S.C. 1905 (to the extent that they qualify under those provisions).

(d) A commercial processor engaged in the processing of acidified foods shall promptly report to the Food and Drug Administration any instance of spoilage, process deviation, or contamination with microorganisms, the nature of which has potential health-endangering significance, where any lot of such food has in whole or in part entered distribution in commerce.

(e) A commercial processor engaged in the processing of acidified foods shall prepare and maintain files on a current procedure for use for products under the processor's control, which that processor will ask the distributor to follow, including plans for recalling products that may be injurious to health; for identifying, collecting, warehousing, and controlling products; for determining the effectiveness of recalls; for notifying the Food and Drug Administration of any recalls; and for implementing recall programs.

(f) All plant personnel involved in acidification, pH control, heat treatment, or other critical factors of the operation shall be under the operating supervision of a person who has attended a school approved by the Commissioner for giving instruction in food-handling techniques, food protection principles, personal hygiene, plant sanitation practices, pH controls, and critical factors in acidification, and who has satisfactorily completed the prescribed course of instruction. The Commission will consider students who have satisfactorily completed the required portions of the courses presented under § 108.35 and Part 113 of this chapter before March 16, 1979, as having satisfactorily completed the prescribed course of instruction under this section and Part 114 of this chapter. The Commissioner will not withhold approval of any school qualified to give such instruction.

(g) A commercial processor engaged in the processing of acidified foods shall prepare, review, and retain at the processing plant or other reasonably accessible location for a period of 3 years from the date of manufacture, all records of processing, deviations in processing, pH, and other records specified in Part 114 of this chapter. Upon written demand during the course of a factory inspection under section 704 of the act by a duly authorized employee of the Food and Drug Administration, a commercial processor shall permit the inspection and copying by that employee of these records to verify the pH and the adequacy of processing.

(h) This section shall not apply to the commercial processing of any food processed under the continuous inspection of the meat and poultry inspection program of the Food Safety and Quality Service of the Department of Agriculture under the Federal Meat Inspection Act (34 Stat. 1256, as amended by 81 Stat. 584 (21 U.S.C. 601 et seq.)) and the Poultry Products Inspection Act (71 Stat. 441, as amended by 82 Stat. 791 (21 U.S.C. 451 et seq.)).

(i) Wherever the Commissioner finds that any State regulates the commercial processing of acidified foods under effective regulations specifying at least the requirements of Part 114 of this chapter, the Commissioner shall issue a notice stating that compliance with such State regulations shall constitute compliance with this section, if the State through its regulatory agency or each processor of acidified foods in the State files with the Food and Drug Administration the registration information and the processing information prescribed in paragraph (c) of this section.

(j) Imports: (1) This section applies to any foreign commercial processor engaged in the processing of acidified foods and offering those foods for import into the United States except that, in lieu of providing for the issuance of an emergency permit under paragraph (a) of this section, the Commissioner will request the Secretary of the Treasury to refuse admission into the United States, under section 801 of the act, to any acidified foods which the Commissioner determines, after investigation, may result in the distribution in interstate commerce of processed foods that may be injurious to health as set forth in paragraph (a) of this section.

(2) Any acidified food so refused admission shall not be admitted until the Commissioner determines that the commercial processor offering the food for import has complied with the requirements of this section and that the food is not injurious to health. To assist the Commissioner in making this determination, a duly authorized employee of the Food and Drug Administration shall be permitted to inspect the commercial processor's manufacturing, processing, and packing facilities.

(k) The following information submitted to the Food and Drug Administration under this section is not available for public disclosure unless it has been previously disclosed to the public as defined in § 20.81 of this chapter or it relates to a product or ingredient that has been abandoned and no longer represents a trade secret or confidential commercial or financial information as defined in § 20.61 of this chapter:

(1) Manufacturing methods or processes, including quality control information.

(2) Production, sales, distribution, and similar information, except that any compilation of the information aggregated and prepared in a way that does not reveal information which is not available for public disclosure under this provision is available for public disclosure.

(3) Quantitative or semiquantitative formulas.

Any person who will be adversely affected by this regulation may at any time on or before April 16, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written objections to it and may make a written request for a public hearing on the stated objections. Each objection shall be separately numbered and each numbered objection shall specify the provision of the regulation to which objection is made. Each numbered objection on which a hearing is requested shall specifically so state; failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection if a hearing is held; failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Four copies of all documents shall be submitted and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this regulation. Received objections may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Effective date. Except for the provisions of § 108.25(c)(1) concerning registration, which shall become effective July 16, 1979; § 108.25(c)(2), concerning process filing, which shall become effective 60 days after registration and before packing any new product; and § 108.25(f), concerning personnel training, which shall become effective September 16, 1980; and except for any provisions that may be stayed by the filing of proper objections, compliance with this final regulation will be required by May 15, 1979. Notice of the filing of objections or lack thereof will be published in the FEDERAL REGISTER.

(Secs. 402, 404, 701(e), 52 Stat. 1046-1047 as amended, 1048, 70 Stat. 919 (21 U.S.C. 342, 344, 371(e)))

Dated: March 7, 1979.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-7687 Filed 3-15-79; 8:45 am]

[4110-03-M]

[Docket No. 75N-0333]

PART 113—THERMALLY PROCESSED LOW-ACID FOODS PACKAGED IN HERMETICALLY SEALED CONTAINERS

Current Good Manufacturing Practice

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This document revises the specific current good manufacturing practices (CGMP's) for canning low-acid foods. The primary public health problem associated with these foods is the possibility of botulinal toxin formation, and these revised regulations will ensure safe manufacturing, processing, and packing procedures for low-acid canned foods in hermetically sealed containers.

EFFECTIVE DATE: May 15, 1979.

ADDRESS: Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Melvin R. Johnston, Bureau of Foods (HFF-414), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C St. SW., Washington, DC 20204, 202-245-1514.

SUPPLEMENTARY INFORMATION: In the FEDERAL REGISTER of July 23, 1976 (41 FR 30444), the Commissioner of Food and Drugs proposed to revise the current good manufacturing practice regulations for low-acid canned foods now in Part 113 (21 CFR Part 113) (formerly 21 CFR Part 128b, before the recodification of March 15, 1977 (42 FR 14302)). The Commissioner provided a period of 60 days for filing comments on the proposal. In response to a request by three trade associations and by the Spanish Ministry of Trade, the Commissioner extended the comment period to November 20, 1976 in a notice published in the FEDERAL REGISTER of September 22, 1976 (41 FR 41436).

The National Canners Association (now the National Food Processors Association (NFPA)), the original petitioner for this regulation in 1971, had extensive comments opposing the proposed change to remove the exemptions from the definition of low-acid canned food for tomatoes, pears, and pineapples having a final equilibrium pH of less than 4.7 and figs having an equilibrium pH of 4.9 or below. After the close of the comment period, NFPA requested that the comment period be reopened so that it could develop and submit data to determine the final equilibrium pH of certain products or classes of products that could be exempted from the scope of the regulations and so that it could submit additional data on the use of flow diversion valves in aseptic canning. The Commissioner reopened the comment period until October 3, 1977, by notice published in the FEDERAL REGISTER of July 29, 1977 (42 FR 38608). The agency later received from NFPA, and placed on public file, comments and data supporting its position on tomatoes and figs. However, the Food and Drug Administration (FDA) received no comments concerning pears or pineapples or the use of flow diversion valves in aseptic canning.

In all, FDA received 24 letters, each containing one or more comments, from industry, trade associations, universities, a Federal government agency, members of Congress, and an individual.

Five comments dealt with the Commissioner's proposals on emergency permit control regulations and current good manufacturing practice regulations for pickled, fermented, and acidified foods, which were published in the same July 23, 1976 issue of the FEDERAL REGISTER (41 FR 30441 and 30457, respectively) as proposed § 90.22 (21 CFR 90.22) (now § 108.25 (21 CFR 108.25)) and Part 128g (21 CFR Part 128g) (now Part 114 (21 CFR Part 114)), respectively. Responses to these comments are contained in the preambles to the final regulations resulting from those proposals, referred to below.

The regulations as amended by this document in Part 113 are designed to update the current good manufacturing practices for low-acid canned foods—foods that present a documented threat of *Clostridium botulinum*. Elsewhere in this issue of the FEDERAL REGISTER, the Commissioner (1) is issuing a regulation, 21 CFR 108.25, that, because of the threat of *C. botulinum* from such foods, subjects acidified foods to the emergency permit control system under section 404 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 344); and (2) is promulgating regulations, 21 CFR Part 114, that articulate the current good manufacturing practices for the preparation of acidified foods. The factors used to classify a food as low-acid or acidified, or to exempt it from the categories, are identical, although the categories are discrete. Because the relationships can be confusing, the Commissioner believes it worthwhile to discuss the factors that control *C. botulinum* and their use in categorizing the foods.

The primary factors that control the growth of *C. botulinum* in food are pH, water activity, and storage conditions. *C. botulinum* requires anaerobic atmosphere, and ambient temperature favors its growth. Acidity and pH vary inversely. *C. botulinum* growth is normally prevented in food with a pH of approximately 4.8 or below. The FDA and the food processing industry have historically added a safety factor of 0.2 pH unit, and they have recognized the basic discriminating pH as 4.6 (see the FEDERAL REGISTER of November 12, 1971 (36 FR 21688) and January 24, 1973 (38 FR 2398)). Foods with a pH above 4.6 are considered low-acid foods. All naturally occurring acid-foods (i.e., those foods with a pH of 4.6 or below) present no risk of botulism and therefore are not subject to the requirements of Part 113.

Most fruits have a naturally occurring pH well below 4.6 and are acid foods. They are therefore not subject to regulation as low-acid foods under Part 113 or as acidified foods under Part 114.

Water activity, the measure of free moisture in the food, is the second major factor that restricts *C. botulinum* growth. As the water activity increases, botulism growth becomes more likely if the pH of the food is above 4.6 Ohye and Christian, and Troller (see Refs. 7, 9, 10, and 11 in the preamble to the proposed CGMP's for pickled, fermented, and acidified foods (41 FR 30457, July 23, 1976), which are on file with the Hearing Clerk) have shown that foods with a water activity that is equal to or less than 0.85 present no risk of botulism growth, regardless of the food's pH. The 0.85 factor carries an appropriate margin of safety. Therefore, foods whose water activity is equal to or less than 0.85 are not subject to the provisions of this part or of Part 114.

Some fruits do have a naturally occuring pH that is above 4.6, and they are thus considered to be low-acid foods. All of these fruits and other low-acid foods intended for processing and packaging in hermetically sealed containers are subject to regulation under this part and § 108.35 (21 CFR 108.35) if their water activity is greater than 0.85. In these foods, botulism is controlled by heat treatment, and this document prescribes good manufacturing practices for thermally processing these low-acid foods packaged in hermetically sealed containers. Other foods have a naturally occurring pH that is above 4.6, and processors of these foods may control the growth of *C. botulinum* in them by intentionally acidifying the food to a pH

of 4.6 or below. Such foods are considered acidified foods, and if they have a water activity value that is above 0.85, they are subject to regulation under § 108.25 and Part 114. If the food is intended to be acidified only to a pH of 4.7, it is considered a low-acid food and subject to regulation as such. The following table illustrates the relationships between pH, water activity, and regulatory status of most foods.

pH (final equilibrium)	a_w	Low-acid (21 CFR 113)	Acidified (not naturally) (21 CFR 114)
<4.5	≤0.85	No	No
<4.5	>0.85	No	Yes
4.6	≤0.85	No	No
4.6	>0.85	No	Yes
≥4.7	≤0.85	No	No
≥4.7	>0.85	Yes	No

Low-acid foods that are not subject to these regulations are low-acid foods packaged in containers that intentionally provide an aerobic atmosphere (containing oxygen). When improperly processed or stored, these foods spoil, but they normally do not present a risk of botulism.

The remaining comments are summarized, and the Commissioner's responses are given, below.

1. In the proposal the Commissioner stated that the growth of spore-forming microorganisms in a product can be prevented by the control of water activity (a_w), the use of salt, sugar, or other chemicals, or some unique characteristic of the food, and that the growth of non-spore-forming microorganisms can be controlled by a thermal process that is insufficient to destroy the spore-forming microorganisms. Then the Commissioner cited examples. Based on this discussion, three comments requested that processed cheese be excluded from the regulation. One comment asked that caviar be excluded, and another, that sirups be excluded.

The Commissioner recognize that a proper combination of heat and a_w will produce a safe product. But processors of all foods that rely on a combination of pH, water activity, and other factors to produce foods that present essentially no risk from *C. botulinum* must file their processes with FDA, and the material filed must show that the spores and spore-forming microorganisms will not grow in the product. The material filed also must show that the heat processes will be adequate to destroy the vegetative cells that might grow in such products. No data have been filed with FDA to demonstrate that microorganisms of public health significance will not grow in the foods for which specific exemptions from the regulations were requested by the comments, and the Commissioner has no basis for exempting those foods from the regulations. Therefore, all processors of foods such as processed cheese, caviar, and sirups must register their plants and file their processes as directed in § 108.35 and comply with all other provisions of this part if the a_w of the food is greater than 0.85 and the pH is above 4.6. To clarify any arguable misunderstanding, the Commissioner has expanded § 113.81(f) (formerly 128b.3(f)) to specify its applicability to low-acid foods that have a water activity of greater than 0.85.

Definitions

2. "Commercial processor" (§ 113.3(d)): Questions have been asked concerning whether or not manufacturers of samples of low-acid canned foods intended for consumer tests and test marketing are within the scope of these regulations.

Because such food is being produced for human consumption, the Commissioner concludes that consumers of the test-marketed food are entitled to the same public health protection as consumers of other canned foods. The Commissioner has, therefore, clarified the definition of "commercial processor" to include persons producing foods for use in market or consumer tests.

3. "Commercial sterility" (§ 113.3(e)): One comment suggested that "the definition should be reworded to allow the implementation of the Commissioner's desires to incorporate foods in which the water activity or other inhibiting agents prevent growth of spore-forming microorganisms." The comment further suggested that the definition be reworded as follows:

> Commercial sterility of thermally processed food means the condition achieved by application of heat which renders such food free of viable forms of microorganisms, of public health as well as nonhealth significance, capable of reproducting in the food under normal nonrefrigerated conditions of storage and distribution.
>
> Commercial sterility of equipment and containers used for aseptic processing and packaging of food means the condition achieved by application of heat, chemical sterilant(s), or other appropriate treatment which renders such equipment and containers free of viable forms of microorganisms, of public health as well as nonhealth significance, capable of reproducing in the food under normal nonrefrigerated conditions of storage and distribution.

The Commissioner intended the definition of commercial sterility of thermally processed food to include foods in which water activity is used to prevent the growth of spore-forming microorganisms. Therefore, the Commissioner has revised the definition to clarify this point. Thermally processed foods, whether rendered commercially sterile by heat alone or by controlling water activity together with the application of heat, must be free of microorganisms capable of reproducing in the food under normal nonrefrigerated conditions of storage and distribution. The Commissioner has also changed the regulation to clarify that foods in which water activity prevents the reproduction of spores of microorganisms of public health significance may contain spores that cannot reproduce because of low water activity. However, foods that are sterilized by heat alone may not contain any living microorganisms (including spores) of public health significance.

Concerning the definition of commercial sterility of equipment and containers used for aseptic processing and packaging of food, the Commissioner sees no substantial differences between the suggested wording and that published in the proposal and thus has made no changes in the definitions.

4. "Low-acid foods" (§ 113.3(n)).

a. The proposal would have revoked the exemption from the definition of low-acid canned food that exists in the current regulations for tomatoes, pears, pineapples, and figs. In its initial comments, NFPA requested that the exemption be maintained until additional data were available to show that the exemption is appropriate. Data were later presentd to demonstrate that the outgrowth of *C. botulinum* is prevented in tomato products with an equilibrium pH of less than 4.9. Data on figs were also submitted.

The United States Department of Agriculture (USDA) Eastern Regional Research Center in Philadelphia, Pennsylvania, conducted research on the acidity of numerous tomato varieties, which it submitted as a comment on the proposed changes in the regulations. Its 1975 study found no tomato samples having a population mean pH higher than 4.55, and no individual fruits having a pH of 4.8 or higher; in its 1976 study, some of the individual tomatoes exceeded a pH of 4.8. The USDA also commented that the proposed rules did not specify whether the required pH is to be the pH of a composite of raw material, the mean of replicate analysis of different raw material units, or some other value.

The Commissioner proposed to define a low-acid food as one with a finished equilibrium pH of greater than 4.6, and the current regulation also uses the term "finished equilibrium pH." For this reason, the Commissioner believes that the pH discriminate established by the regulation is clear; it is the equilibrium pH of the finished food, not the pH of a composite of raw material or the mean of replicate analysis of different raw material units. The Commissioner also notes that the USDA studies show that some varieties of tomatoes have a pH greater than 4.7. The need to exercise a high degree of care in the processing

and pH control of tomato products is obvious.

Based on the tomato data submitted by NFPA, the Commissioner concludes that in tomato products a finished equilibrium pH of less than 4.9 will prevent the outgrowth of *C. botulinum;* accordingly, the Commissioner has retained the exemption from the definition of low-acid foods for tomatoes and tomato products having a finished equilibrium pH less than 4.7 which includes a safety factor of 0.2 pH unit.

The Commissioner, however, believes the data for figs are inconclusive and is revoking their exemption with this order. Therfore, figs are low-acid foods that are subject to manufacture in accordance with this part, but if the figs are acidified to a pH of 4.6 or below, they are regulated as acidified foods under Part 114. The FDA evaluation of these data has been placed on display for public review at the office of the Hearing Clerk, FDA (address above).

Because no data were submitted to support the exclusion of pears and pineapples from the requirements of the regulations, no change has been made in the definition, and the exemption has been removed.

b. Another comment asked that the water activity requirement be changed from 0.85 to 0.92.

The Commissioner advises that some vegetative forms of microorganisms of public health concern are not inhibited at an a_w of 0.92. A thermal process adequate to destroy these microorganisms in products having an a_w above 0.85 must be established by a competent processing authority. Therefore, the Commissioner has not made the suggested change in the water activity provision of the definition for low-acid foods.

PERSONNEL

5. One comment suggested that the parenthetical phrase "including systems wherein water activity is used in conjunction with thermal processing" be deleted from the requirement for supervision schooling because this subject is adequately covered with the statement "instruction appropriate to the preservation technology involved."

The Commissioner believes that the supervisor of a process in which water activity is used as a part of the thermal process must have some knowledge of the role of water activity in that process. To emphasize the point, the Commissioner declines to make this change in the regulation.

EQUIPMENT AND PROCEDURES

6. Temperature-recording device (§ 113.40(a)(2)): Three comments agreed that the temperature chart of the recording device should closely agree with the known accurate mercury-in-glass thermometer. However, all three objected to the requirement that the temperature chart recording never be higher than the mercury-in-glass thermometer. One comment stated that, because of the difference in response times between the temperature recorder bulb and the mercury-in-glass thermometer, the recorder temperature might momentarily be above that of the mercury-in-glass thermometer. The other two comments asked that the wording in the current regulation, which allows the recorder reading to be within 1° F of the mercury-in-glass thermometer reading, be restored. They argued that slight changes should not be considered a processing deviation.

The Commissioner rejects the comments because it is in the interest of public safety that the recorder temperature be no higher than the mercury-in-glass thermometer readings. The current regulation might lead to an erroneous conclusion about the potential hazard associated with the processing that has actually occurred. The Commissioner advises, however, that small momentary variations in which the temperature indicated by the recorder may be slightly above the mercury-in-glass thermometer reading, will not be considered deviations.

The same three comments also objected to the proposed requirement for an air supply to the temperature controllers that is separate from the air supply to the rest of the plant. They argued that the manner in which clean dry air is obtained should be left to the discretion of the packer.

The Commissioner agrees and has deleted the proposed requirement from this and the other sections in which it was proposed.

7. Pressure gages (§ 113.40(a)(3)): A comment objected to the Commissioner's proposal for deleting the requirement for a pressure gage on retorts and gave several reasons why the operator needs to know the pressure in the retort. The reasons stated were: (1) The steam retort is a hazardous device, and the operator must know the pressure in the retort to ensure a safe operation of the device; (2) under certain operating conditions, a superheated steam condition can exist in the steam retort, and only with the pressure gage can the operator identify that condition; (3) automatic control devices occasionally fail, and the pressure gage is the only device that will immediately indicate that a failure is occurring; and (4) the readings of an accurate pressure gage can be converted into temperature and the pressure gage therefore offers another point of measurement and control.

The Commissioner's statement in the preamble to the proposed regulation remains valid: The pressure gage serves no mandatory function in the thermal processing of low-acid canned foods. However, for the reasons given in the comment, the pressure gage may serve a function, and the Commissioner has retained the wording of the proposal which makes the pressure gage optional.

8. Steam spreaders (§ 113.40(a)(7)): One comment suggested that the wording of this section be changed to permit retorts in which steam is allowed to enter the top or the bottom as long as the vent is opposite the steam inlet. This comment and two others also asked the Commissioner to make clear that the number of perforations in the spreaders be such that the total cross-sectional area of the perforations be equal to 1½ to 2 times that of the smallest restriction in the steam inlet.

The Commissioner agrees with both suggestions and has made the appropriate changes. In the Commissioner's opinion, that formula is appropriate to maintain the proper distribution of steam for sterilization.

9. Bleeders (§ 113.40(a)(8)): One comment suggested rewording this section to clarify precisely where near the "end of the shell of the retort" the bleeders should be. The comment stated that the need for bleeding of steam arises in areas that contain cans, and it suggested the following change for horizontal still retorts: "Bleeders shall be located within one foot of the outmost location of containers in the retort."

The Commissioner agrees and has made the appropriate change in the regulation.

10. Air valves and water valves (§ 113.40(a) (10) and (11)): One comment asked for a specific list of the types of air and water valves that are acceptable for use in the cooling of retorts.

The Commissioner advises that there are a number of suitable valves which may be used, and each processor must pick the proper valve for its process. Therefore, the Commissioner believes that the variables render a list inappropriate and has made no change.

11. Critical factors (§ 113.40(a)(13)):

a. The regulation requires that critical factors such as consistency, percent solids, and fill-in or drained weight, which are usually determined at a location some distance from the retort, be recorded on the processing record. One comment suggested deleting this requirement.

The Commissioner agrees that it is unnecessary to carry all test results back to the retort room, but this information is important and must be combined at some time (but not necessarily rewritten) in one place. This point

is all that is required by the regulation, and in the Commissioner's opinion it is clear. Therefore, the Commissioner has retained the wording in the regulation to avoid a misunderstanding of what actually is required.

b. Section 113.40(a)(13)(iii): One comment protested that it is unnecessary to make measurements and recordings of all critical factors at intervals of 15 minutes or less.

Measurements and recordings at intervals of sufficient frequency to ensure that the critical factors are within the limits specified in the scheduled process are mandatory. The Commissioner agrees that they may be measured less often than every 15 minutes. The suggestion that they be measured at least every 15 minutes is an advisory procedure, because procedures vary. Nevertheless, the Commissioner cautions on the need for scrupulous, timely monitoring.

12. Air supply and controls (§ 113.40(b)(10)(i)): One comment agreed with the Commissioner's desire to have the adequacy of air or water circulation established by a competent processing authority, but it noted that such determinations should also be accepted if they were made in accordance with procedures recognized by competent processing authorities.

The Commissioner agrees and has made appropriate changes here and in other similar sections of the regulation.

13. Vertical and horizontal still retorts (§ 113.40(b)(13)): A comment stated that it is not always necessary for a processor to have heat distribution data on file, but the firm may have operating and installation requirements from the manufacturer or a processing authority who does have such data on file.

The Commissioner agrees that this approach is acceptable and has made appropriate changes in the regulations.

14. Bleeders (§ 113.40(c)(5)): Two comments stated that the proposed 15-minute interval for checking the condensate bleeder is too short. One comment suggested checks at 30-minute intervals, and the other suggested that the regulations permit bleeder function to be checked at intervals established by the company to ensure adequate operation of the retort. A comment also asked for permission to use automatic alarm systems to detect condensate bleeder malfunction.

As with the requirement for measuring critical factors, the Commissioner advises that the regulations require that the condensate bleeder be checked with sufficient frequency to ensure adequate removal of condensate. The 15-minute interval for checking the bleeder is merely advisory. The Commissioner agrees that the optional use of automatic alarm systems to detect condensate bleeder malfunction is appropriate to serve as a continuous monitor, and such a provision has been incorporated.

15. Retort speed timing (§ 113.40(c)(7)): One comment noted that, in the sections concerning temperature-recording devices, the Commissioner explained how to satisfy the requirement that "a means of preventing unauthorized changes in adjustment shall be provided." The comment suggested that a statement also be included in this section to spell out satisfactory means to satisfy the requirement.

The Commissioner agrees that this was an oversight in the proposal and therefore has included such a provision here and in similar sections of this part. To prevent unauthorized changes in the retort timing speed, the regulations recognizes a lock or a notice from management, posted at or near the speed-adjustment device, which provides a warning that only authorized persons are permitted to make adjustments, as satisfactory preventive measures.

16. Emergency stops (§ 113.40(c)(8)):

a. In the case of an emergency stop, the proposal would have required that a still process be used or that all the containers be either reprocessed, repacked and reprocessed, or discarded. A comment argued that sterilizing processes other than still processes should be acceptable if an emergency stop is required; and it suggested that the regulation be changed to allow the use of other processes if they have been established to ensure commercial sterility.

The Commissioner agrees, and such a change in the regulation has been made.

b. Another comment suggested that subparagraph (iii), concerning handling emergencies, be deleted. The comment found this requirement redundant with the requirement of § 113.89 and thought it more appropriate to have all requirements concerning process deviations in a single section.

The Commissioner agrees and has deleted proposed § 113.40(c)(8)(iii) and included the requirement in § 113.89.

17. Critical factors (§ 113.40(c)(10)):

a. A comment stated that net weight measurements are appropriate as a measure of volume and headspace in homogeneous liquids, whether the containers are conventional sanitary cans or lap seam (vent hole) cans. Accordingly, the comment asked that the regulation be rewritten to permit the measurement of headspace by net weight measurements of homogeneous liquid products in conventional sanitary cans.

For a specific homogeneous liquid product, the Commissioner agrees that processes can be established to measure volume and headspace for both the conventional sanitary cans and lap seam cans on the basis of maximum net weight, taking into account the specific can end profile and other factors that affect container headspace. Therefore, the Commissioner has revised the regulation accordingly.

b. The same comment suggested that the requirement for the measurement of headspace every 15 minutes be replaced by a requirement that sampling be conducted on the basis of throughput and that the number of samples taken and the intervals of sampling be determined from standard acceptable quality level (AQL) tables.

The Commissioner agrees that the use of such methods could ensure that critical factors are measured and recorded at sufficient frequency to guarantee that the factors are within the limits specified in the scheduled process. Nevertheless, because the frequency requirement for recording the measurements is advisory, not mandatory, no change has been made in the regulation.

18. Temperature-indicating device (§ 113.40(g)(1)(i)(*a*)): One comment pointed out that this section requires thermometers and temperature-indicating devices to be tested for accuracy at least once a month, although in other sections the requirement is once a year. The operation of aseptic system does not provide any more opportunities for thermometers or temperature-measuring devices to become inaccurate than does the operation of any other system. Therefore, the comment requested that testing be required once a year or more frequently, if necessary, to ensure the accuracy of thermometers and temperature-indicating devices.

The Commissioner accepts this change but nonetheless stresses the importance of accurate temperature measurements, especially in high-temperature short-time systems.

19. Flow-diversion system (§ 113.40(g)(1)(i)(*h*)):

a. The Commissioner proposed a new section for aseptic processing and packaging systems to require that a flow-diversion valve be installed between the cooler and filler. The proposed provision would have required the system to be controlled to divert product flow away from the filler when the temperature of the product in the holding tube falls below the sterilization temperature specified in the scheduled processes. However, it would have provided an exception from the requirement for the flow-diversion valve when products with discrete particles are being processed. Two processors of aseptic foods com-

mented that the use of flow-diversion valves on the sterile side of an aseptic product processing line could result in product contamination.

Based on these comments, the Commissioner believes that the proposed flow-diversion valve requirement may have been misunderstood. The Commissioner recognizes that possibility of contamination if flow-diversion systems are inadequately designed or improperly operated, but the function of this section is to establish a provision for preventing insufficiently heated products from reaching the aseptic filler. An inspection of all domestic aseptic processing operations that have been filed with FDA confirms that all processors in this country currently use Dole aseptic canning units. All but one of these canning units have a manually operated system that can divert product from the filler. Some processors are using the diversions systems as they were supplied by the manufacturer, while other processors have modified the systems for automatic control. These inspectional observations do not support the contention of contamination. A summary of the findings of these inspections has been placed on display for public review in the office of the Hearing Clerk (HFA—305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane Rockville, MD 20857.

A packaging system supplier stated that, in addition to the use of a flow-diversion valve, there are a number of different technical solutions to the problem of preventing insufficiently heated products from reaching the aseptic filler. Also, one processor commented that it has successfully used a diversion system that is different from the Dole system to divert product from the filler automatically when the temperature at the holding-tube outlet drops below the scheduled process. Moreover, some aseptic processing and packaging establishments have elected not to use flow diversion when temperature drops occur in the product-holding tube. The processors usually stop the cans from entering the container filling area, switch to water, and resterilize the system, including the filler. Another processor commented that all aseptic processors using Dole aseptic canning units are supplied with manually operated systems to divert product from the filler, and these systems can handle both liquid products and products containing discrete particles.

Finally, one processor commented that it would not be opposed to a provision for flow diversion; however, it recommended that the provision focus on the diversion principle to prevent the packaging of nonsterile product, rather than on diversion hardware such as a flow-diversion valve.

For all the above reasons the Commissioner has revised § 113.40(g)(1)(i)(*h*). The Commissioner has substituted the term "flow-diversion system" for the proposed "flow-diversion valve," and such a diversion system is a requirement. The Commissioner has also eliminated the exception from the proposed requirement for a flow-diversion valve in equipment that processes products with discrete particles. In addition, the Commissioner finds that revision in § 113.40(g)(1)(ii) and (2)(ii)(*b*) are necessary. These provisions now describe the design, function, and purpose of the flow-diversion system. The revisions also recommend that the flow-diversion system be designed and instrumented to operate automatically when the temperature in the holding tube drops below the minimum temperature required in the scheduled process, when proper pressure in the product-to-product regenerator is not maintained, or when deviations from container or container closure sterilization processes occur. For any processor who does not practice flow diversion and whose product, subjected to system failure, is filled into containers, the regulation contains a provision that the product shall be segregated and that the deviation shall be handled in accordance with § 113.89 (i.e., reprocessed, destroyed, or when possible, evaluated by a processing authority for public health significance).

b. One comment interpreted the proposal for a flow-diversion valve as a substitution for the incubation requirement.

This interpretation is not the case. Diversion of product from the container-filling and -closing areas is intended to prevent underprocessed product from being packaged and to prevent contamination of those areas with underprocessed product. In sum, flow diversion is intended to provide an additional check to detect mechanical or human-system operations failures that cause product contamination with microorganisms. On the other hand, the incubation of samples was not originally, and is not now, intended to substitute for current good manufacturing practices, including the record-keeping, record review, and evaluation of deviation requirements of the regulations. It is intended to provide a quality control and public health protection function.

c. Some comments indicated concern that valves or other pieces of equipment downstream from the holding tube could provide points for potential entry of microorganisms into the product.

The Commissioner agrees and therefore has added new § 113.40(g)(1)(i)(*i*) to provide for use of steam seals (or other effective barriers) at such potential access points.

CONTAINERS

20. Can seam measurements (§ 113.60(a)(1)(i) (*a*) and (*b*)): Two comments objected to making the measurement of seam thickness mandatory. One comment contended that seam thickness cannot be measured or observed using a seam scope.

As the Commissioner explained in the proposal, thickness in can seaming is critical to ensuring the manufacture of safe products, and its measurement is now required. The Commissioner recognizes, however, that if a seam scope or projector is used for can seam measurements, a micrometer must be used to measure the thickness. Therefore, the Commission has revised the regulation to make this clear.

21. Cooling water (§ 113.60(b)): The proposal would have required measurable free chlorine residue at the water discharge point of the container cooler, and it would have permitted the use of other safe chemicals or physical water treatment that has the equivalent bactericidal effect as chlorine. One comment pointed out that, even in properly chlorinated container cooling water, it is not always possible to have a measurable free chlorine residue at the water discharge. For that reason, the comment recommended that the section be reworded to require proper sanitizing of the water in cooling canals, but it felt the Commissioner should recommend, not require, a measurable residue of the chemical sanitizing agent at the water discharge point.

The Commissioner agrees, and this change in the regulation has been made.

22. Raw materials (§ 113.81(a)): Two comments stated that it would be impractical to hold raw materials until an evaluation of the microbiological quality of the product could be made.

The Commissioner did not intend that a processor keep raw materials until a plate count, for example, could be made. Rather, the Commissioner intended to list specific ways by which processors can be certain, before using such, that their raw materials and ingredients susceptible to microbiological contamination are suitable for use. The methods include receiving the materials under a supplier's guarantee or under any other acceptable means in addition to testing by the processor. The Commissioner, therefore, has changed the regulation to clarify these intentions.

23. pH (§ 113.81(e)):

a. One comment suggested that a safety factor of two-tenths of a pH unit should be included in this paragraph.

When the maintenance of pH (above 4.6) of a normally low-acid food is the basis for a scheduled process, the scheduled process must be filed with FDA under § 108.35 of this chapter, and the scheduled process, as filed, will have the necessary and appropriate safety factor as described earlier. Therefore, the Commissioner rejects this suggestion.

b. Another comment stated that the reference to the methodology for pH determinations is too restrictive because it requires the methodology described in § 114.90 (21 CFR 114.90) to be used.

The Commissioner agrees. Because the methodology in § 114.90 is advisory, the Commissioner has changed the regulation from "shall" to "should."

24. Scheduled process (§ 113.81(f)): The Commissioner has expanded this section to clarify good processing practices when the scheduled process sets forth such critical factors as water activity to prevent the growth of microorganisms not destroyed by the thermal process.

OPERATIONS IN THE THERMAL PROCESSING ROOM

25. Thermal processes (§ 113.87(a)): A comment stated that the operating processes should be made available to the operator. In some instances, it is desirable that scheduled processes be made available to the supervisor but not to the operator.

The Commissioner agrees that it is unnecessary that the scheduled processes be available to the operator as long as they are available to the supervisor and to any duly authorized FDA employees and has made the appropriate revisions in the regulations.

26. Product traffic (§ 113.87(b)): Three comments were received concerning the proposal to establish systems for product traffic control in the retort room. One comment stated that a traffic control plan would be welcomed by all food canners and said that if such a plan exists, it should be spelled out in detail. Two comments suggested that the Commissioner eliminate the recommedation that all visual checks of the heat-sensitive indicators be recorded.

The Commissioner recognizes that there can be no single system for product traffic control that would be applicable to all plants. Nevertheless, the Commissioner believes that it is necessary for each plant to outline its own system in order to minimize the danger of unretorted product being packed as retorted product. Keeping a written record of the visual checks of heat-sensitive indicators is good practice, but that practice is not, in the Commissioner's opinion, mandatory. Therefore, no changes in this section are warranted.

27. Initial temperature (§ 113.87(c)): One comment stated that it is not necessary to determine and record preprocess temperatures when a preheater is used in a continuous retort operation.

The Commissioner advises that the effect of initial temperature is taken into account during the process of establishing as safe continuous retort operation. The instructions in this provision for filing the scheduled processes for continuous agitating retorts are clear. The minimum initial temperature of the contents at the entry to the preheater (along with other preheater operating parameters) shall be reported to ensure that the temperature complies with the established process. The initial temperature of the product must be measured at this point to ensure that the temperature is no lower than the minimum specified in the scheduled process. The instructions do not require reporting of the product temperature at the exit from the preheater (which is the entry to the first sterilizer shell).

28. Timing devices (§ 113.87(d)): One comment requested that digital clocks be allowed for timing purposes. The comment stated that digital clocks are now in use and have not been shown to be less accurate for timing purposes than other types of clocks, that there is the possibility of an inherent one-minute difference if seconds are not read with a second hand using a wall clock or if the digital clock has no place for seconds, and that the digital clock has the inherent advantage of being easier to read.

The Commissioner agrees that digital clocks are also usable and has modified the regulation to allow their use. Most digital clocks now in use, however, are not graduated in seconds. For this reason, they may be used only if the operating process of heating the food has a safety factor of one minute or greater.

29. Steam supply (§ 113.87(f)): One comment questioned whether a firm will be in violation of this section if the steam pressure falls below that validated as the minimum steam pressure for venting. This same comment suggested that the firm have a series of steam-pressure-versus-time venting schedules correlated to various lower pressures in increments of 10 pounds per square inch to correct for any pressure drops below that validated for venting. The comment also recommended that an alarm be placed on the retort steam header line to warn of an impending lowering of steam pressure.

The Commissioner agrees that venting is very important and that a firm must know the steam-pressure-versus-time relationship for venting. A firm will not be considered in violation of this provision should the steam pressure fall below the level validated as a minimum under the following conditions: (1) There is an alternate venting schedule available for the lower steam pressure; (2) the schedule has been filed with FDA; and (3) the schedule has been shown to be effective. Any significant drops in pressure will be recorded on the retort charts. For this reason, the Commissioner finds that an alarm system is not necessary and has not changed the regulation in this regard.

DEVIATIONS IN PROCESSING, VENTING, OR CONTROL OF CRITICAL FACTORS

30. Separate file for deviations (§ 113.89): Two comments objected to the need for processors to keep a separate file detailing all deviations in processing, venting, or control of critical factors.

Because this information must be recorded and maintained under the regulations, the Commissioner believes it is obvious that the information will have to be filed and eventually retrieved. Therefore, the information must be available for review.

The comments further stated that there does not appear to be adequate justification at this time for the Commissioner to require an entirely separate, but duplicate, filing system for such records. The Commissioner did not intend to propose a complete duplicate system of records, but rather proposed that processors maintain a separate file of process deviations to enable the processor as well as an FDA investigator to ascertain readily which products may have been underprocessed. The FDA's experience in investigating establishments demonstrates that some system which permits rapid identification of potentially underprocessed lots is necessary for efficient use of regulatory manpower. The regulation has therefore been revised to delete the requirement for a complete duplicate file of all records. Based on experience in reviewing logs in industry plants, the Commissioner concludes that a log identifying the appropriate data is sufficient.

PROCESSING AND PRODUCTION RECORDS

31. Water activity and alternate systems (§ 113.100(a)(6) and (7)): One comment asked that these sections be deleted because they are redundant and because they place an undue emphasis on maintaining records of such critical factors as water activity and pH. Alternatively, the comment proposed a rewording and combination of the two provisions.

The Commissioner advises that if water activity and pH are used as a part of the scheduled process, their control is critical. These two provisions have been clarified, but the Com-

missioner has retained the requirement in the final regulation that records about these systems be maintained.

32. Record initialing (§ 113.100(b)): One comment objected to the proposed requirement that processing records be dated, and initialed or signed, when they are reviewed by the management representative. The proposal would have required this to be done not later than one working day after the actual processing and before shipment or release of the food for distribution. As an alternative, the comment suggested a statement that could be initialed or signed by the reviewer, and that indicates that these processing and production records have been checked within one working day.

The Commissioner sees no advantage in the suggested alternative and has not accepted it.

33. Initial distribution (§ 113.100(d)): Three comments objected to the requirement that processors maintain records identifying the initial distribution of finished products on the ground that this requirement is a recall tool and is covered under § 103.35(f). One comment further stated that the present system of batch codes on shipping documents is adequate and should be acceptable.

Section 108.35(f) establishes only the general, basic requirement of maintaining records. Section 113.100(d), on the other hand, prescribes the specific good manufacturing practices that require the processor to maintain records that identify the initial distribution of finished products. The Commissioner concludes that the benefits to the consumer from this requirements are clear. It expedites the recall of dangerous or potentially dangerous products from the market (see *National Confectioner's Ass'n* v. *Califano*, 569 F. 2d 690 (D. C. Cir. 1978)).

The remaining comments requested that portions of the proposal be clarified. The Commissioner has clarified portions of the final order so that there may be better implementation of the proposed regulations. Accordingly, having evaluated all of the comments received and other relevant material, the Commissioner concludes that the regulation should be promulgated as set forth below.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 402(a)(3) and (4), 701(a), 52 Stat. 1046, 1055 (21 U.S.C. 342(a)(3) and (4), 371(a))) and under authority delegated to the Commissioner (21 CFR 5.1), Chapter I of Title 21 of the Code of Federal Regulations is amended by revising Part 133 as follows:

PART 113—THERMALLY PROCESSED LOW-ACID FOODS PACKAGED IN HERMETICALLY SEALED CONTAINERS

Subpart A—General Provisions

Sec.
113.3 Definitions.
113.5 Current good manufacturing practice.
113.10 Personnel.

Subpart B—[Reserved]

Subpart C—Equipment

113.40 Equipment and procedures.

Subpart D—Control of Components, Food Product Containers, Closures, and In-process Material

113.60 Containers.

Subpart E—Production and Process Controls

113.81 Product preparation.
113.83 Establishing scheduled processes.
113.87 Operations in the thermal processing room.
113.89 Deviations in processing.

Subpart F—Records and Reports

113.100 Records.

AUTHORITY: Secs. 402(a)(3) and (4), 701(a), 52 Stat. 1046, 1055 (21 U.S.C. 342(a)(3) and (4), 371(a)).

Subpart A—General Provisions

§ 113.3 Definitions.

For the purposes of this part, the following definitions apply:

(a) "Aseptic processing and packaging" means the filling of a commercially sterilized cooled product into presterilized containers, followed by aseptic hermetical sealing, with a presterilized closure, in an atmosphere free of microorganisms.

(b) "Bleeders" means openings used to remove air that enters with steam from retorts and steam chambers and to promote circulation of steam in such retorts and steam chambers. Bleeders may serve as a means of removing condensate.

(c) "Come-up-time" means the time which elapses between the introduction of steam into the closed retort and the time when the retort reaches the required processing temperature.

(d) "Commercial processor" includes any person engaged in commercial, custom, or institutional (church, school, penal, or other organization) processing of food, including pet food. Persons engaged in the production of foods that are to be used in market or consumer tests are also included.

(e) "Commercial sterility": (1) "Commercial sterility" of thermally processed food means the condition achieved—

(i) By the application of heat which renders the food free of—

(*a*) Microorganisms capable of reproducing in the food under normal nonrefrigerated conditions of storage and distribution; and

(*b*) Viable microorganisms (including spores) of public health significance; or

(ii) By the control of water activity and the application of heat, which renders the food free of microorganisms capable of reproducing in the food under normal nonrefrigerated conditions of storage and distribution.

(2) "Commercial sterility" of equipment and containers used for aseptic processing and packaging of food means the condition achieved by application of heat, chemical sterilant(s), or other appropriate treatment that renders the equipment and containers free of viable microorganisms having public health significance, as well as microorganisms of nonhealth significance, capable of reproducing in the food under normal nonrefrigerated conditions of storage and distribution.

(f) "Critical factor" means any property, characteristic, condition, aspect, or other parameter, variation of which may affect the scheduled process and the attainment of commercial sterility.

(g) "Flame sterilizer" means an apparatus in which hermetically sealed containers are agitated at atmospheric pressure, by either continuous, discontinuous, or reciprocating movement, with impinging gas flames to achieve sterilization temperatures. A holding period in a heated section may follow the initial heating period.

(h) "Headspace, gross" is the vertical distance between the level of the product (generally the liquid surface) in an upright rigid container and the top edge of the container (the top of the double seam of a can or the top edge of a glass jar).

(i) "Headspace, net" of a container is the vertical distance between the level of the product (generally the liquid surface) in the upright rigid container and the inside surface of the lid.

(j) "Hermetically sealed container" means a container that is designed and intended to be secure against the entry of microorganisms and thereby to maintain the commercial sterility of its contents after processing.

(k) "Incubation" means the holding of a sample(s) at a specified temperature for a specified period of time for the purpose of permitting or stimulating the growth of microorganisms.

(l) "Initial temperature" means the average temperature of the contents of the coldest container to be processed at the time the thermal processing cycle begins, as determined after thorough stirring or shaking of the filled and sealed container.

(m) "Lot" means that amount of a product produced during a period of time indicated by a specific code.

(n) "Low-acid foods" means any foods, other than alcoholic beverages, with a finished equilibrium pH greater than 4.6 and a water activity (a_w) greater than 0.85. Tomatoes and tomato products having a finished equilibrium pH less than 4.7 are not classed as low-acid foods.

(o) "Minimum thermal process" means the application of heat to food, either before or after sealing in a hermetically sealed container, for a period of time and at a temperature scientifically determined to be adequate to ensure destruction of microorganisms of public health significance.

(p) "Operating process" means the process selected by the processor that equals or exceeds the minimum requirements set forth in the scheduled process.

(q) "Retort" means any closed vessel or other equipment used for the thermal processing of foods.

(r) "Scheduled process" means the process selected by the processor as adequate under the conditions of manufacture for a given product to achieve commercial sterility. This process may be in excess of that necessary to ensure destruction of microorganisms of public health significance, and shall be at least equivalent to the process established by a competent processing authority to achieve commercial sterility.

(s) "Shall" is used to state mandatory requirements.

(t) "Should" is used to state recommended or advisory procedures or to identify recommended equipment.

(u) "Vacuum-packed products" means those products that are sealed in a container under the vacuum specified in the scheduled process, the maintenance of which vacuum is critical to the adequacy of the scheduled process.

(v) "Vents" means openings through the retort shell, controlled by gate, plug cock, or other adequate valves used for the elimination of air during the venting period.

(w) "Water activity" (a_w) is a measure of the free moisture in a product and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

§ 113.5 Current good manufacturing practice.

The criteria in §§ 113.10, 113.40, 113.60, 113.81, 113.83, 113.87, 113.89, and 113.100 shall apply in determining whether the facilities, methods, practices, and controls used by the commercial processor in the manufacture, processing, or packing of low-acid foods in hermetically sealed containers are operated or administered in a manner adequate to protect the public health.

§ 113.10 Personnel.

The operators of processing systems, retorts, aseptic processing and packaging systems and product formulating systems (including systems wherein water activity is used in conjunction with thermal processing) and container closure inspectors shall be under the operating supervision of a person who has attended a school approved by the Commissioner for giving instruction appropriate to the preservation technology involved and who has been identified by that school as having satisfactorily completed the prescribed course of instruction. This person shall supervise only in those areas for which a school approved by the Commissioner identifies the person as having satisfactorily completed training.

Subpart B—[Reserved]

Subpart C—Equipment

§ 113.40 Equipment and procedures.

(a) *Equipment and procedures for pressure processing in steam in still retorts*—(1) *Indicating mercury-in-glass thermometer.* Each retort shall be equipped with at least one mercury-in-glass thermometer whose divisions are easily readable to 1° F and whose temperature range does not exceed 17° F per inch of graduated scale. Thermometers shall be tested for accuracy against a known accurate standard thermometer upon installation and at least once a year thereafter, or more frequently if necessary, to ensure their accuracy. Records of thermometer accuracy checks that specify date, standard used, method used, and person performing the test should be maintained. Each thermometer should have a tag, seal, or other means of identity that includes the date on which it was last tested for accuracy. A thermometer that has a divided mercury column or that cannot be adjusted to the standard shall be repaired or replaced before further use of the retort. Thermometers shall be installed where they can be accurately and easily read. Bulbs of indicating thermometers shall be installed either within the retort shell or in external wells attached to the retort. External wells or pipes shall be connected to the retort through at least a ¾-inch diameter opening and equipped with a 1/16-inch or larger bleeder opening so located as to provide a full flow of steam past the length of the thermometer bulb. The bleeders for external wells shall emit steam continuously during the entire processing period. The mercury thermometer—not the recorder chart—shall be the reference instrument for indicating the processing temperature.

(2) *Temperature-recording device.* Each still retort shall have an accurate temperature-recording device. Graduations on the temperature-recording devices shall not exceed 2° F within a range of 10° F of the processing temperature. Each chart shall have a working scale of not more than 55° F per inch within a range of 20° F of the processing temperature. The temperature chart shall be adjusted to agree as nearly as possible with, but to be in no event higher than, the known accurate mercury-in-glass thermometer during the process time. A means of preventing unauthorized changes in adjustment shall be provided. A lock, or a notice from management posted at or near the recording device which provides a warning that only authorized persons are permitted to make adjustments, is a satisfactory means for preventing unauthorized changes. The recorder may be combined with the steam controller and may be a recording-controlling instrument. The temperature-recorder bulb shall be installed either within the retort shell or in a well attached to the shell. Each temperature-recorder bulb well shall have a 1/16-inch or larger bleeder which emits steam continuously during the processing period. Air-operated temperature controllers should have adequate filter systems to ensure a supply of clean, dry air.

(3) *Pressure gages.* Each retort should be equipped with a pressure gage that should be graduated in divisions of 2 pounds or less.

(4) *Steam controller.* Each retort shall be equipped with an automatic steam controller to maintain the retort temperature. This may be a recording-controlling instrument when combined with a recording thermometer. The steam controller may be air-operated and actuated by a temperature sensor positioned near the mercury-in-glass thermometer in the retort; a steam controller activated by the steam pressure of the retort is acceptable if it is carefully maintained mechanically so that it operates satisfactorily.

(5) *Steam inlet.* The steam inlet to each still retort shall be large enough to provide sufficient steam for proper operation of the retort. Steam may enter either the top portion or the bottom portion of the retort but, in any case, shall enter the portion of the retort opposite the vent; for example, steam inlet in bottom portion and vent in top portion.

(6) *Crate supports.* A bottom crate support shall be used in vertical still retorts. Baffle plates shall not be used in the bottom of still retorts.

(7) *Steam spreaders.* Steam spreaders are continuations of the steam inlet line inside the retort. Horizontal still retorts shall be equipped with

steam spreaders that extend the length of the retort. For steam spreaders along the bottom of the retort, the perforations should be along the top 90° of this pipe, that is, within 45° on either side of the top center. Horizontal still retorts over 30 feet long should have two steam inlets connected to the spreader. In vertical still retorts, the steam spreaders, if used, should be perforated along the center line of the pipe facing the interior of the retort or along the sides of the pipe. The number of perforations should be such that the total cross-sectional area of the perforations is equal to 1½ to 2 times the cross-sectional area of the smallest restriction in the steam inlet line.

(8) *Bleeders.* Bleeders, except those for thermometer wells, shall be one-eighth inch or larger and shall be wide open during the entire process, including the come-up-time. For horizontal still retorts, bleeders shall be located within approximately 1 foot of the outermost locations of containers at each end along the top of the retort; additional bleeders shall be located not more than 8 feet apart along the top. Bleeders may be installed at positions other than those specified above, as long as there is evidence in the form of heat distribution data that they accomplish adequate removal of air and circulation of steam within the retort. Vertical retorts shall have at least one bleeder opening located in that portion of the retort opposite the steam inlet. In retorts having top steam inlet and bottom venting, a bleeder shall be installed in the bottom of the retort to remove condensate. All bleeders shall be arranged so that the operator can observe that they are functioning properly.

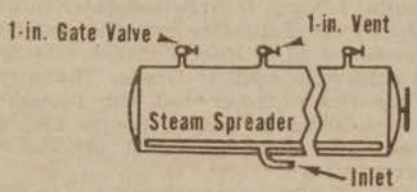
(9) *Stacking equipment and position of containers.* Crates, trays, gondolas, etc., for holding containers shall be made of strap iron, adequately perforated sheet metal, or other suitable material. When perforated sheet metal is used for the bottoms, the perforations should be approximately the equivalent of 1-inch holes on 2-inch centers. If dividers are used between the layers of containers, they should be perforated as above. The positioning of containers in the retort, when specified in the scheduled process, shall be in accordance with that process.

(10) *Air valves.* Retorts using air for pressure cooling shall be equipped with a suitable valve to prevent air leakage into the retort during processing.

(11) *Water valves.* Retorts using water for cooling shall be equipped with a suitable valve to prevent leakage of water into the retort during processing.

(12) *Vents.* Vents shall be installed in such a way that air is removed from the retort before timing of the process is started. Vents shall be controlled by gate, plug cock, or other adequate type valves which shall be fully open to permit rapid discharge of air from the retort during the venting period. Vents shall not be connected directly to a closed drain system. If the overflow is used as a vent, there shall be an atmospheric break in the line before it connects to a closed drain. The vent shall be located in that portion of the retort opposite the steam inlet; for example, steam inlet in bottom portion and vent in top portion. Where a retort manifold connects several vent pipes from a single still retort, it shall be controlled by a gate, plug cock, or other adequate type valve. The retort manifold shall be of a size that the cross-sectional area of the pipe is larger than the total cross-sectional area of all connecting vents. The discharge shall not be directly connected to a closed drain without an atmospheric break in the line. A manifold header connecting vents or manifolds from several still retorts shall lead to the atmosphere. The manifold header shall not be controlled by a valve and shall be of a size that the cross-sectional area is at least equal to the total cross-sectional area of all connecting retort manifold pipes from all retorts venting simultaneously. Timing of the process shall not begin until the retort has been properly vented and the processing temperature has been reached. Some typical installations and operating procedures reflecting the requirements of this section for venting still retorts are given in paragraph (a)(12)(i)(*a*) through (*d*) and (ii)(*a*) and (*b*) of this section.

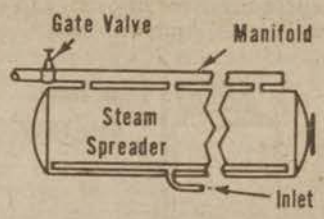
(i) *Venting horizontal retorts.* (*a*) Venting through multiple 1-inch vents discharging directly to atmosphere.



Specifications. One 1-inch vent for every 5 feet of retort length, equipped with a gate or plug cock valve and discharging to atmosphere; end vents not more than 2½ feet from ends of retort.

Venting method. Vent valves should be wide open for at least 5 minutes and to at least 225° F, or at least 7 minutes and to at least 220° F.

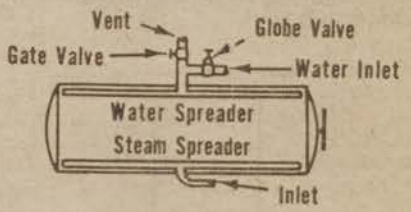
(*b*) Venting through multiple 1-inch vents discharging through a manifold to atmosphere.



Specifications. One 1-inch vent for every 5 feet of retort length; and vents not over 2½ feet from ends of retort: Size of manifold—for retorts less than 15 feet in length, 2½ inches; for retorts 15 feet and over in length, 3 inches.

Venting method. Manifold vent gate or plug cock valve should be wide open for at least 6 minutes and to at least 225° F, or for at least 8 minutes and to at least 220° F.

(c) Venting through water spreaders.

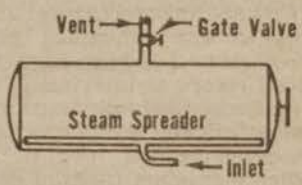


Size of vent and vent valve. For retorts less than 15 feet in length, 2 inches; for retorts 15 feet and over in length, 2½ inches.

Size of water spreader. For retorts less than 15 feet in length, 1½ inches; for retorts 15 feet and over in length, 2 inches. The number of holes should be such that their total cross-sectional area is approximately equal to the cross-sectional area of the vent pipe inlet.

Venting method. Water spreader vent gate or plug cock valve should be wide open for at least 5 minutes and to at least 225° F, or for at least 7 minutes and to at least 220° F.

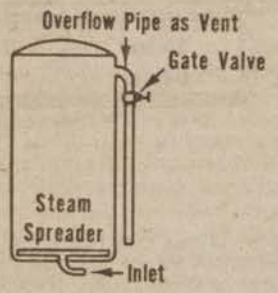
(*d*) Venting through a single 2½-inch top vent (for retorts not exceeding 15 feet in length).



Specifications: A 2½-inch vent equipped with a 2½-inch gate or plug cock valve and located within 2 feet of the center of the retort.

Venting method: Vent gate or plug cock valve should be wide open for at least 4 minutes and to at least 220° F.

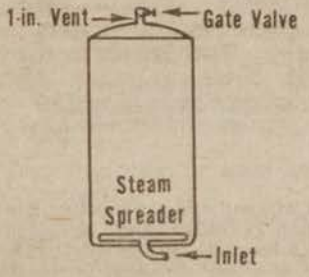
(ii) *Venting vertical retorts.* (*a*) Venting through a 1½-inch overflow.



Specifications. A 1½-inch overflow pipe equipped with a 1½-inch gate or plug cock valve and with not more than 6 feet of 1½-inch pipe beyond the valve before break to the atmosphere or to a manifold header.

Venting method. Vent gate or plug cock valve should be wide open for at least 4 minutes and to at least 218° F, or for at least 5 minutes and to at least 215° F.

(*b*) Venting through a single 1-inch side or top vent.



Specifications. A 1-inch vent in lid or top side, equipped with a 1-inch gate or plug cock valve and discharging directly into the atmosphere or to a manifold header.

Venting method. Vent gate or plug cock valve should be wide open for at least 5 minutes and to at least 230° F, or for at least 7 minutes and to at least 220° F.

(iii) Other installations and operating procedures that deviate from the above specifications may be used if there is evidence in the form of heat distribution data, which shall be kept on file, that they accomplish adequate venting of air.

(13) *Critical factors.* Critical factors specified in the scheduled process shall be measured and recorded on the processing record at intervals of sufficient frequency to ensure that the factors are within the limits specified in the scheduled process.

(i) When maximum fill-in or drained weight is specified in the scheduled process, it shall be measured and recorded at intervals of sufficient frequency to ensure that the weight of the product does not exceed the maximum for the given container size specified in the scheduled process.

(ii) Closing machine vacuum in vacuum-packed products shall be observed and recorded at intervals of sufficient frequency to ensure that the vacuum is as specified in the scheduled process.

(iii) Such measurements and recordings should be made at intervals not to exceed 15 minutes.

(iv) When the product style results in stratification or layering of the primary product in the containers, the positioning of containers in the retort shall be according to the scheduled process.

(b) *Equipment and procedures for pressure processing in water in still retorts*—(1) *Indicating mercury-in-glass thermometer.* Each retort shall be equipped with at least one mercury-in-glass thermometer whose divisions are easily readable to 1° F and whose temperature range does not exceed 17° F per inch of graduated scale. Thermometers shall be tested for accuracy against a known accurate standard thermometer upon installation and at least once a year thereafter, or more frequently if necessary, to ensure their accuracy. Records of thermometer accuracy checks which specify date, standard used, method used, and person performing the test should be maintained. Each thermometer should have a tag, seal, or other means of identity that includes the date when it was last tested for accuracy. A thermometer that has a divided mercury column or that cannot be adjusted to the standard shall be repaired or replaced before further use of the retort. Thermometers shall be installed where they can be accurately and easily read. Bulbs of indicating thermometers shall be located in such a position that they are beneath the surface of the water throughout the process. On horizontal retorts, this entry should be made in the side at the center, and the thermometer bulbs shall be inserted directly into the retort shell. In both vertical and horizontal retorts, the thermometer bulbs shall extend directly into the water a minimum of at least 2 inches without a separable well or sleeve. The mercury thermometer—not the recorder chart—shall be the reference instrument for indicating the processing temperature.

(2) *Temperature-recording device.* Each still retort shall have an accurate temperature-recording device. Graduations on the temperature-recording devices shall not exceed 2° F within a range of 10° F of the processing temperature. Each chart shall have a working scale of not more than 55° F per inch within a range of 20° F of the processing temperature. The temperature chart shall be adjusted to agree as nearly as possible with, but to be in no event higher than, the known accurate mercury-in-glass thermometer during the process time. A means of preventing unauthorized changes in adjustment shall be provided. A lock, or a notice from management posted at or near the recording device which provides a warning that only authorized persons are permitted to make adjustments, is a satisfactory means for preventing unauthorized changes. The recorder may be combined with the steam controller and may be a recording-controlling instrument. The recording-thermometer bulb should be located adjacent to the bulb of the mercury-in-glass thermometer, except in the case of a vertical retort equipped with a combination recorder-controller. In such vertical retorts, the temperature recorder-control bulb shall be located at the bottom of the retort below the lowest crate rest in such a position that the steam does not strike it directly. In horizontal retorts, the temperature recorder-control bulb shall be located between the water surface and the horizontal plane passing through the center of the retort so that there is no opportunity for direct steam impingement on the control bulb. Air-operated temperature controllers should have adequate filter systems to ensure a supply of clean, dry air.

(3) *Pressure gages.* (i) Each retort should be equipped with a pressure gage, which should be graduated in divisions of 2 pounds or less.

(ii) Each retort should have an adjustable pressure relief or control valve of a capacity sufficient to prevent an undesired increase in retort pressure when the water valve is wide open and should be installed in the overflow line.

(4) *Steam controller.* Each retort shall be equipped with an automatic steam controller to maintain the retort temperature. This may be a recording-controlling instrument when combined with a recording thermometer.

(5) *Steam introduction.* Steam shall be distributed in the bottom of the retort in a manner adequate to provide uniform heat distribution throughout the retort. In vertical retorts, uniform steam distribution can be achieved by any of several methods. In horizontal retorts, the steam distributor shall run the length of the bottom of the retort with perforations distributed uniformly along the upper part of the pipe.

(6) *Crate supports.* A bottom crate support shall be used in vertical still retorts. Baffle plates shall not be used in the bottom of the retort. Centering guides should be installed so as to ensure that there is about a 1½-inch clearance between the side wall of the crate and the retort wall.

(7) *Stacking equipment and position of containers.* Crates, trays, gondolas, etc., for holding containers shall be

made of strap iron, adequately perforated sheet metal, or other suitable material. When perforated sheet metal is used for the bottoms, the perforations should be approximately the equivalent of 1-inch holes on 2-inch centers. If divider plates are used between the layers of containers, they should be perforated as above. The positioning of containers in the retort, when specified in the scheduled process, shall be in accordance with that process. Dividers, racks, trays, or other means of positioning of flexible containers shall be designed and employed to ensure even circulation of heating medium around all containers in the retort.

(8) *Drain valve.* A nonclogging, water-tight valve shall be used. Screens should be installed over all drain openings.

(9) *Water level indicator.* There shall be a means of determining the water level in the retort during operation, e.g., by using a gage, water glass, or petcock(s). Water shall cover the top layer of containers during the entire come-up-time and processing periods and should cover the top layer of containers during the cooling periods. The operator shall check and record the water level at intervals sufficient to ensure its adequacy.

(10)(i) *Air supply and controls.* In both horizontal and vertical still retorts for pressure processing in water, a means shall be provided for introducing compressed air at the proper pressure and rate. The proper pressure shall be controlled by an automatic pressure control unit. A check valve shall be provided in the air supply line to prevent water from entering the system. Air or water circulation shall be maintained continuously during the come-up-time and during processing and cooling periods; the adequacy of the air or water circulation for uniform heat distribution within the retort shall be established in accordance with procedures recognized by a competent processing authority and records shall be kept on file; if air is used to promote circulation, it shall be introduced into the steam line at a point between the retort and the steam control valve at the bottom of the retort.

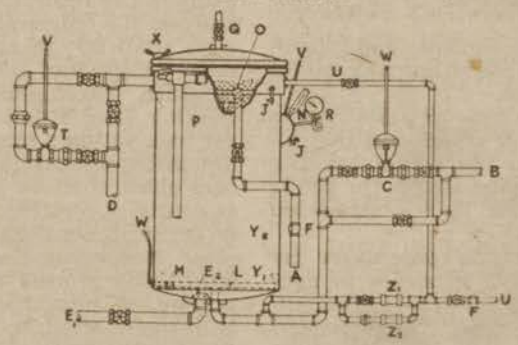
(ii) *Water circulation.* When a water circulating system is used for heat distribution, is shall be installed in such a manner that water will be drawn from the bottom of the retort through a suction manifold and discharged through a spreader which extends the length of the top of the retort. The holes in the water spreader shall be uniformly distributed and should have an aggregate area not greater than the cross-section area of the outlet line from the pump. The suction outlets should be protected with nonclogging screens to keep debris from entering the circulating system. The pump shall be equipped with a pilot light or other signaling device to warm the operator when it is not running, and with a bleeder to remove air when starting operations. Alternative methods for circulation of water in the retort may be used when established by a competent authority as adequate for even heat distribution.

(11) *Cooling water supply.* In vertical retorts the cooling water should be introduced at the top of the retort between the water and container levels; in horizontal retorts the cooling water should be introduced into the suction side of the pump. A check valve should be included in the cooling water line.

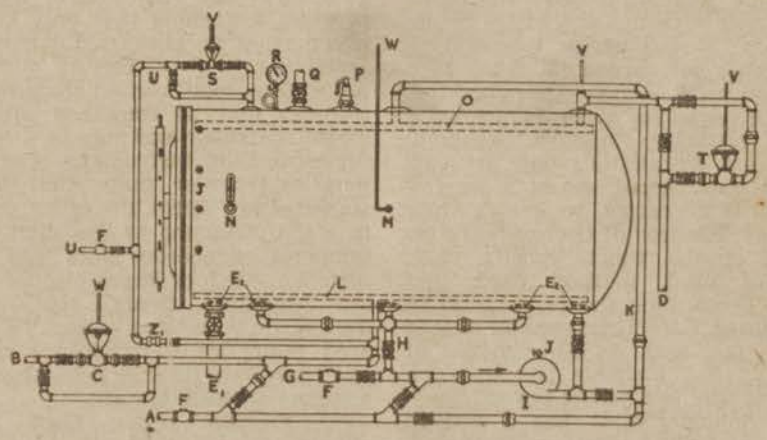
(12) *Retort headspace.* The headspace necessary to control the air pressure should be maintained between the water level and the top of the retort shell.

(13) *Vertical and horizontal still retorts.* Vertical and horizontal still retorts should follow the arrangements in the diagrams below in this paragraph. Other installation and operating procedures that deviate from these arrangements may be used, as long as there is evidence in the form of heat distribution data or other suitable information, which shall be kept on file, that demonstrates that the heat distribution is adequate.

Vertical Retorts



Horizontal Retorts



LEGEND FOR VERTICAL AND HORIZONTAL STILL RETORTS

A—Water line.
B—Steam line.
C—Temperature control.
D—Overflow line.
E_1—Drain line.
E_2—Screens.
F—Check valves.
G—Line from hot water storage.
H—Suction line and manifold.
I—Circulating pump.
J—Petcocks.
K—Recirculating line.
L—Steam distributor.
M—Temperature-controller bulb.
N—Thermometer.
O—Water spreader.
P—Safety valve.
Q—Vent valve for steam processing.
R—Pressure gage.
S—Inlet air control.
T—Pressure control.
U—Air line.
V—To pressure control instrument.
W—To temperature control instrument.
X—Wing nuts.
Y_1—Crate support.
Y_2—Crate guides.
Z—Constant flow orifice valve.
Z_1—Constant flow orifice valve used during come-up.
Z_2—Constant flow orifice valve used during cook.

(14) *Critical factors.* Critical factors specified in the scheduled process shall be measured and recorded on the processing record at intervals of sufficient frequency to ensure that the factors are within the limits specified in the scheduled process.

(i) When maximum fill-in or drained weight is specified in the scheduled process, it shall be measured and recorded at intervals of sufficient frequency to ensure that the weight of the product does not exceed the maximum for the given container size specified in the scheduled process.

(ii) Closing machine vacuum in vacuum-packed products shall be observed and recorded at intervals of sufficient frequency to ensure that the vacuum is as specified in the scheduled process.

(iii) Such measurements and recordings should be made at intervals not to exceed 15 minutes.

(iv) When the product style results in stratification or layering of the primary product in the containers, the positioning of containers in the retort shall be according to the scheduled process.

(c) *Equipment and procedures for pressure processing in steam in continuous agitating retorts*—(1) *Indicating mercury-in-glass thermometer.* Each retort shall be equipped with at least one mercury-in-glass thermometer whose divisions are easily readable to 1° F and whose temperature range does not exceed 17° F per inch of graduated scale. Thermometers shall be tested for accuracy against a known accurate standard thermometer upon installation and at least once a year thereafter, or more frequently if necessary, to ensure their accuracy. Records of thermometer accuracy checks which specify date, standard used, method used, and person performing the test should be maintained. Each thermometer should have a tag, seal, or other means of identity that includes the date on which it was last tested for accuracy. A thermometer that has a divided mercury column or that cannot be adjusted to the standard shall be repaired or replaced before further use of the retort. Thermometers shall be installed where they can be accurately and easily read. Bulbs in indicating thermometers shall be installed either within the retort shell or in external wells attached to the retort. External wells or pipes shall be connected to the retort through at least a ¾-inch diameter opening, and equipped with a 1/16-inch or larger bleeder opening so located as to provide a full flow of steam past the length of the thermometer bulb. The bleeders for external wells shall emit steam continuously during the entire processing period. The mercury thermometer—not the recorder chart—shall be the reference instrument for indicating the processing temperature.

(2) *Temperature-recording device.* Each retort shall have an accurate temperature-recording device. Graduations on the temperature-recording devices shall not exceed 2° F within a range of 10° F of the processing temperature. Each chart shall have a working scale of not more than 55° F per inch within a range of 20° F of the processing temperature. The temperature chart shall be adjusted to agree as nearly as possible with, but to be in no event higher than, the known accurate mercury-in-glass thermometer during the process time. A means of preventing unauthorized changes in adjustment shall be provided. A lock, or a notice from management posted at or near the recording device that provides a warning that only authorized persons are permitted to make adjustments, is a satisfactory means of preventing unauthorized changes. The recorder may be combined with the steam controller and may be a recording-controlling instrument. The temperature-recorder bulb shall be installed either within the retort shell or in a well attached to the shell. Each temperature-recorder bulb well shall have a 1/16-inch or larger bleeder opening emitting steam continuously during the processing period. Air-operated temperature controllers should have adequate filter systems to ensure a supply of clean, dry air.

(3) *Pressure gages.* Each retort should be equipped with a pressure gage that should be graduated in divisions of 2 pounds or less.

(4) *Steam controller.* Each retort shall be equipped with an automatic steam controller to maintain the retort temperature. This may be a recording-controlling instrument when combined with a recording thermometer. A steam controller activated by the steam pressure of the retort is acceptable if it is carefully maintained mechanically so that it operates satisfactorily.

(5) *Bleeders.* Bleeders, except those for thermometer wells, shall be one-eight inch or larger and shall be wide open during the entire process, including the come-up-time. Bleeders shall be located within approximately 1 foot of the outermost location of containers at each end along the top of the retort; additional bleeders shall be located not more than 8 feet apart along the top of the retort. All bleeders shall be arranged so that the operator can observe that they are functioning properly. The condensate bleeder shall be checked with sufficient frequency to ensure adequate removal of condensate or shall be equipped with an automatic alarm system(s) that would serve as a continuous monitor of condensate-bleeder functioning. Visual checks should be done at intervals of not more than 15 minutes. A record of such checks should be kept to show that the bleeder is functioning properly.

(6) *Venting and condensate removal.* Vents shall be located in that portion of the retort opposite the steam inlet. Air shall be removed before processing is started. Heat distribution data or documentary proof from the manufacturer or from a competent processing authority, demonstrating that adequate venting is achieved, shall be kept on file. At the time steam is turned on, the drain should be opened for a time sufficient to remove steam condensate from the retort, and provision shall be made for continuing drainage of condensate during the retort operation. The condensate bleeder in the bottom of the shell serves as an indicator of continuous condensate removal.

(7) *Retort speed timing.* The rotational speed of the retort shall be specified in the scheduled process. The speed shall be adjusted and recorded when the retort is started, at any time

a speed change is made, and at intervals of sufficient frequency to ensure that the retort speed is maintained as specified in the scheduled process. These adjustments and recordings should be made every 4 hours or less. Alternatively, a recording tachometer may be used to provide a continuous record of the speed. A means of preventing unauthorized speed changes on retorts shall be provided. A lock, or a notice from management posted at or near the speed adjustment device that provides a warning that only authorized persons are permitted to make adjustments, is a satisfactory means of preventing unauthorized changes.

(8) *Emergency stops.* If a retort jams or breaks down during processing operations, necessitating cooling the retort for repairs, the retort shall be operated in such a way that ensures that the product is commercially sterile, or the retort is to be cooled promptly and all containers either reprocessed, repacked and reprocessed, or discarded. When operated as a still retort, all containers shall be given a full still retort process before the retort is cooled. If, in such an emergency, a scheduled still process or another process established to ensure commercial sterility is to be used, it shall be made readily available to the retort operator.

(i) Any containers in the retort intake valve or in transfer valves between cooker shells of a continuous retort at the time of breakdown shall either be reprocessed, repacked and reprocessed, or discarded.

(ii) Both the time at which the reel stopped and the time the retort was used for a still retort process, if so used, shall be marked on the recording chart and entered on the other production records required in this chapter. If the alternative procedure of prompt cooling is followed, the subsequent handling methods used for the containers in the retort at the time of stopping and cooling shall be entered on the production records.

(9) *Temperature drop.* If the temperature of the continuous retort drops below the temperature specified in the scheduled process while containers are in the retort, the retort reel shall be stopped promptly. An automatic device should be used to stop the reel when the temperature drops below the specified process temperature. Before the reel is restarted, all containers in the retort shall be given a complete scheduled still retort process if the temperature drop was 10° F or more below the specified temperature, or alternatively, container entry to the retort shall be stopped and the reel restarted to empty the retort. The discharged containers shall be either reprocessed, repacked and reprocessed, or discarded. Both the time at which the reel stopped and the time the retort was used for a still retort process, if so used, shall be marked on the recording chart and entered on the other production records required in this chapter. If the alternative procedure of emptying the retort is followed, the subsequent handing methods used for the containers in the retort at the time of the temperature drop shall be entered on the production records. If the temperature drop was less than 10° F, a scheduled authorized emergency still process approved by a qualified person(s) having expert knowledge of thermal processing requirements may be used before restarting the retort reel. Alternatively, container entry to the retort shall be stopped and an authorized emergency agitating process may be used before container entry to the retort is restarted. When emergency procedures are used, no containers may enter the retort and the process and procedures used shall be noted on the production records.

(10) *Critical factors.* Critical factors specified in the scheduled process shall be measured and recorded on the processing record at intervals of sufficient frequency to ensure that the factors are within the limits specified in the scheduled process. The minimum headspace of containers, if specified in the scheduled process, shall be measured and recorded at intervals of sufficient frequency to ensure that the headspace is as specified in the scheduled process. The headspace of solder-tipped, lapseam (vent hole) cans may be measured by net weight determinations. The headspace of double seamed cans may also be measured by net weight determinations for homogenous liquids, taking into account the specific can end profile and other factors which affect the headspace, if proof of the accuracy of such measurements is maintained and the procedure and resultant headspace is in accordance with the scheduled process. When the product consistency is specified in the scheduled process, the consistency of the product shall be determined by objective measurements on the product taken from the filler before processing and recorded at intervals of sufficient frequency to ensure that the consistency is as specified in the scheduled process. Minimum closing machine vacuum in vacuum-packed products, maximum fill-in or drained weight, minimum net weight, and percent solids shall be as specified in the scheduled process for all products when deviations from such specifications may affect the scheduled process. All measurements and recordings of critical factors should be made at intervals not to exceed 15 minutes.

(d) *Equipment and procedures for pressure processing in steam in discontinuous agitating retorts*—(1) *Indicating mercury-in-glass thermometer.* Each retort shall be equipped with at least one mercury-in-glass thermometer whose divisions are easily readable to 1° F and whose temperature range does not exceed 17° F per inch of graduated scale. Thermometers shall be tested for accuracy against a known accurate standard thermometer upon installation and at least once a year thereafter, or more frequently if necessary, to ensure their accuracy. Records of thermometer accuracy checks which specify date, standard used, method used, and person performing the test should be maintained. Each thermometer should have a tag, seal, or other means of identity that includes the date on which it was last tested for accuracy. A thermometer that has a divided mercury column or that cannot be adjusted to the standard shall be repaired or replaced before further use of the retort. Thermometers shall be installed where they can be accurately and easily read. Bulbs of indicating thermometers shall be installed either within the retort shell or in external wells attached to the retort. External wells or pipes shall be connected to the retort through at least a ¾-inch-diameter opening, and equipped with a 1/16-inch or larger bleeder opening so located as to provide a full flow of steam past the length of the thermometer bulb. The bleeder for external wells shall emit steam continuously during the entire processing period. The mercury thermometer—not the recorder chart—shall be the reference instrument for indicating the processing temperature.

(2) *Temperature-recording device.* Each retort shall have an accurate temperature-recording device. Graduations on the temperature-recording devices shall not exceed 2° F within a range of 10° F of the processing temperature. Each chart shall have a working scale of not more than 55° F per inch within a range of 20° F of the processing temperature. The temperature chart shall be adjusted to agree as nearly as possible with, but to be in no event higher than, the known accurate mercury-in-glass thermometer during the process time. A means of preventing unauthorized changes in adjustment shall be provided. A lock, or a notice from management posted at or near the recording device that provides a warning that only authorized persons are permitted to make adjustments, is a satisfactory means for preventing unauthorized changes. The recorder may be combined with the steam controller and may be a recording-controlling instrument. The temperature-recorder bulb shall be in-

stalled either within the retort shell or in a well attached to the shell. Each temperature-recorder bulb well shall have a 1/16-inch or larger bleeder opening emitting steam continuously during the processing period. Air-operated temperature controllers should have adequate filter systems to ensure a supply of clean, dry air.

(3) *Pressure gages.* Each retort should be equipped with a pressure gage, which should be graduated in divisions of 2 pounds or less.

(4) *Steam controller.* Each retort shall be equipped with an automatic steam controller to maintain the retort temperature. This may be a recording-controlling instrument when combined with a recording thermometer. A steam controller activated by the steam pressure of the retort is acceptable if it is mechanically maintained so that it operates satisfactorily.

(5) *Bleeders.* Bleeders, except those for thermometer wells, shall be one-eighth inch or larger and shall be wide open during the entire process, including the come-up-time. Bleeders shall be located within approximately 1 foot of the outermost location of containers, at each end along the top of the retort; additional bleeders shall be located not more than 8 feet apart along the top. Bleeders may be installed at positions other than those specified above, as long as there is evidence in the form of heat distribution data that they accomplish adequate removal of air and circulation of heat within the retort. In retorts having top steam inlet and bottom venting, a bleeder shall be installed in the bottom of the retort to remove condensate. All bleeders shall be arranged in a way that enables the operator to observe that they are functioning properly.

(6) *Venting and condensate removal.* The air in each retort shall be removed before processing is started. Heat distribution data or documentary proof from the manufacturer or from a competent processing authority, demonstrating that adequate venting is achieved, shall be kept on file. At the time steam is turned on, the drain should be opened for a time sufficient to remove steam condensate from the retort and provision should be made for containing drainage of condensate during the retort operation.

(7) *Retort speed timing.* The rotational speed of the retort shall be specified in the schedules process. The speed shall be adjusted, as necessary, to ensure that the speed is as specified in the scheduled process. The rotational speed as well as the process time shall be recorded for each retort load processed. Alternatively, a recording tachometer may be used to provide a continuous record of the speed. A means of preventing unauthorized speed changes on retorts shall be provided. A lock, or a notice from management posted at or near the speed-adjustment device that provides a warning that only authorized persons are permitted to make adjustments, is a satisfactory means of preventing unauthorized changes.

(8) *Critical factors.* Critical factors specified in the schedules process shall be measured and recorded on the processing record at intervals of sufficient frequency to ensure that the factors are within the limits specified in the scheduled process. The minimum headspace of containers in each retort load to be processed, if specified in the scheduled process, shall be measured and recorded at intervals of sufficient frequency to ensure that the headspace is as specified in the scheduled process. The headspace of solder-tipped, lap seam (vent hole) cans may be measured by net weight determinations. When the product consistency is specified in the scheduled process, the consistency of the product shall be determined by objective measurements on the product taken from the filler before processing and recorded at intervals of sufficient frequency to ensure that the consistency is as specified in the scheduled process. Minimum closing machine vacuum in vacuum-packed products, maximum fill-in or drained weight, minimum net weight, and percent solids shall be as specified in the scheduled process for all products for which deviations from such specifications may affect the scheduled process. All measurements and recordings of critical factors should be made at intervals not to exceed 15 minutes.

(e) *Equipment and procedures for pressure processing in water in discontinuous agitating retorts—(1) Indicating mercury-in-glass thermometer.* Each retort shall be equipped with at least one mercury-in-glass thermometer whose divisions are easily readable to 1° F and whose temperature range does not exceed 17° F per inch of graduated scale. Thermometers shall be tested for accuracy against a known accurate standard thermometer upon installation and at least once a year thereafter, or more frequently if necessary, to ensure their accuracy. Records of thermometer accuracy checks which specify date, standard use, method used, and person performing the test should be maintained. Each thermometer should have a tag, seal, or other means of identity that includes the date on which it was last tested for accuracy. A thermometer that has a divided mercury column or that cannot be adjusted to the standard shall be repaired or replaced before further use of the retort. Thermometers shall be installed where they can be accurately and easily read. Bulbs of indicating thermometers shall be installed either within the retort shell or in external wells attached to the retort. The mercury thermometer—not the recorder chart—shall be the reference instrument for indicating the processing temperature.

(2) *Temperature-recording device.* Each retort shall have an accurate temperature-recording device. Graduations on the temperature-recording devices shall not exceed 2° F within a range of 10° F of the processing temperature. Each chart shall have a working scale of not more than 55° F per inch within a range of 20° F of the processing temperature. The temperature chart shall be adjusted to agree as nearly as possible with, but to be in no event higher than, the known accurate mercury-in-glass thermometer during the process time. A means of preventing unauthorized changes in adjustment shall be provided. A lock, or a notice from management posted at or near the recording device that provides a warning that only authorized persons are permitted to make adjustment, is a satisfactory means for preventing unauthorized changes. This recorder may be combined with the steam controller and may be a recording-controlling instrument. The temperature-recorder bulb shall be installed either within the retort shell or in a well attached to the shell. Air-operated temperature controllers should have adequate filter systems to ensure a supply of clean dry air.

(3) *Pressure gages.* Each retort should be equipped with a pressure gage which should be graduated in divisions of 2 pounds or less.

(4) *Steam controller.* Each retort shall be equipped with an automatic steam controller to maintain the retort temperature. This may be a recording-controlling instrument when combined with a recording thermometer.

(5) *Retort speed timing.* The rotational speed of the retort shall be specified in the scheduled process. The speed shall be adjusted, as necessary, to ensure that the speed is as specified in the scheduled process. The rotational speed as well as the process time shall be recorded for each retort load processed. Alternatively, a recording tachometer may be used to provide a continuous record of the speed. A means of preventing unauthorized speed changes shall be provided. A lock, or a notice from management posted at or near the speed adjustment device that provides a warning that only authorized persons are permitted to make adjustment, is a satisfactory means of preventing unauthorized changes.

(6) *Air supply and controls.* Means shall be provided for introducing com-

pressed air at the proper pressure and rate, which shall be controlled by an automatic pressure control unit. A check valve shall be provided in the air supply line to prevent water from entering the system.

(7) *Critical factors.* Critical factors specified in the scheduled process shall be measured and recorded on the processing record at intervals of sufficient frequency to ensure that the factors are within the limits specified in the scheduled process. The minimum headspace of containers, if specified in the scheduled process, shall be measured and recorded at intervals of sufficient frequency to ensure that the headspace is as specified in the scheduled process. The headspace of solder-tipped, lap seam (vent hole) cans may be measured by net weight determinations. When the product consistency is specified in the scheduled process, the consistency of the product shall be determined by objective measurements on the product taken from the filler before processing and recorded at intervals of sufficient frequency to ensure that the consistency is as specified in the scheduled process. Minimum closing machine vaccum in vacuum-packed products, maximum fill-in or drained weight, minimum net weight, and percent solids shall be as specified in the scheduled process for all products when deviations from such specifications may affect the scheduled process. All measurements and recordings of critical factors should be made at intervals not to exceed 15 minutes.

(f) *Equipment and procedures for pressure processing in steam in hydrostatic retorts*—(1) *Indicating mercury-in-glass thermometer.* Each retort shall be equipped with at least one mercury-in-glass thermometer whose divisions are easily readable to 1° F and whose temperature range does not exceed 17° F per inch of graduated scale. Thermometer shall be tested for accuracy against a known accurate standard thermometer upon installation and at least once a year thereafter, or more frequently if necessary, to ensure their accuracy. Records of thermometer accuracy checks which specify date, standard used, method used, and person performing the test should be maintained. Each thermometer should have a tag, seal, or other means of identity that includes the date on which it was last tested for accuracy. A thermometer that has a divided mercury column or that cannot be adjusted to the standard shall be repaired or replaced before further use of the retort. Thermometers shall be installed where they can be accurately and easily read. The thermometer shall be located in the steam dome near the steam-water interface. When the scheduled process specifies maintenance of particular temperatures in the hydrostatic water legs, a mercury-in-glass thermometer shall be located in each hydrostatic water leg in a position near the bottom automatic recorder. The mercury thermometer—not the recorder chart—shall be the references instrument for indicating the processing temperature.

(2) *Temperature-recording device.* Each retort shall have an accurate temperature-recording device. Graduations on the temperature-recording devices shall not exceed 2° F within a range of 10° F of the processing temperature. Each chart shall have a working scale of not more than 55° F per inch within a range of 20° F of the processing temperature. The temperature chart shall be adjusted to agree as nearly as possible with, but to be in no event higher than, the known accurate mercury-in-glass thermometer during the process time. A means of preventing unauthorized changes in adjustment shall be provided. A lock, or a notice from management posted at or near the recording device that provides a warning that only authorized persons are permitted to make adjustments, is a satisfactory means for preventing unauthorized changes. The recorder may be combined with the steam controller and may be a recording-controlling instrument. The temperature-recorder bulb shall be installed either within the steam dome or in a well attached to the dome. Each temperature-recorder bulb well shall have a 1/16-inch or larger bleeder opening which emits steam continuously during the processing period. Additional temperature-recorder bulbs shall be installed in the hydrostatic water legs if the scheduled process specified maintenance of particular temperatures in the hydrostatic water legs. Air-operated temperature controllers should have adequate filter systems to ensure a supply of clean dry air.

(3) *Pressure gages.* Each retort should be equipped with a pressure gage which should be graduated in divisions of 2 pounds or less.

(4) *Recording of temperatures.* Temperatures indicated by the mercury-in-glass thermometer or thermometers shall be entered on a suitable form during processing operations. Temperatures shall be recorded by an accurate automatic recorder or recorders at the following points:

(i) In the steam chamber between the steam-water interface and the lowest container position.

(ii) Near the top and the bottom of each hydrostatic water leg if the scheduled process specifies maintenance of particular temperatures in the legs.

(5) *Steam controller.* Each retort shall be equipped with an automatic steam controller to maintain the retort temperature. This may be a recording-controlling instrument when combined with a recording thermometer. A steam controller activated by the steam pressure of the retort is acceptable if it is carefully mechanically maintained so that it operates satisfactorily.

(6) *Venting.* Before the start of processing operations, the retort steam chamber or chambers shall be vented to ensure removal of air.

(7) *Bleeders.* Bleeder openings 1/4-inch or larger shall be located at the top of the steam chamber or chambers opposite the point of steam entry. Bleeders shall be wide open and shall emit steam continuously during the entire process, including the come-up-time. All bleeders shall be arranged in such a way that the operator can observe that they are functioning properly.

(8) *Retort speed.* The speed of the container-conveyor chain shall be specified in the scheduled process and shall be determined and recorded at the start of processing and at intervals of sufficient frequency to ensure that the retort speed is maintained as specified. The speed should be determined and recorded every 4 hours. An automatic device should be used to stop the chain when the temperature drops below that specified in the scheduled process. A means of preventing unauthorized speed changes shall be provided. A lock, or a notice from management posted at or near the speed-adjusting device that provides a warning that only authorized persons are permitted to make adjustments, is a satisfactory means of preventing unauthorized changes.

(9) *Critical factors.* Critical factors specified in the scheduled process shall be measured and recorded on the processing record at intervals of sufficient frequency to ensure that the factors are within the limits specified in the scheduled process.

(i) When maximum fill-in or drained weight is specified in the scheduled process, it shall be measured and recorded at intervals of sufficient frequency to ensure that the weight of the product does not exceed the maximum for the given container size specified in the scheduled process.

(ii) Closing machine vacuum in vacuum-packed products shall be observed and recorded at intervals of sufficient frequency to ensure that the vacuum is as specified in the scheduled process.

(iii) Such measurements and recordings should be made at intervals not to exceed 15 minutes.

(g) *Aseptic processing and packaging systems*—(1) *Product sterilizer*—(i) *Equipment*—(a) *Temperature-indicating device.* Each product sterilizer

shall be equipped with at least one mercury-in-glass thermometer or an equivalent temperature-indicating device, such as a thermocouple-recorder. Mercury-in-glass thermometers shall have divisions that are easily readable to 1° F and whose temperature range does not exceed 17° F per inch of graduated scale. Thermometers and temperature-indicating devices shall be tested for accuracy against a known accurate standard thermometer upon installation and at least once a year thereafter, or more frequently if necessary, to ensure their accuracy. Records of accuracy checks which specify date, standard used, method used, and person performing the test should be maintained. Each thermometer and temperature-indicating device should have a tag, seal, or other means of identity that includes the date on which it was last tested for accuracy. A thermometer that has a divided mercury column or that cannot be adjusted to essential agreement with the standard shall be repaired or replaced. Thermometers and temperature-indicating devices shall be installed where they can be accurately and easily read. The temperature-indicating device shall be the reference instrument for indicating the processing temperature.

(b) *Temperature-recording device.* There shall be an accurate temperature recording device on each product sterilizer. The device shall be installed in the product at the holding-tube outlet between the holding tube and the inlet to the cooler. Temperature-recording devices shall have graduations that do not exceed 2° F within a range of 10° F of the processing temperature. Each chart shall have a working scale of not more than 55° F per inch within a range of 20° F of the desired product-sterilization temperature.

The temperature chart shall be adjusted to agree as nearly as possible with, but to be in no event higher than, a known accurate mercury-in-glass thermometer. A means of preventing unauthorized changes in adjustment shall be provided. A lock; or a notice from management posted at or near the recording device that provides a warning that only authorized persons are permitted to make adjustments, is a satisfactory means for preventing unauthorized changes.

(c) *Temperature recorder-controller.* An accurate temperature recorder-controller shall be located in the product sterilizer at the final heater outlet. It shall be capable of ensuring that the desired product sterilization temperature is maintained. The chart graduations shall not exceed 2° F within a range of 10° F of the desired product sterilization temperature. Air-operated temperature controllers should have adequate filter systems to ensure a supply of clean, dry air.

(d) *Product-to-product regenerators.* When a product-to-product regenerator is used to heat the cold unsterilized product entering the sterilizer by means of a heat exchange system, it shall be designed, operated, and controlled so that the pressure of the sterilized product in the regenerator is greater than the pressure of any unsterilized product in the regenerator to ensure that any leakage in the regenerator is from the sterilized product into the unsterilized product.

(e) *Differential pressure recorder-controller.* When a product-to-product regenerator is used, there shall be an accurate differential pressure recorder-controller installed on the regenerator. The scale divisions shall not exceed 2 pounds per square inch on the working scale of not more than 20 pounds per square inch per inch. The controller shall be tested for accuracy against a known accurate standard pressure indicator upon installation and at least once every 3 months of operation thereafter, or more frequently if necessary, to ensure its accuracy. One pressure sensor shall be installed at the sterilized product regenerator outlet and the other pressure sensor shall be installed at the unsterilized product regenerator inlet.

(f) *Metering pump.* A metering pump shall be located upstream from the holding tube and shall be operated to maintain the required rate of product flow. A means of preventing unauthorized speed changes shall be provided. A lock, or a notice from management posted at or near the speed-adjusting device that provides a warning that only authorized persons are permitted to make adjustments, is a satisfactory means of preventing unauthorized changes.

(g) *Product holding tube.* The product-sterilizing holding tube shall be designed to give continous holding of every particle of food for at least the minimum holding time specified in the scheduled process. The holding tube shall be designed so that no portion of the tube between the product inlet and the product outlet can be heated, and it must be sloped upward at least 0.25 inch per foot.

(h) *Flow-diversion systems.* If a processor elects to install a flow-diversion system, it should be installed in the product piping located between the product cooler and the product filler or aseptic surge tank and should be designed to divert flow away from the filler or aseptic surge tank automatically. Controls and/or warning systems should be designed and installed with necessary sensors and actuators to operate whenever the sterilizing temperature in the holding tube or pressure differential in the product regenerator drops below specified limits. Flow-diversion systems should be designed and operated in accordance with recommendations of an aseptic processing and packaging authority.

(i) *Equipment downstream from the holding tube.* Product coolers, aseptic surge tanks, or any other equipment downstream from the holding tube, with rotating or reciprocating shafts, valve stems, instrument connections, or other such points, are subject to potential entry of microorganisms into the product. Such locations in the system should be equipped with steam seals or other effective barriers at the potential access points. Appropriate means should be provided to permit the operator to monitor the performance of the seals or barriers during operations.

(ii) *Operation—(a) Startup.* Before the start of aseptic processing operations the product sterilizer and all product-contact surfaces downstream shall be brought to a condition of commercial sterility.

(b) *Temperature drop in product-sterilizing holding tube.* When product temperature in the holding tube drops below the temperature specified in the scheduled process, product flow should be diverted away from the filler or aseptic surge tank by means of a flow-diversion system. If for any reason product subjected to a temperature drop below the scheduled process is filled into containers, the product shall be segregated from product that received the scheduled process. The processing deviation shall be handled in accordance with § 113.89. The product holding tube and any further system portions affected shall be returned to a condition of commercial sterility before product flow is resumed to the filler or to the aseptic surge tank.

(c) *Loss of proper pressures in the regenerator.* When a regenerator is used, the product may lose sterility whenever the pressure of sterilized product in the regenerator is less than 1 pound per square inch greater than the pressure of unsterilized product in the regenerator. In this case, product flow should be diverted away from the filler or aseptic surge tank by means of the flow-diversion system. If for any reason the product is filled into containers, the product shall be segregated from product that received the scheduled process and shall be reprocessed or destroyed. Product flow to the filler or to the aseptic surge tank shall not be resumed until the cause of the improper pressure relationships in the regenerator has been corrected and the affected system(s) has been returned to a condition of commercial sterility.

(d) *Loss of sterile air pressure or other protection level in the aseptic*

surge tank. When an aseptic surge tank is used, conditions of commercial sterility may be lost when the sterile air overpressure or other means of protection drops below the scheduled process value. Product flow to and/or from the aseptic surge tank shall not be resumed until the potentially contaminated product in the tank is removed, and the aseptic surge tank has been returned to a condition of commercial sterility.

(e) *Records.* Readings at the following points shall be observed and recorded at the start of aseptic packaging operations and at intervals of sufficient frequency to ensure that these values are as specified in the scheduled process: Temperature-indicating device in holding tube outlet; temperature recorder in holding tube outlet; temperature recorder-controller at final heater outlet; differential pressure recorder-controller, if a product-to-product regenerator is used; product flow rate as established by the metering pump or as determined by filling and closing rates and, if an aseptic surge tank is used, sterile air pressure or other protection means; and proper performance of seam seals or other similar devices. The measurements and recordings should be made at intervals not to exceed 1 hour.

(2) *Container sterilizing, filling, and closing operation*—(i) *Equipment*—(a) *Recording device.* The container and closure sterilization system and product filling and closing system shall be instrumented to demonstrate that the required sterilization is being accomplished continuously. Automatic recording devices shall be used to record, when applicable, the sterilization media flow rates, temperature, concentration, or other factors. When a batch system is used for container sterilization, the sterilization conditions shall be recorded.

(b) *Timing method(s).* A method(s) shall be used either to give the retention time of containers, and closures if applicable, in the sterilizing environment specified in the scheduled process, or to control the sterilization cycle at the rate specified in the scheduled process. A means of preventing unauthorized speed changes must be provided. A lock, or a notice from management posted at or near the speed adjusting device that provides a warning that only authorized persons are permitted to make adjustments, is a satisfactory means of preventing unauthorized changes.

(ii) *Operation*—(a) *Startup.* Before the start of packaging operations, both the container and closure sterilizing system and the product filling and closing system shall be brought to a condition of commercial sterility.

(b) *Loss of sterility.* A system shall be provided to stop packaging operations, or alternatively to ensure segregation of any product packaged when the packaging conditions fall below scheduled processes. Compliance with this requirement may be accomplished by diverting product away from the filler, by preventing containers from entering the filler, or by other suitable means. In the event product is packaged under conditions below those specified in the scheduled process, all such product shall be segregated and handled in accordance with § 113.89. In the event of loss of sterility, the system(s) shall be returned to a condition of commercial sterility before resuming packaging operations.

(c) *Records.* Observations and measurements of operating conditions shall be made and recorded at intervals of sufficient frequency to ensure that commercial sterility of the food product is being achieved; such measurements shall include the sterilization media flow rates, temperatures, the container and closure rates (if applicable) through the sterilizing system, and the sterilization conditions if a batch system is used for container sterilization. The measurements and recordings should be made at intervals not to exceed 1 hour.

(3) *Incubation.* Incubation tests should be conducted on a representative sample of containers of product from each code; records of the test results should be maintained.

(4) *Critical factors.* Critical factors specified in the scheduled process shall be measured and recorded on the processing record at intervals of sufficient frequency to ensure that the factors are within the limits specified in the scheduled process. Such measurements and recordings should be done at intervals not to exceed 15 minutes.

(h) *Equipment and procedures for flame sterilizers.* The container conveyor speed shall be specified in the scheduled process. The container conveyor speed shall be measured and recorded at the start of operations and at intervals of sufficient frequency to ensure that the conveyor speed is as specified in the scheduled process. Such measurements and recordings should be done at 1-hour intervals. Alternatively, recording tachometer may be used to provide a continuous record of the speed. A means of preventing changes in flame intensity and unauthorized speed changes on the conveyor shall be provided. A lock, or a notice from management posted at or near the speed adjusting device that provides a warning that only authorized persons are permitted to make adjustments, is a satisfactory means of preventing unauthorized changes. The surface temperature of at least one container from each conveyor channel shall be measured and recorded at the entry and at the end of the holding period at intervals of sufficient frequency to ensure that the temperatures specified in the scheduled process are maintained. Such measurements and recordings should be done at intervals not to exceed 15 minutes.

(1) *Process interruption.* In the event of process interruption wherein the temperature of the product may have dropped, an authorized, scheduled emergency plan approved by a qualified person having expert knowledge of the process requirements may be used.

(2) *Critical factors.* Critical factors specified in the scheduled process shall be measured and recorded on the processing record at intervals of sufficient frequency to ensure that the factors are within the limits specified in the scheduled process.

(i) *Equipment and procedures for thermal processing of foods wherein critical factors such as water activity are used in conjunction with thermal processing.* The methods and controls used for the manufacture, processing, and packing of such foods shall be as established in the scheduled process and shall be operated or administered in a manner adequate to ensure that the product is safe. The time and temperature of processing and other critical factors specified in the scheduled process shall be measured with instruments having the accuracy and dependability adequate to ensure that the requirements of the scheduled process are met. All measurements shall be made and recorded at intervals of sufficient frequency to ensure that the critical factors are within the limits specified in the scheduled process.

(j) *Other systems.* All systems, whether or not specifically mentioned in this part, for the thermal processing of low-acid foods in hermetically sealed containers shall conform to the applicable requirements of this part and the methods and controls used for the manufacture, processing, and packing of these foods shall be as established in the scheduled process. These systems shall be operated or administered in a manner adequate to ensure that commercial sterility is achieved. Critical factors specified in the scheduled process shall be measured and recorded at intervals of sufficient frequency to ensure that the critical factors are within the limits specified in the scheduled process.

Subpart D—Control of Components, Food Product Containers, Closures, and In-Process Materials

§ 113.60 Containers.

(a) *Closures.* Regular observations shall be maintained during production

runs for gross closure defects. Any such defects shall be recorded and corrective action taken and recorded. At intervals of sufficient frequency to ensure proper closure, the operator, closure supervisor, or other qualified container closure inspection person shall visually examine either the top seam of a can randomly selected from each seaming head or the closure of any other type of container being used and shall record the observations made. For double-seam cans, each can should be examined for cutover or sharpness, skidding or deadheading, false seam, droop at the crossover or lap, and condition of inside of countersink wall for evidence of broken chuck. Such measurements and recordings should be made at intervals not to exceed 30 minutes. Additional visual closure inspections shall be made immediately following a jam in a closing machine, after closing machine adjustment, or after startup of a machine following a prolonged shutdown. All pertinent observations shall be recorded. When irregularities are found, the corrective action shall be recorded.

(1) Teardown examinations for double-seam cans shall be performed by a qualified individual and the results therefrom shall be recorded at intervals of sufficient frequency on enough containers from each seaming station to ensure maintenance of seam integrity. Such examinations and recordings should be made at intervals not to exceed 4 hours. The results of the teardown examinations shall be recorded and the corrective action taken, if any, shall be noted.

(i) Required and optional can seam measurements:

(*a*) Micrometer measurement system:

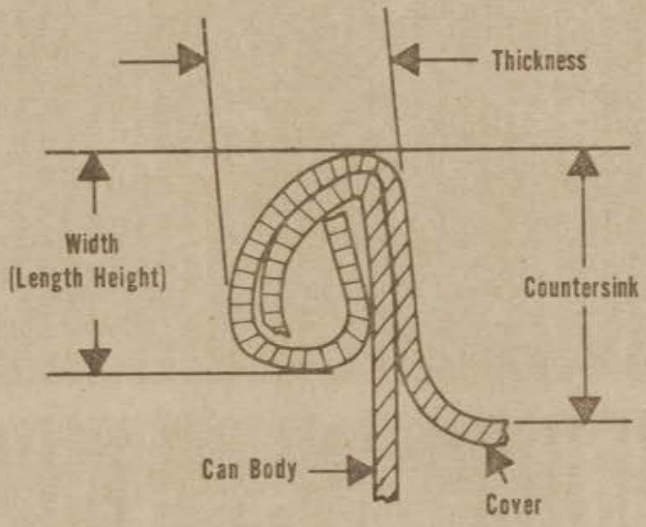
Required	*Optional*
Cover hook.	Overlap (by calculation).
Body hook.	Countersink.
Width (length, height).	
Tightness (observation for wrinkle).	
Thickness.	

(*b*) Seam scope or projector:

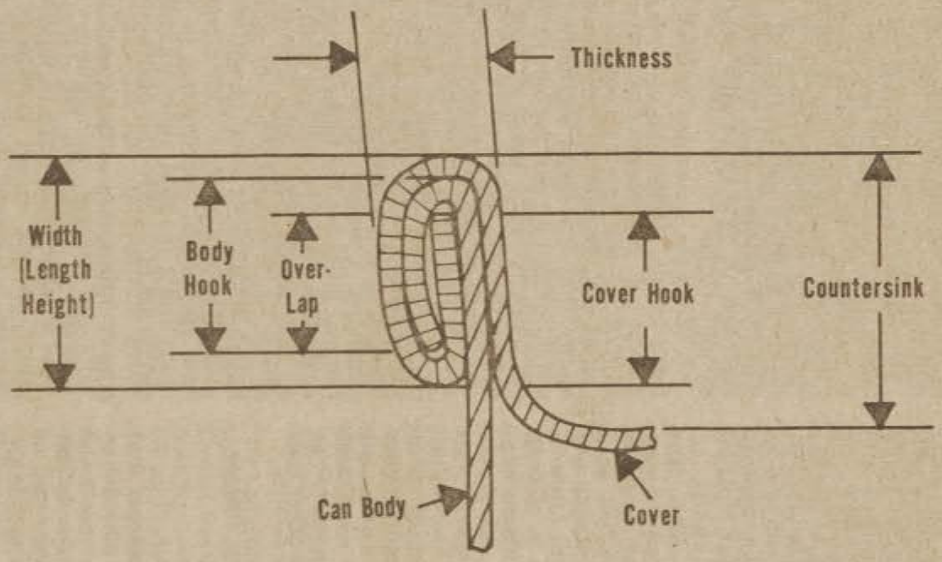
Required	*Optional*
Body hook.	Width (length, height).
Overlap.	Cover hook.
Tightness (observation for wrinkle).	Countersink.
Thickness by micrometer.	

(*c*) Can double seam terminology:

[4110-03-C] FIRST OPERATION ROLL SEAM



SECOND OPERATION ROLL SEAM



[4110-03-M]

(*1*) "Crossover": The portion of a double seam at the lap.

(*2*) "Cutover": A fracture, sharp bend, or break in the metal at the top of the inside portion of the double seam.

(*3*) "Deadhead": A seam which is incomplete due to chuck spinning in the countersink.

(*4*) "Droop": Smooth projection of double seam below bottom of normal seam.

(*5*) "False seam": A small seam breakdown where the cover hook and the body hook are not overlapped.

(*6*) "Lap": Two thicknesses of material bonded together.

(ii) Two measurements at different locations, excluding the side seam, shall be made for each double seam characteristic if a seam scope or seam projector is used. When a micrometer is used, three measurements shall be made at points approximately 120° apart, excluding the side seam.

(iii) Overlap length can be calculated by the following formula:

The theoretical overlap length = CH + BH + T − W, where
CH = cover hook
BH = body hook
T = cover thickness, and
W = seam width (height, length)

(2) For glass containers with vacuum closures, capper efficiency must be checked by a measurement of the cold water vacuum. This shall be done before actual filling operations, and the results shall be recorded.

(3) For closures other than double seams and glass containers, appropriate detailed inspections and tests shall be conducted by qualified personnel at intervals of sufficient frequency to ensure proper closing machine performance and consistently reliable hermetic seal production. Records of such tests shall be maintained.

(b) *Cooling water.* Container cooling water shall be chlorinated or otherwise sanitized as necessary for cooling canals and for recirculated water supplies. There should be a measurable residual of the sanitizer employed at the water discharge point of the container cooler.

(c) *Coding.* Each hermetically sealed container of low-acid processed food shall be marked with an identifying code that shall be permanently visible to the naked eye. When the container does not permit the code to be embossed or inked, the label may be legibly perforated or otherwise marked, if the label is securely affixed to the product container. The required identification shall identify in code the establishment where packed, the product contained therein, the year packed, the day packed, and the period during which packed. The packing period code shall be changed with sufficient frequency to enable ready identification of lots during their sale and distribution. Codes may be changed on the basis of one of the following: intervals of 4 to 5 hours; personnel shift changes; or batches, as long as the containers that constitute the batch do not extend over a period of more than one personnel shift.

(d) *Postprocess handling.* When cans are handled on belt conveyors, the conveyors should be so constructed as to minimize contact by the belt with the double seam, i.e., cans should not be rolled on the double seam. All worn and frayed belting, can retarders, cushions, etc. should be replaced with new nonporous material. All tracks and belts that come into contact with the can seams should be thoroughly scrubbed and sanitized at intervals of sufficient frequency to avoid product contamination. Automatic equipment used in handling filled containers should be so designed and operated as to preserve the can seam or other container closure integrity.

Subpart E—Production and Process Controls

§ 113.81 Product preparation.

(a) Before using raw materials and ingredients susceptible to microbiological contamination, the processor shall ensure that those materials and ingredients are suitable for use in processing low-acid food. Compliance with this requirement may be accomplished by receiving the raw materials and ingredients under a supplier's guarantee that they are suitable for use, by examining them for their microbiological condition, or by other acceptable means.

(b) Blanching by heat, when required in the preparation of food for canning, should be effected by heating the food to the required temperature, holding it at this temperature for the required time, and then either rapidly cooling the food or passing it to subsequent processing without delay. Thermophilic growth and contamination in blanchers should be minimized by the use of adequate operating temperatures and by cleaning. If the blanched food product is washed before filling, potable water should be used.

(c) The filling of containers, either mechanically or by hand, shall be controlled so as to ensure that the filling requirements specified in the scheduled process are met.

(d) The exhausting of containers for the removal of air shall be controlled so as to meet the conditions for which the process was designed. Compliance with the requirement may be accomplished by heat exhausting, mechanical exhausting, hot brining, or steam injection.

(e) When the maintenance of pH (above 4.6) of a normally low-acid food is a basis for a scheduled process, there shall be careful supervision to ensure that the equilibrium pH of the finished product meets that of the scheduled process. The methodology described in § 114.90 of this chapter should be used.

(f) When the scheduled process sets forth critical factors to prevent the growth of microorganisms not destroyed by the thermal process, the factors shall be carefully controlled to ensure that the limits established in the scheduled process are not exceeded. When normally low-acid foods require sufficient solute to permit safe processing at low temperatures, such as in boiling water, there shall be careful supervision to ensure that the equilibrium water activity (a_w) of the finished product meets that of the scheduled process. The scheduled thermal processes for foods having an a_w greater than 0.85 and less than the a_w that would allow the growth of spores of microorganisms of public health significance shall be sufficient to render the food free of microorganisms capable of reproducing in the food under normal nonrefrigerated conditions of storage and distribution.

§ 113.83 Establishing scheduled processes.

Scheduled processes for low-acid foods shall be established by qualified persons having expert knowledge of thermal processing requirements for low-acid foods in hermetically sealed containers and having adequate facilities for making such determinations. The type, range, and combination of variations encountered in commercial production shall be adequately provided for in establishing the scheduled process. Critical factors, e.g., minimum headspace, consistency, maximum fill-in or drained weight, a_w, etc., that may affect the scheduled process, shall be specified in the scheduled process. Acceptable scientific methods of establishing heat sterilization processes shall include, when necessary, but shall not be limited to, microbial thermal death time data, process calculations based on product heat penetration data, and inoculated packs. Calculation shall be performed according to procedures recognized by competent processing authorities. If incubation tests are necessary for process confirmation, they shall include containers from test trials and from actual commercial production runs during the period of instituting the process. The incubation tests for confirmation of the scheduled processes should include the containers from the test trials and a number of containers from each of four or more actual commercial pro-

duction runs. The number of containers from actual commercial production runs should be determined on the basis of recognized scientific methods to be of a size sufficient to ensure the adequacy of the process. Complete records covering all aspects of the establishment of the process and associated incubation tests shall be prepared and shall be permanently retained by the person or organization making the determination.

§ 113.87 Operations in the thermal processing room.

(a) Operating processes and retort venting procedures to be used for each product and container size being packed shall either be posted in a conspicuous place near the processing equipment or be made readily available to the retort or processing system operator and any duly authorized employee of the Food and Drug Administration. Scheduled processes must be made readily available to the supervisor and any duly authorized employee of the Food and Drug Administration.

(b) A system for product traffic control in the retort room shall be established to prevent unretorted product from bypassing the retort process. Each retort basket, truck, car, or crate used to hold containers in a retort, or one or more containers therein, shall, if it contains any retorted food product, be plainly and conspicuously marked with a heat-sensitive indicator, or by other effective means that will indicate visually, to thermal processing personnel, those units that have been retorted. A visual check shall be performed to determine whether or not the appropriate change has occurred in the heat-sensitive indicator as a result of retorting for all retort baskets, trucks, cars, or crates, to ensure that each unit of product has been retorted. A written record of these checks should be made.

(c) The initial temperature of the contents of the containers to be processed shall be determined and recorded with sufficient frequency to ensure that the temperature of the product is no lower than the minimum initial temperature specified in the scheduled process. For those operations that use water during the filling of the retort or during processing, provision shall be made to ensure that the water will not, before the start of each thermal process, lower the initial temperature of the product below that specified in the scheduled process.

(d) Timing devices used in recording thermal process time information shall be accurate to the extent needed to ensure that the processing time and venting time specified in the scheduled process are achieved. Pocket or wrist watches are not considered satisfactory for timing purposes. Digital clocks may be used if the operating process and the venting schedule have a 1-minute or greater safety factor over the scheduled process.

(e) Clock times on recording-temperature charts should reasonably correspond to the time of day on the written processing records to provide correlation of these records.

(f) The steam supply to the thermal processing system shall be adequate to the extent needed to ensure that sufficient steam pressure is maintained during thermal processing, regardless of other demands of steam by the plant.

(g) If mufflers are used on bleeders or vent systems, evidence that the bleeders or vents are operated in a manner that does not significantly impede the removal of air shall be kept on file. This evidence may be in the form of heat distribution data or other satisfactory evidence such as a letter from the manufacturer, the designer, or a competent processing authority.

§ 113.89 Deviations in processing, venting, or control of critical factors.

Whenever any process is less than the scheduled process or when critical factors are out of control for any low-acid food or container system as disclosed from records by processor check or otherwise, the commerical processor of that low-acid food shall either fully reprocess that portion of the production involved, keeping full records of the reprocessing conditions or, alternatively, must set aside that portion of the product involved for further evaluation as to any potential public health significance. Such evaluation shall be made by a competent processing authority and shall be in accordance with procedures recognized by competent processing authorities as being adequate to detect any potential hazard to public health. Unless this evaluation demonstrates that the product had been given a thermal process that rendered it free of microorganisms of potential public health significance, the product set aside shall be either fully reprocessed to render it commercially sterile or destroyed. A record shall be made of the evaluation procedures used and the results. Either upon completion of full reprocessing and the attainment of commerical sterility or after the determination that no significant potential for public health hazard exists, that portion of the product involved may be shipped in normal distribution. Otherwise, the portion of the product involved shall be destroyed. All process deviations involving a failure to satisfy the minimum requirements of the scheduled process, including emergencies arising from a jam or breakdown of a continuous agitating retort necessitating cooling the retort for repairs, shall be recorded and made the subject of a separate file (or a log identifying the appropriate data) detailing those diviations and the actions taken.

Subpart F—Records and Reports

§ 113.100 Processing and production records.

(a) Processing and production information shall be entered at the time it is observed by the retort or processing system operator, or other designated person, on forms that include the product, the code number, the date, the retort or processing system number, the size of container, the approximate number of containers per coding interval, the initial temperature, the actual processing time, the mercury-in-glass and recording thermometer readings, and other appropriate processing data. Closing machine vacuum in vacuum-packed products, maximum fill-in or drained weight, or other critical factors specified in the scheduled process shall also be recorded. In addition, the following records shall be maintained:

(1) *Still retorts.* Time steam on; time temperature up to processing temperature; time steam off; venting time and temperature to which vented.

(2) *Agitating retorts.* Functioning of condensate bleeder; retort speed; and, when specified in the scheduled process, headspace, consistency, maximum drained weight, minimum net weight, and percent solids.

(3) *Hydrostatic retorts.* The temperature in the steam chamber between the steam-water interface and the lowest container position; speed of the container conveyor chain; and, when the scheduled process specifies maintenance of particular temperatures in the hydrostatic water legs, the temperatures near the top and the bottom of each hydrostatic water leg.

(4) *Aseptic processing and packaging systems.* Product temperature in the holding tube outlet as indicated by the temperature-indicating device and the temperature recorder; product temperature in the final heater outlet as indicated by the temperature recorder-controller; differential pressure as indicated by the differential pressure recorder-controller, if a product-to-product regenerator is used; product flow rate, as determined by the metering pump or by filling and closing rates; sterilization media flow rate or temperature or both; retention time of containers, and closures when applicable, in the sterilizing environment; and, when a batch system is used for container and/or closure sterilization, sterilization cycle times and temperatures.

(5) *Flame sterilizers.* Container conveyor speed; surface temperature at the beginning and at the end of the holding period; nature of container.

(6) *Food preservation methods wherein critical factors such as water activity are used in conjunction with thermal processing.* Product formulation and scheduled processes used, including the thermal process, its associated critical factors, as well as other critical factors, and results of a_w determinations.

(7) *Other systems.* Critical factors specified in the formulation of the product or in the scheduled process.

(b) Recording thermometer charts shall be identified by date, retort number, and other data as necessary, so they can be correlated with the written record of lots processed. Each entry on the processing and production records shall be made by the retort or processing system operator, or other designated person, at the time the specific retort or processing system condition or operation occurs, and this retort or processing system operator or other designated person shall sign or initial each record form. Not later that 1 working day after the actual process, and before shipment or release for distribution, a representative of plant management who is qualified by suitable training or experience shall review all processing and production records for completeness and to ensure that the product received the scheduled process. The records, including the recording thermometer chart(s), shall be signed or initialed and dated by the reviewer.

(c) Written records of all container closure examinations shall specify the product code, the date and time of container closure inspections, the measurements obtained, and all corrective actions taken. Records shall be signed or initialed by the container closure inspector and reviewed by management with sufficient frequency to ensure that the containers are hermetically sealed.

(d) Records shall be maintained to identify the initial distribution of the finished product to facilitate, when necessary, the segregation of specific food lots that may have become contaminated or otherwise rendered unfit for their intended use.

(e) Copies of all records provided for in this part, except those required under § 113.83 establishing scheduled processes, shall be retained at the processing plant for a period of not less than 1 year from the date of manufacture, and at the processing plant or other reasonably accessible location for an additional 2 years. If, during the first year of the 3-year record-retention period, the processing plant is closed for a prolonged period between seasonal packs, the records may be transferred to some other reasonably accessible location at the end of the seasonal pack.

Effective date. This regulation is effective May 15, 1979.

(Secs. 402(a)(3) and (4), 701(a), 52 Stat. 1046, 1055 (21 U.S.C. 342(a)(3) and (4), 371(a)).)

Dated: March 7, 1979.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-7689 Filed 3-15-79; 8:45 am]

[4110-03-M]

[Docket No. 75P-0334]

PART 114—ACIDIFIED FOODS

Current Good Manufacturing Practice

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This document prescribes the specific current good manufacturing practices (CGMP's) for acidified foods. The primary public health problem associated with these foods is the possibility of botulinal toxin formation, and this regulation will ensure safe manufacturing, processing, and packing procedures for these foods.

DATES: Effective May 15, 1979, except that the provisions of § 114.10 (21 CFR 114.10), which concerns personnel training, shall become effective on September 16, 1980.

ADDRESS: Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Melvin R. Johnston, Bureau of Foods (HFF-414), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C St. SW., Washington, DC 20204, 202-245-1514.

SUPPLEMENTARY INFORMATION: In the FEDERAL REGISTER of July 23, 1976 (41 FR 30457), the Commissioner of Food and Drugs proposed to establish CGMP regulations for pickled, fermented, and acidified foods under 21 CFR Part 114 (21 CFR Part 128g before the recodification of March 15, 1977 (42 FR 14302)).

A period of 60 days was provided for the filing of comments on the proposal, and in response to a request by three trade associations and the Spanish Ministry of Trade, the comment period was extended to November 20, 1976, by a notice published in the FEDERAL REGISTER of September 22, 1976 (41 FR 41436). The July 1976 proposal was published concurrently with a proposal to establish a new section (21 CFR 108.25 (formerly 21 CFR 90.22)) for the regulation of those foods under section 404 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 344) and one to revise the CGMP regulations for low-acid canned foods (21 CFR Part 113 (formerly 21 CFR Part 128b)), which are already subject to regulation under section 404 of the act (see 41 FR 30441 and 41 FR 30444, July 23, 1976).

Under the current Part 113 CGMP regulations (amended elsewhere in this issue of the FEDERAL REGISTER), tomatoes, pears, pineapples, and their juices that have a finished equilibrium pH of less than 4.7 and figs that have a pH of 4.9 or below are not classified as low-acid foods. Therefore, they are not subject to regulation under Parts 108 and 113. The July 1976 proposal to establish Part 114 would have revoked the exemption for those foods and made them subject to the requirements of section 404 of the act and to the provisions of Parts 108 and 113 as amended by the respective July 1976 proposals cited above.

The National Canners Association (now the National Food Processors Association (NFPA)) filed extensive comments on the change proposed in the regulation to remove the exemptions from the definition of low-acid foods. After the comment period ended, NFPA requested that the comment period be reopened to allow it to develop and submit data on the final pH of certain products or classes of products to determine whether they should be exempted from the regulations. Accordingly, the comment period was reopened until October 3, 1977, by notice published in the FEDERAL REGISTER of July 29, 1977 (42 FR 38609).

Forty-one letters, each containing one or more comments, were received from industry, trade associations, universities, Federal government agencies, members of Congress, and an individual. The comments and the Commissioner's responses are given below.

GENERAL

1. The United States Department of Agriculture Eastern Regional Research Center in Philadelphia commented that the proposed rules did not specify whether the discriminating pH is the pH of a composite of raw material, the mean of replicate analyses of different raw material units, or some other value.

The Commissioner disagrees. In the proposal, acidified foods were defined as foods acidified to a pH value of 4.6 or lower, and fermented foods were defined as foods prepared from low-acid ingredients and fermented to an *equilibrium* pH of 4.6 or lower. Further, the Commissioner proposed to define

low-acid foods as those with a *finished equilibrium* pH value of greater than 4.6 and a water activity of greater than 0.85. For these reasons the Commissioner believes the proposed definitions were clear; nevertheless, the Commissioner has revised the final regulation to resolve any potential misunderstanding. Because the function of these regulations is to ensure that foods are properly acidified to protect the public from *C. botulinum*, the Commissioner has revised the definition of acidified foods to state specifically that the Food and Drug Administration (FDA) is concerned with the equilibrium pH value of the finished food, and not the pH of a composite of raw material or the mean of replicate analyses of different raw material units.

Moreover, the Commissioner believes it useful to explain the interrelationship of the foods subject to regulation under section 404 of the act and the CGMP regulations for those foods.

C. botulinum will not normally grow in a food that has a pH of approximately 4.8 or below. pH is a measure of a food's acidity, and pH and acidity vary inversely. Because other uncontrollable variables may come into play, FDA and the food-processing industry have historically added a safety factor of 0.2 pH unit and made the basic discriminating pH value 4.6 (see 36 FR 21688, November 12, 1971, and 38 FR 2398, January 24, 1973). In addition to pH, other factors are also conducive to *C. botulinum* growth: high water activity, anaerobic environment, and ambient temperature. Certain foods are acidified to a pH of 4.6 or below (e.g., beans, peppers, puddings, and fish) to prevent growth of *C. botulinum*. These foods are designated acidified, and they are generally subject to regulation under section 404 of the act in accordance with § 108.25 (established elsewhere in this issue of the FEDERAL REGISTER) and the CGMP regulations promulgated by this notice (Part 114).

C. botulinum will grow in many foods when the pH is higher than 4.6 (i.e., low-acid foods), and those foods have been classified as low-acid foods. Such foods present a health hazard when they are intended for marketing as products that are intended for use in conjunction with other conditions that are conducive to botulinum growth (e.g., canned nonrefrigerated food). Low-acid foods packaged in hermetically sealed containers present this problem. These foods must be thermally processed and are subject to Part 113 and § 108.35 (21 CFR 108.35).

Also, Ohye and Christian, and Troller (see Refs. 7, 9, 10, and 11 in the preamble to the proposal) have shown that *C. botulinum* will not grow in food with a water activity of 0.85 or below. In sum, the foods subject to Part 114 are foods intended to be acidified to a pH of 4.6 or below and have a water activity that is greater than 0.85.

Most fruits have a natural pH that is below 4.6. Accordingly, these foods present no health hazard from botulism, and they are not subject to regulations either as acidified foods under § 108.25 and Part 114 or as low-acid foods under § 108.35 and Part 113. These acid and low water-activity foods are regulated under the umbrella CGMP regulations (21 CFR Part 110). To clarify their regulatory status, the Commissioner has specified their exempt status in the definition of low-acid foods.

Some fruits, however, have a pH that is above 4.6, and products made from these fruits may be intentionally acidified to an equilibrium pH of 4.6 or below. If they have a water activity that is greater than 0.85, these acidified foods may present a health hazard, and they are subject to regulation under § 108.25 and Part 114. Foods that are acidified to a pH above 4.6 and that have a water activity greater than 0.85 are considered low-acid foods. These foods, when thermally processed and packaged in hermetically sealed containers, are subject to regulation under § 108.35 and Part 113. The following table illustrates the relationship between pH, water activity, and regulatory status of most foods.

pH (final equilibrium)	a_w	Low-acid (21 CFR 113)	Acidified (not naturally) (21 CFR 114)
<4.5	≤0.85	No	No
<4.5	>0.85	No	Yes
4.6	≤0.85	No	No
4.6	>0.85	No	Yes
≥4.7	≤0.85	No	No
≥4.7	>0.85	Yes	No

The equilibrium pH of tomatoes varies from approximately 4.0 to 4.7, depending on the variety, ripeness, etc., and NFPA filed data with FDA showing that *C. botulinum* will not grow in tomatoe products with a pH below 4.9. For this reason, the Commissioner has specifically exempted from the definition of low-acid foods tomatoes and tomato products that have a finished equilibrium pH below 4.7 (using the 0.2 pH unit safety factor). These foods are therefore exempt from regulation under § 108.35 and Part 113; they are subject to regulation under the basic provisions of the act and the umbrella CGMP regulations. But tomatoes and tomato products with a finished equilibrium pH that is 4.7 or above are low-acid foods subject to the requirements of § 108.35 and Part 113 when those foods are intended for use in hermetically sealed containers.

2. The proposal stated that the final regulations would become effective 60 days after the date of publication, and one comment stated that 60 days is inadequate time to implement all the requirements proposed. The comment argued that if all the proposed provisions were to be required within 60 days, modifications within processing plants would be necessary, and it alleged that some processes might even have to be reestablished. All processes and modifications require time to develop. The comment therefore recommended that the Commissioner delay the effective date of the final order until 6 months after publication. Further, the comment contended that at least 18 months should be allowed to properly train a sufficient number of personnel.

The Commissioner agrees that portions of the regulation will require more than 60 days for implementation and has made adjustments for that fact. The Commissioner will require registration under § 108.25 within 120 days after the date of publication of the document (referred to above) establishing that section and require the filing of processes within 60 days after registration. The Commissioner is also allowing an effective date 18 months after the date of its publication in the FEDERAL REGISTER for the provision of § 114.10 that concerns personnel training. However, the Commissioner emphasizes that these regulations prescribe practices that are the minimum state of the art, and most processors should already be in compliance with the basic provisions.

The same comment questioned the inclusion of fermented foods in the regulation on the ground that the proposal document cited no examples in which fermentation procedure was proved to cause a food to be a health hazard. The comment went on to say that if the Commissioner desires to regulate the sanitation of plants fermenting cucumbers, the regulating should be done by implementing the appropriate sections of Part 110.

The Commissioner agrees. As the Commissioner explains in the discussion of the decision to exclude fermented foods from § 108.25 (see the preamble to the final rule establishing § 108.25, referred to above), there is insufficient evidence that commercially fermented foods require regulation under section 404 of the act. For this reason, the Commissioner has concluded that fermented foods also should not be subject to Part 114. Processing of fermented foods is covered by the umbrella CGMP regulations in Part 110.

DEFINITIONS

3. "Acid foods" (§ 114.3(a)): One comment suggested that a new definition

for acid foods be added to distinguish between acidified foods, which are covered by this regulation, and acid foods, which are not covered.

The Commissioner agrees that such a definition is meaningful and has added it to the final regulation.

4. "Acidified foods" (§ 114.3(b)):

a. In addition to the comment on equilibrium pH discussed above, a number of comments were received concerning the definition for acidified foods. Many of these comments asked for exclusions from the definition for specific classes of foods. Exemptions were requested for such things as jams, jellies, products containing pectin, products containing small amounts of low-acid ingredients that have no significant effect on the pH of a finished product, products that have a pH below 4.0, and products that are refrigerated. One comment asked for a more specific identification of the foods to which the regulations are intended to apply.

The Commissioner agrees that some revision of the definition in general is necessary to clarify the scope of the regulations and has revised the definition, which specifies several examples of acidified foods, to cover foods that are acidified to have a finished equilibrium pH of 4.6 or lower and that have a water activity greater than 0.85. The Commissioner has now specifically excluded, however, several foods from this general definition because experience and review of the evidence show that bacteria of public health significance cannot and do not grow in these foods. The definition of acidified foods now excludes (1) jams, jellies, preserves, and other acid foods that have a water activity of 0.85 or less; (2) acid foods that contain small amounts of low-acid foods and have a resultant equilibrium pH that does not significantly differ from that of the predominant acid food (and is 4.6 or below); and (3) foods that are stored, distributed, and retailed under refrigeration.

The Commissioner refuses to exempt foods having an equilibrium pH of 4.0 or below from the definition of acidified foods because the potential for improper acidification in the preparation of these products could result in the preparation of a food that poses a significant health hazard.

b. Another comment suggested that the Commissioner add a definition for the term "low-acid food ingredients," which was used in the proposed definition of acidified foods.

Food ingredients are also foods; therefore, the Commissioner has deleted the word "ingredients."

c. One comment asked for clarification of the wording for the exclusion of salad dressings from the definition of acidified foods. It requested that the definition be revised to state that "carbonated beverages and standardized and nonstandardized dressings for salads and condiment sauces" are excluded from the coverage of Part 114.

The Commissioner agrees with the comment. "Salad dressing" is a specific standardized food. Nevertheless, many assume the term includes those foods standardized in 21 CFR Part 169 as "food dressings" as well as nonstandardized foods intended for the same use. The Commissioner, therefore, has reworded this provision of the definition to make clear that food dressings and condiment sauces are excluded from the definition if the resultant equilibrium pH does not significantly differ from that of the predominant acid or acid food.

d. One comment asked the Commissioner to delete the phrase "to prevent growth of microorganisms of public health significance" from the definition on the ground that the reason for adding acid to the food is irrelevant if the final food product achieves an equilibrium pH of 4.6 or below and is therefore safe. But another comment on the scope of the proposed definition requested that the Commissioner confirm that the definition of acidified foods does not extend to foods to which acid is added for technological purposes unrelated to preventing the growth of microorganisms.

The Commissioner believes that the crucial point is the intended equilibrium pH of the food. As long as the final food product is acidified to achieve an equilibrium pH of 4.6 or below, it makes no difference why acid is added to a food, because spore growth and toxin formation are impossible at or below that pH. For that reason, the Commissioner has deleted from the definition the phrase on the prevention of microorganism growth. The Commissioner recognizes that, in specific instances, foods to which acid is added can be exempt from the definition, and will address those instances on a case-by-case basis when petitions for exemption are filed.

e. Another comment requested that the Commissioner exempt foods with a pH higher than 4.6 from the definition of acidified foods when data show that the outgrowth of spores is prevented by acidity even at the higher pH values. The comment requested that the phrase "the food shall be acidified to pH 4.6 or lower except where a higher pH has been shown to inhibit the growth of *C. botulinum* spores" be included in the definition of acidified food.

The Commissioner has decided against including this broad language in the definition because, to date, data have been presented that support an exemption only for tomatoes and tomato products having an equilibrium pH below 4.7. Further, no evidence has been submitted suggesting that the cutoff point of 4.6 is inappropriate or unreasonable. For this reason, thermally processed foods that are packaged in hermetically sealed containers and that have an equilibrium pH greater than 4.6 are properly included under Part 113. If data are developed showing that spores of *C. botulinum* are prevented from growing in particular foods at higher pH values, the data should be used in support of the development of scheduled processes as specified in 21 CFR 113.83. When adequate data are collected, the Commissioner will determine whether to exempt the specific foods from the regulations.

5. "Fermented foods" (proposed as § 128g.1(b)): All comments received on this provision asked for exemptions from the definition for products such as vinegar, black olives, soy sauce, fermented tea, coffee, cacao, and vanilla because the *C. botulinum* growth is inhibited by other mechanisms in these fermented foods.

The Commissioner has concluded that fermented foods will continue to be regulated under Part 110 and has deleted the definition from the final regulation. Therefore, these comments are moot.

6. "Lot" (§ 114.3(c)): One comment found the definition misleading. Under the proposed definition, the term "lot" means a product produced during a period indicated by a specific code, and the requirements for coding are clearly spelled out in § 114.80(b). The comment was concerned with those instances in which acidified foods are manufactured in a multiple vat arrangment owing to potential pH problems.

The Commissioner agrees that it is inadvisable to use a common code for a multiple vat operation. If problems arise with the processing in one vat, the entire lot is suspect and must be set aside for evaluation. For this reason, processors are advised to avoid a single code for multiple vats. However, it is not always possible to code every vat in a multiple vat arrangement, and coding every vat in a multiple vat arrangement, although desirable, is not required because, should any problems arise, the entire lot could be retained. Therefore, the Commissioner has made no change in the definition of "lot."

7. "Low-acid foods" (§ 114.3(d)): As proposed, the definition for low-acid foods would not have recognized specific exemptions. In its initial comments on this notice and the proposal to revise Part 113, NFPA requested that the current exemption from the definition of "low-acid foods" for certain tomato, pineapple, pear, and fig products be maintained in the proposed definition until additional data

were available to bolster the claims for exemption. The NFPA later submitted data to prove that an equilibrium pH of less than 4.9 will prevent the outgrowth of *C. botulinum* in tomato products. Data on figs were also submitted, but no data were submitted on pears or pineapples.

After reviewing the data, the Commissioner agrees that an equilibrium pH of less than 4.9 will prevent the outgrowth of *C. botulinum* in tomato products and has changed the definition of low-acid foods to exempt tomatoes and tomato products having a finished equilibrium pH of less than 4.7 from the definition of low-acid foods. However, the Commissioner believes the data submitted on figs are inconclusive and has not made any allowance for their exemption from this regulation. If figs are not acidified, or are acidified but only to a pH above 4.6, they are low-acid foods, and if they are thermally processed and packaged in hermetically sealed containers, they are subject to Part 113. If figs are acidified to a pH of 4.6 or below, they are subject to Part 114. Because no data were submitted in support of excluding pears and pineapples, no change was made in the definition in this regard. The Commission advises that foods containing pears and pineapples will be subject to Part 110 and, depending on the pH and water activity, may be subject to § 108.25 or 108.35 and Part 113 or 114.

8. "Pickled foods" (proposed as § 128g.1(e)): One comment suggested that the reference to pickled food in the title of the regulation and in all other parts be deleted because of its redundancy. Pickles are defined in terms of acidified foods and fermented foods.

Consistent with the determination that only acidified foods should be subject to § 108.25 and Part 114, the Commissioner has eliminated the definition of the term "pickled" from both documents because the term does connote both acidified and fermented foods. However, pickled foods that are acidified are included in these regulations.

9. "Scheduled process" (§ 114.3(e)): Two comments stated that this definition is not applicable to all products covered by the regulation. Two other comments desired to have the scheduled process reflect only those conditions that are required to control pH.

The Commissioner agrees that the scheduled process may be different for different products, but concludes that factors other than pH must be controlled in order to protect the public health. Accordingly, the Commissioner has revised the definition of scheduled process to emphasize the control of pH and other critical factors, although the definition does not enumerate the other specific critical factors.

PERSONNEL

10. Personnel (§ 114.10):

a. Two comments requested that students who have attended schools designed to comply with the requirements of Part 113 for the training of supervisors be exempt from attending schools prescribed under this regulation. Many of the subjects covered under this regulation have already been covered in the courses presented on Part 113.

The Commissioner agrees and has reworded this section to allow persons who were certified before the publication of this final regulation to be exempt from the requirement for further schooling. However, the Commissioner recommends that all persons involved in processing acidified foods attend a course with more details on those foods to ensure that supervisors are fully knowledgeable in this area.

b. Another comment felt that the cost of training is unnecessary because the management of a firm is motivated to hire qualified personnel in order to protect the firm's products.

The Commissioner disagrees. Most manufacturers are already subject to these requirements under Part 113, but the Commissioner's experiences in the compliance program area show numerous instances of improperly acidified foods and thus suggest that supervisory personnel have not been properly trained. The Commissioner emphasizes that such training is essential to make employees cognizant of the factors involved in producing safe acidified foods.

c. A fourth comment suggested that, for practical purposes, supervisors need an extension of time for attendance at these schools because schools meeting this requirement do not now exist and will require some time to develop.

The Commissioner agrees and has allowed a period of 18 months after the date of publication of this regulation in the FEDERAL REGISTER for the training of supervisors.

PROCESSES AND CONTROLS

11. Section 114.80(a)(1):

(a) One of the critical factors in the scheduled process for acidified foods is heat processing. Because heat processing is no longer specifically mentioned in the definition of "scheduled process" (§ 114.3(e)), the Commissioner has rewritten a portion of this paragraph to clarify that the quality control procedures for the thermal processing must be sufficient to ensure that the finished food does not present a health hazard.

(b) Several comments objected to the proposed requirement that all products that purport to be, or are represented as, "pickles," "pickled," or "acidified," have an equilibrium pH of 4.6 or lower unless they are thermally processed as low-acid foods. They point out that many perishable foods rely on refrigeration as the primary mode of preservation during their normal shelf-life and that it is not equitable to exclude "half sour" pickles from introduction into interstate commerce.

The Commissioner agrees that these products are safe when properly refrigerated and has reconsidered the proposed requirement to exclude pickled products from interstate commerce if they have a pH greater than 4.6 and are not thermally processed as low-acid foods. Although the Commissioner notes that some consider that pickles having a pH above 4.6 may constitute a potential public health problem, the agency has no evidence to support that contention. The Commissioner, therefore, has deleted from the regulation the requirement that products that purport to be, or are represented as, "pickles," "pickled," or "acidified," must have an equilibrium pH of 4.6 or lower unless they are thermally processed as low-acid foods. On the other hand, the Commissioner advises, foods that have a pH above 4.6 are covered under 21 CFR Part 110. They are also covered under 21 CFR Part 113 if they are thermally processed and packaged in hermetically sealed containers. The Commissioner has revised the regulation to exclude foods that are stored, distributed, and retailed under refrigeration.

12. Section 114.80(a)(2): One comment suggested that maximum time intervals for the frequency of pH testing be spelled out and that a recording pH meter be required on those processes of a continuous nature.

The Commissioner advises that sufficient control of pH is required to ensure that the finished equilibrium pH of a given food is not higher than 4.6. The manner in which the controls are accomplished is left up to the manufacturer. Also, the manufacturer may use any of the acceptable methods for measuring the pH in continuous operations, and the use of a recording pH meter, although desirable, is not mandatory. The Commissioner has not made the suggested changes in the regulation, but rather has clarified the requirement.

13. Dilution of brine (proposed as § 128g.7(c)(4)): One comment suggested that this paragraph, concerning the dilution of brine in tanks, be deleted because it is unnecessary to the protection of the public health. A significant dilution of brine in tanks may result in either improper fermentation or improper curing owing to a reduced amount of salt.

Because fermented foods are no longer covered by this part, the Commissioner has deleted this paragraph.

14. Section 114.80(a)(5): One comment recommended deleting the requirement that the final packaging operation be in an enclosed building.

The Commissioner has deleted this requirement from this regulation because requirements for general sanitation, plants, and grounds are included in the "umbrella" CGMP regulations, Part 110. Part 110 does not require that the final packaging operation be in an enclosed building.

15. Fermentation and salt curing (proposed as § 128g.7(b)): This provision is applicable only to fermented foods and has accordingly been deleted.

16. Coding (§ 114.80(b)): One comment suggested that it is unnecessary to include product identification in a code on a container in which the food product is visible, and the comment asked that the regulation be changed to exempt such products.

The Commissioner rejects the comment. Coding permits rapid and positive identification of a suspected food if a recall is needed. Most causes of recalls simply cannot be detected by visual inspection of the food in the container, and *C. botulinum* definitely cannot be observed.

ESTABLISHING SCHEDULED PROCESSSES

17. Establishing scheduled processes (§ 114.83): To emphasize the importance of this provision, the Commissioner has created this new section from proposed § 114.80(b)(1) (formerly § 128g.7(b)(1)).

DEVIATIONS FROM SCHEDULED PROCESSES

18. Deviations from scheduled processes (§ 114.89):

a. One comment asked for clarification of the term "fully rework," and it asked that a time limit be set to ensure speedy followup on deviant lots. Another comment stated that it would be unsafe to allow reworking if the product has been at a pH above 4.6 for more than 12 hours.

In response to these comments, the Commissioner has made changes to clarify the regulation and has eliminated the term "fully rework." The Commissioner has added the requirement that reprocessing be done by a process established by a competent processing authority. Adding this provision will eliminate the necessity of establishing a time limit on reprocessing because the processing authority will take all safety aspects into consideration in determining whether a new process can be established.

b. Another comment asked that the words "or otherwise" be deleted from the requirement for the "ph * * * as determined by a qualified analyst or otherwise." The comment stated that only a qualified analyst should be permitted to examine the records to determine whether the equilibrium pH is above 4.6.

Apparently the wording has caused some misinterpretation of the regulation. The Commissioner did not intend that only a qualified analyst be permitted to examine the records to determine whether the equilibrium pH is above 4.6. Rather, the regulation, indeed the entire Part 114, is designed to provide maximum public protection against botulism. The regulations require personnel training and are aimed at requiring everyone in the production process to be able to participate in, or to initiate, the public protection elements of the regulations. For these reasons, the regulations are designed so that a person who is properly trained, but who is not a qualified analyst, is capable of examining the records. Because controls to be used in processing the foods are outlined in § 114.80(a)(2) and records are listed in § 114.100, the Commissioner has removed from § 114.89 reference to the means by which pH is determined or disclosed. Nevertheless, when a deviation from the scheduled process occurs, the Commissioner intends to require measurement of the food's pH by one of the options outlined in §§ 114.80(a)(2) and 114.90, and proper recording of the pH.

19. Methodology (§ 114.90):

a. Two comments questioned the value of including a methodology section in the regulation. One comment stated that a methodology section is unnecessary and costly because it will require additional labor to check and recheck instruments. A second comment claimed that better pH methodology can be obtained by reference to appropriate texts, reference books and, most importantly, the instruction manual provided by each manufacturer for the care and operation of its particular pH measuring devices.

Testing food to determine its pH or acidity is necessary to ensure that proper controls and manufacturing practices have been used in processing the food. The Commissioner reaffirms the position that describing appropriate methods for measuring pH or acidity of foods benefits many processors, because experience shows many processors lack this knowledge. A review of available manufacturer's instructions, owner's manuals, and reference books (including Official Methods of Analysis of the Association of Official Analytical Chemists) disclosed that those publications do not list detailed instructions for testing the variety of food systems that are covered by this regulation. Therefore, the Commissioner concludes that this methodology section, with some editorial changes, is necessary and is retaining it as a part of the final regulation. The Commissioner further advises that the regulation does not preclude the use of instrument manufacturer's instructions, owner's manuals, or published scientific literature. Methods that may be used to determine pH or acidity for acidified foods include, but are not limited to, those specified in the regulation.

b. A comment objected to the mandatory requirement that the methods given in this section be used if the pH is higher than 4.0.

The Commissioner agrees that methods other than those given in this regulation may be used to determine the pH of the food and has eliminated the mandatory requirement that this prescribed potentiometric method be used. Nevertheless, the Commissioner still requires that some potentiometric method be used to measure the pH of foods that have a finished equilibrium pH above 4.0, because the other available methods are not sufficiently sensitive.

c. A number of other comments suggested minor changes in the methodology presented in the proposal.

Because most of these changes will help clarify the methodology, the Commissioner has made the appropriate changes.

RECORDS

20. Section 114.100(a): Several comments suggested that this section concerning records of the examination of raw materials, packaging materials, and finished products be eliminated or revised because the records are unrelated to the critical factors in an adequate process and are unrelated to safety.

The Commissioner believes that maintaining records covering sanitation and quality control testing is necessary. For this reason, the Commissioner declines to revise the regulation.

21. Section 114.100(b): Two comments asked that this paragraph be reworded to require maintenance of only those records relating to food safety. One comment recommended that records "showing adherence to scheduled processes" be substituted for "covering processes intended to pasteurize or otherwise heat treat products."

The Commissioner basically agrees with the comments and has changed this paragraph in the regulation accordingly.

22. Section 114.100(c): Two comments stated that there did not appear to be adequate justification to require an entirely separate, and duplicate, filing system of records.

Based on experience regulating the low-acid canned food industry, the Commissioner concludes that a separate file of process deviations must be kept to enable the processor, as well as an FDA investigator, to ascertain readily which products may have been underprocessed. However, a completely duplicate file of all records is unnecessary. A log identifying the appropriate data will suffice, and the Commissioner has changed the regulation accordingly.

23. Section 114.100(d): Three comments objected to the requirement that records be maintained to identify the initial distribution of finished products on the ground that this requirement is a recall tool and is therefore covered under § 108.25(e).

The Commissioner believes the comment has misunderstood the interaction between Parts 108 and 114. Section 108.25(e) established the general basic requirement that the manufacturers of acidified foods develop a program and maintain records on product distribution for recalling products that may be injurious to health based on considerations of section 404 of the act. But § 108.25(e) does not specify the need to maintain records to identify the initial distribution of finished products, which may arise for numerous other reasons. Section 114.100(d) and analogous provisions (§§113.100(d) (proposed as § 128b.8(d)) and 118.100(c))) will expedite and have expedited the recall of dangerous or potentially dangerous products from the market. Their benefits to the consumer are apparent (see the Commissioner's comments in the preamble to the final rule establishing recall policy (43 FR 26202, June 16, 1978)). Therefore, the Commissioner rejects the suggestions in the comments and has made no change in the regulation.

24. Section 114.100(e): One comment recommended that the records should be kept for a period of 3 years instead of "an additional 2 years."

The Commissioner agrees and has made the appropriate change in the regulation.

All other comments have been carefully considered by the Commissioner and, when deemed appropriate, have been incorporated into the regulation. In addition to amending the proposal to reflect the comments received, the Commissioner has made other modifications found to be necessary for implementing the proposed regulation. Accordingly, having evaluated the comments received and other relevant material, the Commissioner concludes that the regulation should be promulgated as set forth below.

Therefore, under the Federal Food, Drug, and Cosmetic Act, (secs. 402(a) (3) and (4), 701(a), 52 Stat. 1046, 1055 (21 U.S.C. 342(a) (3) and (4), 371(a))) and under authority delegated to the Commissioner (21 CFR 5.1), Chapter I of Title 21 of the Code of Federal Regulations is amended by adding a new Part 114 to read as follows:

PART 114—ACIDIFIED FOODS

Subpart A—General Provisions

Sec.
114.3 Definitions.
114.5 Current good manufacturing practices.
114.10 Personnel.

Subparts B-D—[Reserved]

Subpart E—Production and Process Controls

114.80 Processes and controls.
114.83 Establishing scheduled processes.
114.89 Deviations from scheduled procedures.
114.90 Methodology.

Subpart F—Records and Reports

114.100 Records.

AUTHORITY: Secs. 402(a) (3) and (4), 701(a), 52 Stat. 1046, 1055 (21 U.S.C. 342(a) (3) and (4), 371(a)).

Subpart A—General Provisions

§ 114.3 Definitions.

For the purposes of this part, the following definitions apply.

(a) "Acid foods" means foods that have a natural pH of 4.6 or below.

(b) "Acidified foods" means low-acid foods to which acid(s) or acid food(s) are added; these foods include, but are not limited to, beans, cucumbers, cabbage, artichokes, cauliflower, puddings, peppers, tropical fruits, and fish, singly or in any combination. They have a water activity (a_w) greater than 0.85 and have a finished equilibrium pH of 4.6 or below. These foods may be called, or may purport to be, "pickles" or "pickled ————." Carbonated beverages, jams, jellies, preserves, acid foods (including such foods as standardized and nonstandardized food dressings and condiment sauces) that contain small amounts of low-acid food(s) and have a resultant finished equilibrium pH that does not significantly differ from that of the predominant acid or acid food, and foods that are stored, distributed, and retailed under refrigeration are excluded from the coverage fo this part.

(c) "Lot" means the product produced during a period indicated by a specific code.

(d) "Low-acid foods" means any foods, other than alcoholic beverages, with a finished equilibrium pH greater than 4.6 and a water activity (a_w) greater than 0.85. Tomatoes and tomato products having a finished equilibrium pH less than 4.7 are not classed as low-acid foods.

(e) "Scheduled process" means the process selected by a processor as adequate for use under the conditions of manufacture for a food in achieving and maintaining a food that will not permit the growth of microorganisms having public health significance. It includes control of pH and other critical factors equivalent to the process established by a competent processing authority.

(f) "Shall" is used to state mandatory requirements.

(g) "Should" is used to state recommended or advisory procedures or to identify recommended equipment.

(h) "Water activity" (a_w) is a measure of the free moisture in a product and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

§ 114.5 Current good manufacturing practice.

The criteria in §§ 114.10, 114.80, 114.83, 114.89, and 114.100, as well as the criteria in Part 110 of this chapter, apply in determining whether an article of acidified food is adulterated (1) within the meaning of section 402(a)(3) of the act (21 U.S.C. 342(a)(3)) in that it has been manufactured under such conditions that it is unfit for food, or (2) within the meaning of section 402(a)(4) of the act (21 U.S.C. 342(a)(4)) in that it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.

§114.10 Personnel.

All operators of processing and packaging systems shall be under the operating supervisions of a person who has attended a school approved by the Commissioner for giving instruction in food-handling techniques, food-protection principles, personal hygiene and plant sanitation practices, pH controls and critical factors in acidification, and who has been identified by that school as having satisfactorily completed the prescribed course of instruction. The Commissioner will consider students who have satisfactorily completed the required portions of the courses presented under § 108.35 and Part 113 of this chapter before March 16, 1979, to be in compliance with the requirement of this section.

Subparts B-D—[Reserved]

Subpart E—Production and Process Controls

§ 114.80 Processes and controls.

(a) *Processing operations.* The manufacturer shall employ appropriate quality control procedures to ensure that finished goods do not present a health hazard.

(1) Acidified foods shall be so manufactured, processed, and packaged that a finished equilibrium pH value of 4.6 or lower is achieved within the time designated in the scheduled process and maintained in all finished foods. Manufacturing shall be in accordance with the scheduled process. Acidified foods shall be thermally processed to an extent that is sufficient to destroy the vegetative cells of microorganisms of public health significance and those of nonhealth significance capable of reproducing in the food under the conditions in which the food is stored, distributed, retailed and held by the user. Permitted preservatives may be used to inhibit reproduction of microorganisms of nonhealth significance (in lieu of thermal processing).

(2) Sufficient control, including frequent testing and recording of results, shall be exercised so that the finished equilibrium pH values for acidified foods are not higher than 4.6. Measurement of acidity of foods in-process may be made by potentiometric methods, titratable acidity, or colorimetric methods. If the finished equilibrium pH of the food is above 4.0, the measurement of the finished equilibrium pH shall be by a potentiometric method, and the in-process measurements by titration or colorimetry shall be related to the finished equilibrium pH. If the finished equilibrium pH is 4.0 or below, then the measurement of acidity of the final product may be made by any suitable method. Special care should be taken when food ingredients have been subjected to lye, lime, or similar high pH materials.

(3) Procedures for acidification to attain acceptable equilibrium pH levels in the final food include, but are not limited to, the following:

(i) Blanching of the food ingredients in acidified aqueous solutions.

(ii) Immersion of the blanched food in acid solutions. Although immersion of food in an acid solution is a satisfactory method for acidification, care must be taken to ensure that the acid concentration is properly maintained.

(iii) Direct batch acidification, which can be achieved by adding a known amount of an acid solution to a specified amount of food during acidification.

(iv) Direct addition of a predetermined amount of acid to individual containers during production. Liquid acids are generally more effective than solid or pelleted acids. Care must be taken to ensure that the proper amount of acid is added to each container.

(v) Addition of acid foods to low-acid foods in controlled proportions to conform to specific formulations.

(4) Testing and examinations of containers shall occur often enough to ensure that the container suitably protects the food from leakage or contamination.

(b) *Coding.* Each container or product shall be marked with an identifying code permanently visible to the naked eye. If the container does not permit the code to be embossed or inked, the label may be legibly perforated or otherwise marked, as long as the label is securely affixed to the product container. The required identification shall specify in code the establishment where the product was packed, the product contained therein, and the year, day, and period during which it was packed. The packing period code shall be changed often enough to enable ready identification of lots during their sale and distribution. Codes may be changed periodically on one of the following bases: intervals of 4 to 5 hours; personnel shift changes; or batches, as long as the containers constituting the batch do not represent those processed during more than one personnel shift.

§ 114.83 Establishing scheduled processes.

The scheduled process shall be established by a qualified person who has expert knowledge acquired through appropriate training and experience in the acidification and processing of acidified foods.

§ 114.89 Deviations from scheduled processes.

Whenever any process operation deviates from the scheduled process for any acidified food and/or the equilibrium pH of the finished product is higher than 4.6, the commercial processor of the acidified food shall either: (a) Fully reprocess that portion of the food by a process established by a competent processing authority as adequate to ensure a safe product; (b) thermally process it as a low-acid food under Part 113 of this chapter; or (c) set aside that portion of the food involved for further evaluation as to any potential public health significance. The evaluation shall be made by a competent processing authority and shall be in accordance with procedures recognized by competent processing authorities as being adequate to detect any potential hazard to public health. Unless the evaluation demonstrates that the food has undergone a process that has rendered it safe, the food set aside shall either be fully reprocessed to render it safe, or be destroyed. A record shall be made of the procedures used in the evaluation and the results. Either upon completion of full reprocessing and the attainment of a safe food, or after the determination that no significant potential for public health hazard exists, that portion of the food involved may be shipped in normal distribution. Otherwise, the portion of the food involved shall be destroyed.

§ 114.90 Methodology.

Methods that may be used to determine pH or acidity for acidified foods include, but are not limited to, the following:

(a) *Potentiometric method for the determination of pH*—(1) *Principles.* The term "pH" is used to designate the intensity or degree of acidity. The value of pH, the logarithm of the reciprocal of the hydrogen ion concentration in solution, is determined by measuring the difference in potential between two electrodes immersed in a sample solution. A suitable system consists of a potentiometer, a glass electrode, and a reference electrode. A precise pH determination can be made by making an electromotive force (emf) measurement of a standard buffer solution whose pH is known, and then comparing that measurement to an emf measurement of a sample of the solution to be tested.

(2) *Instruments.* The primary instrument for use in pH determination is the pH meter or potentiometer. For most work, an instrument with a direct-reading pH scale is necessary. Battery and line-operated instruments are available commercially. If the line voltage is unstable, line-operated instruments should be fitted with voltage regulators to eliminate drifting of meter-scale readings. Batteries should be checked frequently to ensure proper operation of battery operated instruments. An instrument using an expanded unit scale or a digital readout system is preferred since it allows more precise measurements.

(3) *Electrodes.* The typical pH meter is equipped with a glass membrane electrode and a reference electrode or a single probe combination electrode. Various types of electrodes designed for specific uses are available. The most commonly used reference electrode is the calomel electrode, which incorporates a salt bridge filled with saturated potassium chloride solution.

(i) *Care and use of electrodes.* Calomel electrodes should be kept filled with saturated potassium chloride solution or other solution specified by the manufacturer because they may become damaged if they are allowed to dry out. For best results, electrodes should be soaked in buffer solution, distilled or deionized water, or other liquid specified by the manufacturer for several hours before using and kept ready by storing with tips immersed in distilled water or in buffer solution used for standardization. Electrodes should be rinsed with water before immersing in the standard buffers and rinsed with water or the solution to be measured next between sample determinations. A lag in meter

response may indicate aging effects or fouling of the electrodes, and cleaning and rejuvenation of the electrodes may be necessary and may be accomplished by placing the electrodes in 0.1 molar sodium hydroxide solution for 1 minute and then transferring them to 0.1 molar hydrochloric acid solution for 1 minute. The cycle should be repeated two times, ending with the electrodes in the acid solution. The electrodes should then be thoroughly rinsed with water and blotted with soft tissue before proceeding with the standardization.

(ii) *Temperature.* To obtain accurate results, a uniform temperature should be maintained for the electrodes, the standard buffer solutions, and the samples. Tests should be made at a temperature between 20° and 30° C, the optimum being 25° C. Any temperature determinations made without meter compensation may affect pH values. An automatic temperature compensator may be used.

(iii) *Accuracy.* The accuracy of most pH meters is stated to be approximately 0.1 pH unit, and reproducibility is usually ±0.05 pH unit or less. Some meters permit the expansion of any pH unit range to cover the entire scale and have an accuracy of approximately ±0.01 pH unit and a reproducibility of ±0.005 pH units.

(4) *General procedure for determining pH.* When operating an instrument, the operator should use the manufacturer's instructions and should observe the following techniques for pH determinations:

(i) Switch the instrument on and allow the electronic components to warm up and stabilize before proceeding.

(ii) Standardize the instrument and electrodes with commercially-prepared standard 4.0 pH buffer or with freshly prepared 0.05 molar potassium acid phthalate buffer solution prepared as outlined in "Official Methods of Analysis of the Association of Official Analytical Chemists," 12th ed., 1975, section 50.007(c), page 943.[1] Note the temperature of the buffer solution and set the temperature compensator control at the observed temperature (room temperature is near 25°C).

(iii) Rinse the electrodes with water and blot, but do not wipe, with soft tissue.

(iv) Immerse the tips in the buffer solution and take the pH reading, allowing about 1 minute for the meter to stabilize. Adjust the standardization control so that the meter reading corresponds to the pH of the known buffer (for example, 4.0) for the temperature observed. Rinse the electrodes with water and blot with soft tissue. Repeat procedure with fresh portions of buffer solution until the instrument remains in balance on two successive trials. To check the operation of the pH meter, check the pH reading using another standard buffer such as one having a pH of 7.0, or check it with freshly prepared 0.025 molar phosphate solution prepared as outlined in "Official Methods of Analysis of the Association of Official Analytical Chemists," 12th ed., 1975, section 50.007(e), page 943.[1] Expanded scale pH meters may be checked with pH 3.0 or pH 5.0 standard buffers. Buffers and instruments can be further checked by comparison with values obtained with a second properly standardized instrument.

(v) Indicating electrodes may be checked for proper operation by first using an acid buffer and then a base buffer. First standardize the electrodes using a pH 4.0 buffer at or near 25°C. Standardization control should be adjusted so that the meter reads exactly 4.0. Electrodes should be rinsed with water, then blotted and immersed in a pH 9.18 borax buffer prepared as outlined in "Official Methods of Analysis of the Association of Official Analytical Chemists," 12th ed., 1975, section 50.007(f), page 943.[1] The pH reading should be within ±0.3 units of the 9.18 value.

(vi) The pH meter can be tested for proper operation by shorting the glass and reference electrode inputs, thereby reducing the voltage to zero. In some meters this shorting is done by switching the instrument to standby, and in other instruments by use of a shorting strap. With the instrument shorted out, standardization control should be turned from one extreme to another. This operation should produce a deflection greater than ±1.5 pH unit from center scale.

(5) *Determining pH on samples.* (i) Adjust the temperature of the sample to room temperature (25°C), and set the temperature compensator control to the observed temperature. With some expanded scale instruments, the sample temperature must be the same as the temperature of the buffer solution used for the standardization.

(ii) Rinse and blot the electrodes. Immerse the electrodes in the sample and take the pH reading, allowing 1 minute for the meter to stabilize. Rinse and blot the electrodes and repeat on a fresh portion of sample. Oil and grease from the samples may coat the electrodes; therefore, it is advisable to clean and standardize the instrument frequently. When oily samples cause fouling problems, it may become necessary to rinse the electrodes with ethyl ether.

(iii) Determine two pH values on the well-mixed sample. These readings should agree with one another to indicate that the sample is homogeneous. Report values to the nearest 0.05 pH unit.

(6) *Preparation of samples.* Some food products may consist of a mixture of liquid and solid components that differ in acidity. Other food products may be semisolid in character. The following are examples of preparation procedures for pH testing for each of these categories:

(i) *Liquid and solid component mixtures.* Drain the contents of the container for 2 minutes on a U.S. standard No. 8 sieve (preferably stainless steel) inclined at a 17- to 20-degree angle. Record weight of the liquid and solid portions and retain each portion separately.

(*a*) If the liquid contains sufficient oil to cause electrode fouling, separate the layers with a separatory funnel and retain the aqueous layer. The oil layer may be discarded. Adjust the temperature of the aqueous layer to 25° C and determine its pH.

(*b*) Remove the drained solids from the sieve, blend to a uniform paste, adjust the temperature of the paste to 25° C and determine its pH.

(*c*) Mix aliquots of solid and liquid fractions in the same ratio as found in the original container and blend to a uniform consistency. Adjust the temperature of the blend to 25° C and determine the equilibriated pH. Alternatively, blend the entire contents of the container to a uniform paste, adjust the temperature of the paste to 25° C, and determine the equilibriated pH.

(ii) *Marinated oil products.* Separate the oil from the solid product. Blend the solid in a blender to a paste consistency; it may become necessary to add a small amount of distilled water to some samples to facilitate the blending. A small amount of added water will not alter the pH of most food products, but caution must be exercised concerning poorly buffered foods. No more than 20 milliliters of distilled water should be added to each 100 grams of product. Determine the pH by immersing electrodes in the prepared paste after adjusting the temperature to 25° C.

(iii) *Semisolid products.* Food products of a semisolid consistency, such as puddings, potato salad, etc., may be blended to a paste consistency, and the pH may be determined on the prepared paste. If more fluidity is required, 10 to 20 milliliters of distilled water may be added to 100 grams of product. Adjust the temperature of the prepared paste to 25° C and determine its pH.

(iv) *Special product mixtures.* For special product mixtures such as antipasto, pour off the oil, blend the remaining product to a paste, and determine the pH of the blended paste. If

[1] Copies may be obtained from: Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, D.C 20044.

more fluidity is required, add 10 to 20 milliliters of distilled water to each 100 grams of product and blend. Adjust the temperature of the prepared paste to 25° C and determine its pH.

(7) *Process pH determination.* Obtain sample portions of material for pH determination.

(i) For process liquids, adjust the temperature of the liquid to 25° C and determine the pH by immersing the electrodes in the liquid.

(ii) Drain solid materials on a sieve and blend to a workable paste. Adjust the temperature of the prepared paste to 25° C and determine its pH.

(iii) If enough solid materials are available to make a paste, blend representative aliquots of liquid and solid materials to a workable paste. Adjust the temperature of the prepared paste to 25° C and determine the equilibrated pH. Alternatively, blend the entire contents of the container to a uniform paste, adjust the temperature of the paste to 25° C, and determine the equilibrated pH.

(b) *Colorimetric methods for the determination of pH.* This method may be used in lieu of the potentiometric method if the pH is 4.0 or lower.

(1) *Principle.* The colorimetric method for pH involves the use of indicator dyes in solutions that gradually change color over limited pH ranges. An indicator that has the greatest color change at approximately the pH of the sample being tested is selected. The pH is determined by the color of the indicator when exposed to the sample under test.

(2) *Indicator solutions.* Most indicator solutions are prepared as a 0.04 percent solution of the indicator dye in alcohol. In testing, a few drops of indicator solution are added to 10-milliliter portions of the sample solution. Colors should be compared using a bright background. Approximate determinations can be made on white porcelain spot plates, the test colors being compared thereon with a set of color standards. More accurate colorimetric tests can be made using a comparator block fitted with sets of tubes of standard indicator solutions of known pH.

(3) *Indicator paper.* A paper tape treated with indicator dye is dipped into the sample solution. Depending upon the pH of the solution, the tape will change color and an approximate pH can be determined by comparison with a standard color chart.

(c) *Titratable acidity.* Acceptable methods for determing titratable acidity are described in "Official Methods of Analysis of the Association of Official Analytical Chemists," 12th ed., 1975, sections 22.060-22.061, page 401.[1] The procedure for preparing and standardizing the sodium hydroxide solution is described in the same publication, sections 50.032-50.035, page 946.[1]

Subpart F—Records and Reports

§ 114.100 Records.

(a) Records shall be maintained of examinations of raw materials, packaging materials, and finished products, and of suppliers' guarantees or certifications that verify compliance with Food and Drug Administration regulations and guidelines or action levels.

(b) Processing and production records showing adherence to scheduled processes, including records of pH measurements and other critical factors intended to ensure a safe product, shall be maintained and shall contain sufficient additional information such as product code, date, container size, and product, to permit a public health hazard evaluation of the processes applied to each lot, batch, or other portion of production.

(c) All departures from scheduled processes having a possible bearing on public health or the safety of the food shall be noted and the affected portion of the product identified; these departures shall be recorded and made the subject of a separate file (or log identifying the appropriate data) delineating them, the action taken to rectify them, and the disposition of the portion of the product involved.

(d) Records shall be maintained identifying initial distribution of the finished product to facilitate, when necessary, the segregation of specific food lots that may have become contaminated or otherwise unfit for their intended use.

(e) Copies of all records provided for in paragraphs (b), (c), and (d) of this section shall be retained at the processing plant or other reasonably accessible location for a period of 3 years from the date of manufacture.

Effective date. Except for the provisions of § 114.10, which concerns personnel training and which shall become effective September 16, 1979, this final regulation shall become effective May 15, 1979.

(Secs. 402(a) (3) and (4), 701(a), 52 Stat. 1046, 1055 (21 U.S.C. 342(a) (3) and (4), 371(a)))

Dated: March 7, 1979.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-7688 Filed 3-15-79; 8:45 am]

[1] Copies may be obtained from: Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, D.C 20044.

FRIDAY, MARCH 16, 1979

PART IV



federal register

ENVIRONMENTAL PROTECTION AGENCY

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TOXIC SUBSTANCES CONTROL

Discussion of Premanufacture Testing Policy and Technical Issues; Request for Comment

[6560-01-M]

ENVIRONMENTAL PROTECTION AGENCY

[OTS-050003; FRL-1069-1]

TOXIC SUBSTANCES CONTROL ACT PREMANUFACTURE TESTING OF NEW CHEMICAL SUBSTANCES

Guidance for Premanufacture Testing: Discussion of Policy Issues, Alternative Approaches, and Test Methods

AGENCY: Environmental Protection Agency.

ACTION: Discussion of policy and technical issues; request for public comment.

SUMMARY: Section 5 of the Toxic Substances Control Act (TSCA) requires prior notice of intent to manufacture or import a new chemical substance for a commercial purpose or manufacture import, or process for commercial purposes a chemical substance for a significant new use. The premanufacture notice must contain information about the chemical substance that is known to or reasonably ascertainable by the person submitting the notice, including information derived from testing for health or environmental effects. This document contains a discussion of policy and technical issues concerning guidance for premanufacture testing of new chemical substances. It also contains a series of tests and methods which the Agency has tentatively identified as appropriate for testing certain properties and effects of chemical substances. It does not constitute a proposal of premanufacture testing guidance. Rather, the purpose of the publication is to solicit public comment to aid in the formulation of a proposal to be published at a later date.

DATES: Interested persons should comment on this document on or before (90 days after publication).

ADDRESS: Written comments should bear the document control number OTS-050003 and should be submitted to Ms. Joyce Barbour, Document Control Officer (TS-793), Office of Toxic Substances, U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, D.C. 20460.

FOR FURTHER INFORMATION CONTACT:

Mr. John B. Ritch, Director, Industry Assistance Office (TS-799), Office of Toxic Substances, Environmental Protection Agency, 401 M Street, S.W., Washington, D.C. 20460, 800-424-9065 toll free; in Washington, D.C. call 554-1404.

SUPPLEMENTARY INFORMATION: This document consists of two major parts. The first part (DISCUSSION OF ISSUES) contains a discussion of a number of policy and technical issues related to the creation of guidance for premanufacture testing of new chemical substances. EPA solicits comment on all issues identified in this part as well as any other issues related to premanufacture testing of chemical substances.

The second part (REFERENCE TESTS AND METHODS) contains a series of "reference tests" for eliciting information about the fate, health effects, and environmental effects of chemical substances. This part also contains, for each test, a discussion of its information objectives, the rationale for its inclusion as a "reference test", a detailed description of recommended test methods, and appropriate references. EPA solicits comments on the choice of tests and methods. A "Draft Technical Support Document" containing more detail about the tests and methods is available. It can be requested from Mr. John B. Ritch, Director, Industry Assistance Office (TS-799), Office of Toxic Substances, Environmental Protection Agency, 401 M Street, SW., Washington, D.C. 20460, 800-424-9065 toll free, in Washington, D.C. call 554-1404. Any person who intends to comment on tests and methods should review the relevant parts of the "Draft Technical Support Document."

Dated: February 20, 1979.

STEVEN D. JELLINEK,
Assistant Administrator for Toxic Substances.

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I. Discussion of Issues

A. Summary and Request for Comments

EPA believes that guidelines for premanufacture testing can substantially benefit the Section 5 premanufacture notice program and intends to propose such guidelines later this year.

The guidelines could be constructed in several different ways. The various approaches would differ in the degree of specificity of the guidance concerning premanufacture testing decisions. Of these different approaches, EPA's present long term goal is to publish a series of recommended tests and methods along with relatively detailed guidance concerning the need for testing for certain effects in given situations.

However, the inherent diversity of new chemical substances and exposure/use situations subject to the premanufacture notice program has thus far hampered EPA's attempts to construct detailed guidance. Therefore, EPA presently anticipates publishing guidelines which will be relatively general in nature. As the Agency gains experience with the premanufacture notice program, guidance concerning testing decisions can be made more detailed.

EPA is soliciting comment on the wisdom of both its long-term and short-term goals. In addition, the Agency solicits comment on how premanufacture testing guidelines can be constructed to encourage efficient testing of new chemical substances so that the maximum amount of useful information can be gained at least expense.

Specifically, the Agency would like to direct the attention of commentors to the following:

(1) Should guidance concerning the extent of testing and construction of testing systems be general or detailed? Is detailed guidance an obtainable objective?

(2) How can premanufacture testing guidance best be constructed to encourage cost-efficient testing?

(3) Should EPA adopt a base set approach to testing guidelines? Should the base set be "comprehensive" or "flexible," as those terms are defined in Part I? In either case, what tests should appear in a base set?

(4) Should EPA's testing guidelines relate the type or extent of recommended testing to projected production levels? To predicted market value or profitability?

(5) Should testing guidelines for new chemical substances address certain environmental or health effects, but not others? Should decisions not to address a particular effect be based on the adequacy of available test methods? The cost of testing for the effect? A judgment concerning the seriousness of the effect? Other criteria? Which effects should testing guidelines address?

(6) For what health and environmental effects do valid screening tests exist? For each screening test, what criteria should guide a decision to perform additional testing?

(7) In terms of guidelines for health effects testing, how should potential exposure to the new chemical substance relate to the type and extent of recommended testing? Can and should testing decision criteria be based on anticipated exposure? How should such criteria be constructed? For example, should they consider both extent of exposure (e.g., in a consumer product) and also intensity of exposure (e.g., plant workers)?

(8) How should testing guidelines address the question of the form of a substance which should be tested (e.g., pure substance, technical grade, formulation)? What are the cost implications of testing these different forms of a chemical substance?

(9) How should the cost of testing affect the structure of testing guidelines? For example, should the sequencing of tests in a tiered testing structure be determined in whole or in part by the relative cost of testing for various effects?

(10) What measures are available and desirable for reducing the economic impact of premanufacture testing consisting with EPA's information needs for assessing the risk of new chemical substances?

(11) Are there unpublished data that would improve EPA's and industry's ability to perform structure-activity analysis to determine whether testing for a particular effect is needed? EPA requests that any such data be made available to the Agency.

(12) What type of tests do companies now perform on new chemicals (known or suspected to be toxic; of unknown toxicity, etc.) and what type of risk assessments to they perform? What costs do companies experience in performing such tests?

(13) What kind of information (besides their own tests data) do companies have available on manufactured chemicals?

(14) Which specific tests do companies find useful for testing chemicals of various classes (or of various degrees of known toxicity)?

(15) In the context of Part II of this notice, REFERENCE TESTS AND METHODS, EPA solicits comments on the technical merits of the tests and methods set forth.

(16) Are the tests and methods described in Part II cost effective approaches for testing for the various effects? In what ways can the tests described in Part II be modified to decrease cost without substantially sacrificing scientific validity?

B. Summary of Relevant Provisions of TSCA

This section briefly summarizes relevant TSCA provisions in order to show how the section 5 premanufacture notification program relates to other information gathering and regulatory authorities.

Section 5(a) of TSCA requires premanufacture notification of intent to manufacture or import a new chemical substance for a commercial purpose. Section 5(d) requires that this notification include certain types of information, including studies of health and environmental risks.

Section 5(e) provides authority to limit or prohibit the manufacture of a new chemical substance pending the development of adequate information for an assessment of risk in certain circumstances. Section 5(f) provides authority for immediate regulation of a new chemical substance by administrative order in certain circumstances.

Section 4 of TSCA provides general authority to require testing of specific chemicals or categories of chemicals according to test standards promulgated by EPA. New chemicals which are subject to a section 4 test rule must satisfy the testing requirements before notice of intent to manufacture is submitted pursuant to section 5. Section 4(g) provides a mechanism whereby a person subject to the section 5 notice requirement may petition EPA to prescribe test standards for the development of test data.

Section 8 provides authority to require the maintenance of records and

the reporting of health and safety studies, information indicating the presence of substantial risk, and allegations concerning significant adverse effects on health or the environment.

Sections 6 and 7 provide general regulatory authority over chemical substances. Section 6 authorizes regulation by rule. Regulatory options range from labelling requirements to prohibition of manufacture, distribution, use or disposal. Section 7 authorizes EPA to commence civil action in district court for seizure of, or relief concerning, imminently hazardous chemical substances.

C. BACKGROUND

The Environmental Protection Agency (EPA) recently proposed rules and reporting forms to govern the submission of premanufacture notices for new chemical substances pursuant to section 5 of TSCA (40 CFR Part 720; 44 FR 2242; January 10, 1979). Section 5 of TSCA requires that any person who intends to manufacture or import a new chemical substance for a nonexempt commercial purpose in the United States, or manufacture, import or process for commerical purposes a chemical substance for a significant new use, must notify EPA at least ninety days in advance and provide certain information about the substance. This information will be used by EPA in performing risk assessments of new chemical substances proposed to be manufactured. The rules and forms referred to above propose the content and format of premanufacture notices. TSCA § 5(d)(1)(B) requires each notice to contain "any test data in the possession or control of the person giving such notice which are related to the effect of any manufacture, processing, distribution in commerce, use, or disposal of such substance or any article containing such substance, or of any combination of such activities, on health or the environment." Proposed § 720.23 would implement that requirement. The Agency has not yet proposed regulations for notification of significant new uses of chemical substances.

Because section 5 provides for submission of existing test data to EPA and EPA's use of these data to assess risk, the Agency plans to publish guidelines for new chemical testing as an aid to the development and submission of such data in premanufacture notices. The responsibility for deciding whether and how to test chemicals and assess risk rests initially on the manufacturer. Testing guidelines would be useful to the manufacturer because they would help him decide how much and what kinds of data are needed for a risk assessment.

EPA intends to propose testing guidelines later this year. However, during the course of developing testing guidelines, the Agency has encountered a number of policy and technical issues on which the Agency desires further discussion before guidelines are formally proposed. The purpose of this document is to solicit public comment on questions and issues related to guidelines for premanufacture testing of new chemical substances. In Part II of this document, a number of specific tests and methods are set forth for technical comment. The Agency will propose testing guidelines, including recommended tests and methods, after the review of public comments on this document.

D. STATUTORY FRAMEWORK FOR REGULATING CHEMICAL SUBSTANCES

The following discussion briefly describes TSCA as a regulatory mechanism and the contribution which testing guidelines might make to its effective implementation. Its purpose is to establish the role of the premanufacture notice process in the overall program of regulation created by TSCA.

1. *General Intent and Regulatory Structure.* A primary purpose of TSCA is "to assure that * * * innovation and commerce in * * * chemical substances and mixtures do not present an unreasonable risk of injury to health or the environment." (Section 2(b)(3)). The Environmental Protection Agency is charged with the responsibility of determining whether a new or existing chemical substance presents or may present an unreasonable risk of injury to health or the environment. Upon making such a determination, the Agency has available a range of regulatory authorities to eliminate or mitigate the risk.

The responsibility for developing the data and other information to enable EPA to perform risk assessments rests upon the manufacturers and processors of chemical substances. TSCA § 2(b)(1) expresses a policy that: "adequate data should be developed with respect to the effect of chemical substances and mixtures on health and the environment and that the development of such data should be the responsibility of those who manufacture and those who process such chemical substances and mixtures."

For purposes of regulation, TSCA distinguishes between (1) existing chemical substances and mixtures and (2) new chemical substances and significant new uses of exising chemical substances.

(a) *Existing Chemical Substances and Mixtures.* These are chemical substances included in the inventory that EPA is required to publish pursuant to section 8(b) of TSCA. At this time, the Agency is compiling this inventory and intends to publish it in May, 1979.

Existing chemicals can be regulated under several sections of TSCA, depending on the type and degree of risk to health or the environment which they are found to present. Regulatory options range from seizure of imminently hazardous substances, to prohibition or limitation of manufacture, use or disposal, to hazard warning labeling requirements.

EPA also has broad authority to acquire information concerning possible hazardous effects of chemical substances. TSCA contains various authorities and requirements concerning the retention and submission of records and test data related to health and safety studies, reported adverse effects, and known substantial risks. In addition, section 4 of TSCA gives EPA direct authority to require health and safety testing of existing chemical substances. Under section 4, EPA is required, upon making certain findings concerning possible risk or exposure and the need for test data, to promulgate test rules applicable to specific chemical substances or categories of chemical substances. The necessary findings are (1) that the substance may present an unreasonable risk of injury to health or the environment or that the substance is or will be produced in substantial quantities and lead to substantial environmental release or significant human exposure, (2) that there are insufficient data upon which the effects of the substance on health or the environment can reasonably be determined or predicted, and (3) that testing of the substance is necessary to develop such data. A section 4 test rule requires that certain tests be carried out on the particular substance or on substances in the category and specifies the test methods and data reporting requirements. If the substance is already being manufactured or processed for commercial purposes, the test rule is to specify a time period within which the tests must be conducted. Information developed pursuant to a section 4 test rule can be used in deciding whether and how to regulate the manufacture, processing, distribution, use or disposal of the chemical substance.

EPA has broad latitude in defining "categories" of substances for which testing rules may be promulgated pursuant to section 4, but is expressly prohibited from defining a category solely on the basis of being "new chemical substances" (section 26(c)(2)). However, once a category is defined and a test rule promulgated under section 4, any new chemical substance in the category will be subject to the test rule, and the information developed in accordance with the rule must be reported in the premanufacture notice required by section 5 (TSCA section 5(b)(1); proposed 40 CFR 720.20(j)).

(b) *New Chemical Substances.* A "new" chemical substance is any substance not included in the section 8(b) inventory. The statutory requirements concerning premanufacture notification for new chemical substances will become effective thirty days after publication of the inventory. The Agency also has authority under section 5(a)(2) to determine, by rule, that a particular use of a chemical substance constitutes a significant new use. Upon such a determination, the manufacture, import, or processing for the significant new use of the chemical substance is subject to statutory requirements similar to those pertaining to a new substance. Specifically, TSCA prohibits manufacture or import of a new chemical substance for commercial purposes, or manufacture, import, or processing for commercial purposes of any chemical substance for a significant new use, unless notice of intent is submitted to the Administrator of EPA at least 90 days in advance. For the sake of brevity, the term "new chemical substances" will be used in this discussion to refer to both new substances and significant new uses of existing substances. Similarly, the term "manufacturer" will be used to refer to the person submitting the notice whether, by statutory context, that person is a manufacturer, processor, or importer.

The notice of intent to manufacture a new chemical substance must contain certain information about the substance. This includes test data in the possession or control of the submitter as well as a description of any other data concerning environmental or health effects which is known to or reasonably ascertainable by him. However, section 5 of TSCA does not authorize EPA to require the development of new information on health and environmental effects by premanufacture testing of new chemical substances (except insofar as a new substance is subject to a section 4 test rule for a defined category of substances). Section 5(e) of TSCA does authorize EPA to take action to prohibit or limit manufacture, distribution in commerce, use, or disposal of a new chemical substance pending development of additional information on its health or environmental effects. Such action can be taken when the information available to EPA during the premanufacture notice period is insufficient to permit a reasoned evaluation of the health and environmental effects of a new chemical substance and when, in addition, the Administrator finds that the substance may present an unreasonable risk of injury to health or the environment or that it will be produced in substantial quantities and result in substantial human exposure or environmental release. Once sufficient information has been submitted and evaluated, EPA can proceed, if appropriate, to regulate the chemical substance according to the various authorities in the statute.

In summary, although EPA does not have authority to require premanufacture testing of all new chemical substances under section 5, the Agency can act to prohibit or limit manufacture in certain cases pending development of adequate information for a premanufacture risk assessment. Under section 4, EPA can promulgate test rules applicable to specific chemicals or categories of chemicals, provided certain findings are made. Therefore, there are two ways in which section 4 relates to the premanufacture review program. First, a section 4 test rule applicable to a defined category of chemical substances would apply to any new chemical substances within the defined category. In such cases, TSCA requires that the tests specified in the section 4 test rule be carried out before notice of intent to manufacture the chemical substance is submitted under section 5. Second, promulgation of a section 4 test rule is one of several actions available to EPA at any future time should its review of a chemical substance under section 5, or information from any other source, indicate that such rule is warranted.

2. *EPA's Long Term Strategy.* EPA's long term strategy is to issue section 4 test rules applicable to specific categories of chemical substances which meet the criteria of section 4(a) concerning potential for unreasonable risk or significant exposure. These test rules will require appropriate premanufacture testing of new substances that fall into the defined categories. In the long run, EPA's goal is to issue test rules so that a substantial proportion of new chemical substances will receive adequate premanufacture testing. However, it will be several years before the Agency issues enough section 4 test rules to reach this goal. In the meanwhile, the Agency plans to publish section 5 testing guidelines. These testing guidelines will be generally consistent with test rules which will later be issued pursuant to section 4. Unlike section 4 test rules, however, adherence to section 5 testing guidelines will be voluntary. It will be the responsibility of the manufacturer to determine, for each particular chemical, what type and degree of testing he will carry out before submitting the required premanufacture notice. Eventually, as section 4 test rules become effective, they will supersede the section 5 testing guidelines as they apply to the categories of chemicals covered by the section 4 rules.

E. ROLE OF TESTING INFORMATION IN PREMANUFACTURE REVIEW PROGRAM

The purpose of the premanufacture review program is to provide an opportunity to assess the potential for risk to health or the environment presented by a new chemical substance before significant human exposure or environmental release occurs. When a manufacturer develops a new chemical substance and proposes to produce it for commercial purposes, he should identify and assess risks which the chemical may present to health or the environment and take appropriate steps to eliminate or reduce such risks. Assessing the potential for risk to health or the environment depends upon knowledge of the physical and chemical properties and biological activity of a chemical substance. Many chemical manufacturers routinely perform testing to gain information of this type. The information may lead to a decision not to manufacture a particular substance because of its associated risk. It may also indicate the need for special industrial hygiene practices or restrictions on distribution, use or disposal which the manufacturer may incorporate voluntarily.

1. *"Unreasonable Risk" Determination.* Under TSCA, EPA is responsible for assessing the risk to health or the environment presented by chemical substances and for taking any regulatory actions which are necessary to prevent unreasonable risks. The phrase "unreasonable risk" is not explicitly defined by TSCA. The Agency intends to balance the magnitude of risks and social benefits associated with a chemical substance. In doing this, EPA will consider the seriousness of the risk (including the nature, extent, and reversibility of the adverse effects), the availability of alternatives to the substance and their associated risks, and the benefits (economic and otherwise) which accrue to society from the production and use of the substance. EPA must also consider the relative implications of the range of possible regulatory actions. A stronger determination of risk will be needed to support a ban on manufacture than a labeling requirement, for example.

2. *Risk Assessment.* The question of whether a risk is "unreasonable" cannot be addressed until a determination is made regarding whether a risk exists. To determine whether a substance does, in fact, present a risk of injury to health or the environment requires consideration of two types of factors. First, there must be an analysis of the physical, chemical, and biological properties of the substance and its potential for "injury" to health or the environment. The term "injury" may include various toxic effects in humans and other living organisms, including acutely toxic effects such as

poisoning and irritation of sensitive tissues and chronic effects such as cancer, birth defects, genetic damage, and long term or cumulative damage to living organisms in the environment. It may also include a broad range of other adverse environmental effects such as stratospheric ozone depletion, atmospheric modification, and tainting/odor problems. The second type of risk assessment factor is related to the prospects for human exposure or environmental release such that the potential effects referred to above might be manifested in the short or long term.

Analysis of the first type of factor described above may be referred to as "hazard assessment." Analysis of the second type of factor may be termed "exposure assessment." The dual nature of risk assessment acknowledges the interrelationship between hazard and exposure in the concept of "risk." It recognizes the common sense observation that there is more risk associated with a hazardous substance used, for example, in a consumer product than there is with an equally hazardous substance confined to a reaction vessel. Conversely, it recognizes that a more thorough evaluation of hazard potential is warranted for a product of widespread distribution or release than for a substance with limited distribution or release.

3. *Information Needed for Risk Assessment.* The potential for exposure or release may be judged from consideration of such information as production volume, production methods, and the anticipated distribution, use, and disposal of the substance. Human exposure predictions may focus either on particular segments of the population (e.g., plant workers, infants) or on the general public. Environmental release predictions may focus on the environmental compartment (air, water, land) into which the release is made, the distribution of the release (widespread or at few places), the volume and frequency of release, and the probability that particular organisms may be exposed to the substance in the environment. Regarding both health and environmental risks, attention may be given to potential transport pathways, degradation products, persistence, and tendency to accumulate.

Hazard assessment is the assessment of a substance's potential to cause deleterious effects in humans, other living organisms, or important nonliving environmental components. There are several possible sources of direct or inferential information on which a hazard assessment of a new chemical can be based. For example, most new chemicals are related structurally to existing chemicals. In some cases, the results of previous testing of "chemical cousins"—structural analogues—may indicate a potential for hazard for a new chemical substance.

As another example, substances which are defined as "new" for purposes of TSCA (and for which premanufacture notices thus are required) may in fact be existing chemicals for which test data exist. This could be the case for a TSCA "new chemical substance" which previously was produced and used abroad, one which was only manufactured in the United States before January 1, 1975, or which has previously been manufactured exclusively for a non-TSCA use (e.g., pesticides, drugs, or food additives). For such substances, some relevant data on hazardous effects may exist independent of any tests carried out for purposes of submitting a premanufacture notice. Such data would need to be evaluated for its contribution to risk assessment.

In many cases, however, there will be little or no information about the possible hazardous effects of a new chemical substance subject to premanufacture notice and what kind of information will be needed to support a risk assessment will depend upon the particular chemical substance and its intended use and exposure/release potential. Generally, several types of information may be needed:

(a) Information on the anticipated methods, locations, and volume of production, distribution, use and disposal may be needed to assess the potential human exposure and environmental release.

(b) Information on the substance's physical and chemical properties may be needed to evaluate potential transport pathways, degradation, and bioaccumulation.

(c) Information on potential effects on human health may be needed for a determination of health hazard.

(d) Information on potential effects on the environment may be needed for determination of both biological and non-biological environmental hazard.

Some information of the first type will probably have been accumulated by the manufacturer in the course of developing the chemical substance. Information of the other types, however, would generally be developed by testing the chemical substance in various ways. It is this type of testing that section 5 premanufacture testing guidelines will address.

EPA does not perceive the risk assessment process to be static or inflexible. Rather, it must be tailored to each new chemical substance. In some instances, the consideration of structure-activity data, previously available test data, and information on intended use and expected exposure may indicate that there is little potential that the substance would present a significant risk to health or the environment. In other cases, a more detailed and thorough assessment will be necessary to decide whether some form of regulation may be necessary to avoid creation of an unreasonable risk.

EPA is presently developing its risk assessment process for section 5 premanufacture review. For those new chemicals which will require a detailed assessment, it is apparent that the extent of the assessment may be constrained by the amount of time and data available for the assessment. Under TSCA, EPA has ninety days for premanufacture assessment, which can be extended for up to ninety days if the Administrator finds there is good cause for an extension. In addition, if EPA determines that insufficient information is available for a reasoned evaluation of health and environmental effects, and also makes certain findings related to the possibility of unreasonable risk or substantial environmental or human exposure, the Agency may proceed under section 5(e) to prohibit or limit manufacture pending development of the necessary information (proposed 40 CFR 720.36).

4. *Responsibility for Making Premanufacture Testing Decisions.* Premanufacture testing decisions are, in the first instance, the responsibility of the submitter. In order to clarify the role that voluntary testing guidelines might play in helping the manufacturer make these decisions, it is important to discuss the types of premanufacture decisions the manufacturer must make.

A manufacturer's premanufacture testing decisions can be divided into three groups. It is important to distinguish between these types of decisions, because various issues related to EPA's development of testing guidelines are closely related to the extent to which a particular guidelines approach does or does not lend support to a particular type of decision.

(a) *Whether to Test.* The first question the manufacturer must address is whether he has enough information about his substance to assess risks and make informed decisions concerning manufacture. To some extent, this decision will depend upon his perception of EPA's risk assessment process and information needs. If he decides that more information is needed, he must also decide whether testing is the best way to obtain the needed information. His decision whether to undertake testing may also depend upon factors such as his willingness or ability to pay the cost of the testing.

(b) *Type and Extent of Testing.* A closely related decision will involve determining the properties or effects about which more information is needed and deciding how much testing will be needed to achieve the desired results; in short, the manufacturer

must determine the amount of testing he will undertake. His decision will presumably be influenced by a number of factors, a few of which would include:

- The particular properties or effects which he feels are important for assessing potential hazard;
- The ways in which he anticipates the substance will be manufactured, processed, transported, used, and disposed;
- His ability or willingness to incur the expense of testing; and
- His perception of the amount and type of information EPA will need to have.

Having decided that he wishes to obtain more information about certain properties and effects, he must design a test plan which is responsive to these needs. The test plan should be designed to yield the needed information in a reliable and cost-efficient manner. He may wish to defer decisions concerning some tests until others have been carried out. If so, he may establish prior decision criteria for making that judgment. As discussed below, there are a variety of ways in which test plans could be constucted. The manufacturer must design a test plan to fit his particular needs.

(c) *How to Test.* As part of the design of his test plan, the submitter must choose the particular tests which he will perform. In addition, he must decide upon specific methods for carrying out each test. These decisions will depend, in part, on his perception of the scientific validity of various tests and methods, their relative costs, and his perception of whether EPA prefers certain tests over others for any given property or effect.

Once the above decisions have been made and the test plan has been executed, the manufacturer again faces the first type of decision in terms of the adequacy of information then in his possesion. Eventually, he must decide either that (1) the risks associated with the substance are such that he should proceed no further in its development, (2) that the economic potential of the chemical does not warrant incurring any further expense, or (3) that he will submit a premanufacture notice reflecting the information at hand. The information derived from testing may lead him to develop safeguards in manufacture, processing, distribution, use or disposal to reduce exposure and therefore risks he has identified.

F. STRUCTURE AND FUNCTION OF TESTING GUIDELINES

1. *Alternative Approaches.* There are four general approaches to testing guidelines available to EPA. In the discussion that follows, each is identified and its advantages and disadvantages discussed. The discussion of alternatives is followed by a discussion of different approaches which could be taken in developing guidance consistant with EPA's presently preferred alternative.

Alternative 1: No action.

EPA could say nothing about premanufacture testing, providing no comment on any of the three types of testing decisions mentioned above. An advantage of this approach to EPA would be that it is the easiest course to take, freeing staff resources for work on other current TSCA-related activities. Some manufacturers have indicated a preference for this alternative, stating a concern that even voluntary testing guidelines will be used as a "checklist" when EPA is determining the adequacy of submitted information for a risk assessment. If "no action" were the course followed, the manufacturer would make his own decisions without any guidance from EPA. No explicit or implicit presumptions would be established by EPA regarding the desirability of testing in given situations or the applicability of any particular test.

However, this alternative would also present some disadvantages to both EPA and the manufacturer. The manfacturer would make his decision in ignorance of EPA's expectations regarding the information needed to carry out its assessment of risk. As a result, the Agency might determine that a greater number of premanufacture notices contain insufficient information. EPA might need to proceed more often under section 5(e) to regulate substances pending development of information. This could result in unnecessary delays in manufacturers' production schedules, litigation, and the diversion of EPA's technical and legal resources. In addition, nonuniformity of testing methods would be maximized. EPA's risk assessment of a chemical substance would have to focus as much on evaluating testing methodology as evaluating results. Maintaining an equitable and evenhanded review process would be more difficult.

Alternative 2: List of Tests and Recommended Methods.

Another alternative would be to publish a list of tests which are appropriate for specific properties and effects and recommended methods for carrying out each test. The basic thrust of this alternative would be to say, "If you choose to test for a particular effect or property, here is a test which EPA believes is appropriate and here is a recommended method for conducting the test."

This alternative would offer several advantages to both EPA and the manufacturer. First, EPA's task in preparing guidelines would be relatively easy compared to other alternatives. The Agency's role would be to identify state-of-the-art tests for each effect of concern and choose one or more recommended methods. In terms of the types of premanufacture testing decisions outlines above, it would provide guidance concerning only the third type, "how to test."

The listed tests and recommended methods would not be required. They would be suggestions, and the manufacturer would be free to test for any particular effect in any way he wished. However, to the extent that the recommendations were followed, EPA's (and in many cases the manufacturer's0 risk assessment process would be made somewhat easiér. EPA's attention could be focused on the results of the recommended tests rather than on the scientific validity of a variety of other tests and methods. This would allow a more efficient, thorough and evenhanded risk assessment. In the long run, the creation of a comparative data base on the properties and effects of chemicals, derived from uniform test methods, would prove valuable. Structure-activity correlations might be more readily identified, reducing the future need for certain types of tests. Some types of effects and tests might prove predictive of others, thereby decreasing the need for testing. In the long run, the development of a consistent data base could only make testing and assessment more cost-efficient.

Testing guidelines constructed in this way would have several disadvantages, however. They would provide no guidance at all for decisions about "whether to test" and "type and extent of testing." Nor would they be of much help in deciding how to sequence tests so that preliminary tests would indicate the need for further tests. The absence of such additional guidance from EPA could result in uneven premanufacture testing. In order to guard against delays that might occur when EPA acts to obtain more information, some manufacturers might carry out more testing than EPA would think necessary. Others might underestimate EPA's information needs and, therefore, encounter problems which could have been avoided. Either way, the result would be inefficiency in the premanufacture testing program. The results might be more adverse for small companies for whom testing is a proportionately larger burden and marketing delays a greater threat. Decisions might be made to stop development of chemicals which, had there been some guidance from EPA concerning its information needs, might have been marketed. This could have a needless ad-

verse impact on the pace of chemical innovation.

Alternatively, EPA could provide some form of guidance concerning the applicability of specific tests to different types of chemicals and exposure/use situations. In theory, this guidance could be quite general or quite detailed. For purposes of comparison, this discussion will identify two alternative forms of guidance at opposite ends of the spectrum—relatively general guidance (Alternative 3) and relatively detailed guidance (Alternative 4). It should be understood, however, that these alternatives differ more in degree than in kind. A guidelines package could be general in some respects and detailed in others.

Alternative 3: List of Tests with General Guidance Concerning their Use.

EPA could publish general guidance concerning the applicability of the recommended tests and methods in particular circumstances. The applicability guidance would address "whether to test" and "type and extent of testing" decisions, but it would be relatively general in nature. Thus, it might describe EPA's view of the relationship between potential hazards and potential exposure in making risk assessments. It might indicate in general terms EPA's perceived information needs regarding different types of chemicals and exposure/use situations. It might also discuss ways in which a testing plan could be structured—that is, ways in which tests might be sequenced and, in general, how a manufacturer might decide the kinds of results which indicate the need for certain kinds of additional tests.

Such an approach would have the advantages mentioned above in Alternative 2. In addition, it would remove some (but not all) of the uncertainty regarding EPA's risk assessment process and information needs. To the extent that the guidance adequately reflected EPA's risk assessment process and was followed by the manufacturer, it would result in testing that would be relatively more appropriate for EPA's risk assessment needs. Therefore, testing would be more efficient and there would be fewer notices with information which, in EPA's view, was insufficient. Avoidable delays would be lessened.

On the other hand, general guidance would not completely dispose of the "whether to test" and "type and extent of testing" decisions. If the manufacturer wished to follow EPA's advise, he would need to relate the general guidance to his particular needs. Depending upon his interpretation of the general guidance, he might perform more or less testing than actually warranted.

Alternative 4: Recommended Tests With Detailed Guidance Concerning Their Use.

This alternative would incorporate the recommended tests and methods in Alternative 2 but would contain relatively detailed guidance concerning "whether to test" and "type and extent of testing." There are a number of ways in which detailed testing guidance could be constructed, ranging from a single "base set" of recommended tests to tiered testing schemes based on various scientific and policy considerations. Some of these approaches to detailed guidance are discussed in a later section.

Detailed guidance might specify conditions under which certain types of testing would be warranted. It might also specify quantitative criteria for interpreting test results and determining the need for additional testing.

An advantage of detailed guidance is that it would be more help in resolving "whether to test" and "type and extent of testing" questions. The manufacturer would have stronger assurance that, if he followed EPA's guidance, the information developed would more likely be appropriate for EPA's risk assessment. This alternative would provide more explicit guidance, would probably increase the efficiency and appropriateness of testing, and would minimize delays occasioned by the submission of inadequate information.

A principle drawback is the difficulty of implementing this alternative. Relatively detailed guidance concerning whether and how much to test is difficult to develop unless the particular type of chemical and exposure/use information is known. Actual "whether to test", "type and extent of testing" and test plan design decisions can best be made in the context of particular chemical substances.

Another drawback is that more detailed decision criteria might be perceived as being regulatory requirements, even though issued in the form of voluntary guidelines. They might thereby limit the manufacture's perceived range of choice. Submitters might feel that they could not deviate from EPA's recommendations.

Alternatives 3 and 4 differ in the degree of detail in which guidance concerning "whether to test" and "type and extent of testing" would be stated. In fact, these two alternatives are presented in this way to emphasize the extremes in such guidance for purposes of discussion. These alternatives represent the ends of a spectrum, and the discussion attempts to point out the consequences of guidelines of both extremes.

As the Agency has explored the development of testing guidelines, some individuals have urged the adoption of very general guidance on "whether to test" and "type and extent of testing" questions. They argue that manufactures are experienced at testing and that their scientific judgement should not be constrained or directed by testing guidelines. Others have encouraged the publication of detailed guidance. They point out that, since EPA will assess potential risks presented by new chemical substances, the Agency should disclose its position on testing and the use of test information for assessment in as much detail as possible.

2. *EPA's Long-Term and Short-Term Goals.* EPA's long-term goal concerning premanufacture testing guidelines is to provide recommended tests and detailed guidance on how to use them in a premanufacture testing program. The Agency has been working actively to develop such guidance by the time the premanufacture notice program begins in Spring, 1979. However, it is doubtful that detailed guidance can be fully developed by that time.

Because EPA believes there is a need to have testing guidelines in place as soon as possible, the Agency is considering proposing more general guidelines as an interim approach. More detailed guidance can be published as the Agency gains knowledge about existing testing programs and further develops its risk assessment information needs. EPA is considering developing a guidelines package which would contain recommended tests and methods along with general guidance on "whether to test" and "type and extent of testing" issues. The remainder of Part I of this document discusses the development of testing guidelines addressing these issues. Public comment on these issues will help EPA fashion its proposal of interim testing guidelines, as well as its longer term development of more detailed guidelines. Part II presents a series of tests and methods which the Agency has tentatively identified as appropriate for inclusion in a testing guidelines package. For any particular effect for which decision to test has been made, these "reference tests" would provide guidance on "how to test" questions.

G. DEVELOPMENT OF TESTING GUIDELINES

For the past several months, EPA has made an intensive effort to develop premanufacture testing guidelines which will support the three types of testing decisions described above. During this time, the Agency has received comments and recommendations from a number of trade associations, public interest groups, and other groups and individuals interested in testing issues. For reasons discussed below, EPA has decided not to endorse at this time any of the testing schemes proposed by such groups and

individuals. The following discussion describes the problems and prospects for testing guidelines and identifies related policy and technical issues which must be resolved. The Agency invites public comment on how testing guidelines could best be constructed in order to facilitate the effective and efficient implementation of TSCA.

As noted above, EPA has tentatively identified a number of tests and methods which it feels are appropriate for testing for certain physical and chemical properties and health and environmental effects. The tests and methods which the Agency has selected are set forth in Part II of this document. The tests are intended to function as "reference tests"—that is, recommended tests to which a person may refer once a decision has been made to test for a particular effect or property. These recommended tests were selected because they are standardized tests in common use or because they generally represent the "state of the art." In those cases, futher validation of a particular test is needed. In those cases, the candidate test is judged to be the best available at this time.

More difficult than selecting tests and methods is the problem of providing guidance concerning their use—that is, guidance concerning "whether to test" and "type and extent of testing" decisions. Discussed below are some of the factors which must be considered in developing testing guidance and some alternative ways in which guidance might be constructed.

1. *Context of Testing Decisions.* Any attempt to devise premanufacture testing guidance concerning "whether to test" and "type and extent of testing" is constrained by an unavoidable problem. The purpose of premanufacture testing guidelines, as discussed above, is to assist the manufacturer's decision making process and to encourage testing which is compatible with EPA's performance of risk assessments. The manufacturer makes his testing decisions in the context of particular chemical substances. However, the entire universe of new chemical substances is subject to section 5, so to be comprehensive, premanufacture testing guidelines would have to address the great variety of future chemicals and use and exposure patterns. It is very difficult to develop specific guidance with recommended tests to apply to all such substances and situations. In the case of a chemical substance that would be widespread, mobile, and persistent and is closely related to substances of known toxicity, thorough testing by diverse means would be needed to adequately evaluate risks. At the other extreme, less testing might be needed for a low exposure substance (e.g., one to be reliably contained) unless and until its use should change.

If, as EPA expects, the majority of chemicals subject to premanufacture notice fall somewhere in the middle, it would be neither practical nor prudent to expect the full range of testing for every chemical. A point of diminishing returns can be reached where the additional social benefit of testing is offset by the cost of testing and the possibility of inhibiting the development of a socially beneficial product. EPA cannot identify this point in advance for all yet-unknown chemicals. Rather, it must be evaluated by considering previously available information on toxicity and exposure, societal benefits of producing the chemical, the value society places on relative certainty about the safety of a chemical, and the costs of additional testing. These factors are variable.

2. *Approaches to Testing Guidelines.* There are several approaches to the development of testing guidelines which EPA could adopt in pursuit of its goal of detailed guidance. They can be judged according to several different criteria, including economic impact, scientific validity, and practicability. In the final analysis, there is an implicit tension between society's need for assurance that the chemicals distributed in commerce are safe and the social benefits of chemical innovation. In some cases, the cost of developing sufficient information to be reasonably certain of the health or environmental hazard presented by a chemical might preclude marketing of a new chemical substance. Because many new chemicals will probably present little risk and yet promise social benefit, premanufacture testing must be carried out in a flexible and reasonable manner. Premanufacture testing must be adequate, however, to detect and assess new chemical substances which may present an unreasonable risk of injury to health or the environment.

(a) *Comprehensive base set.* One approach theoretically available to EPA is that of a single "comprehensive base set." EPA defines a comprehensive base set as a set of tests to produce data which EPA would presume to be necessary for every new chemical substance. The tests could address a wide range of effects and physical/chemical properties. The base set would therefore be "comprehensive" in terms of both effects covered and applicability to chemical substances. An ideal comprehensive base set would not be unreasonably expensive, would apply to all chemicals, and would provide enough information for at least a preliminary risk assessment.

A distinguishing characteristic of the comprehensive base set approach is the presumption that a certain set of data is both *necessary* for every new chemical substance and *sufficient* for assessment purposes. The comprehensive base set approach would thus provide a maximum amount of guidance on the question of whether and how much to test a new substance. A manufacturer who carried out every test in the base set could be reasonably assured of fulfilling EPA's assessment information needs. On the other hand, an inflexible comprehensive base set could be inefficient should it include tests which are not appropriate for a significant number of substances.

At this time, EPA believes that the single comprehensive base set approach is not a viable alternative for premanufacture testing guidelines. The diversity of chemical substances subject to the premanufacture notice requirements of section 5 appears to preclude any single set of data which would be both necessary and sufficient for assessing every new substance. Another consideration is cost. A set of tests which would provide sufficient information for a risk assessment for all chemicals would be sufficiently costly to preclude further development of many chemical substances. The difficult tradeoff between the need for information and the cost of testing would still have to be addressed without reference to a particular chemical substance and exposure/use situation.

(b) *Categorical base set.* Another alternative which EPA might pursue is to define categories of chemicals and produce a base set of tests for each category. Chemical categories might be defined based upon chemical structure, intended use, production level, or other factors or combinations of factors.

This approach would avoid some of the problems associated with the diversity of chemical substances. More specific guidance could be written than would be feasible with a single comprehensive base set as discussed above.

EPA would need considerable time to develop categorical base sets. EPA solicits comments on the utility of developing a series of categorical base sets over a period of several years. In particular, the Agency would appreciate comments on how the categorical base set approach could be implemented and whether the contributions to the premanufacture review program would outweigh the resources required to develop the various base sets. The Agency also seeks comment on how it could define categories of chemicals and the types of tests that would be appropriate for each category.

(c) *Flexible base set.* Some of the problems with both the comprehensive and categorical base set approaches result from the attempt to

apply a set of tests to an array of chemical substances to produce, for each substance, sufficient information for a preliminary risk assessment. Ways might be devised, however, to incorporate flexibility into the base set approach. This would allow testing for a particular substance to be "tailored" to its characteristics and, perhaps, its expected exposure patterns. One such approach would be to establish a base set of tests while including a series of exceptions that delete certain tests in certain situations. For example, EPA could advise the submitter to delete tests for physical/chemical properties which were clearly inappropriate for his substance but maintain the presumption that all the health and environmental effects tests be performed.

Further, exceptions could be based on exposure and use considerations. For example, EPA might advise that environmental effects testing is not needed for substances for which the chance of significant environmental release is slight.

Another approach would be to define a minimum base set of tests applicable to all substances and provide guidance for adding other tests appropriate to the particular case. This approach is discussed below as a "tiered testing" approach.

The flexible base set approach would contain more flexibility than the comprehensive or categorical base set approaches. As more flexibility is built in, however, the advantages of detailed guidance are lost. The probability increases that insufficient or inappropriate information may be developed.

EPA solicits comment on the flexible base set approach to testing guidelines. Specifically, the agency would like to receive comments concerning what tests might be placed in the base set and how guidance concerning exceptions might be constructed.

(d) *Tiered Testing Systems*—(1) *General.* In a tiered testing scheme, tests or groups of tests are arranged in a hierachical structure. Testing begins with tests in the lowest tier and proceeds as appropriate to higher tiers. Decisions on whether to go on to higher tier tests or to "exit" from the testing scheme are made according to decision rules or criteria. These decision rules may be general and qualitative or specific and quantitiative. The latter are often referred to as "triggers."

In theory, a tiered testing scheme contains "screening tests" in the first tier, followed by other predictive and confirmative tests in higher tiers. The screening tests are designed to disclose the potential that the chemical may exert a toxic effect. Positive results from screening tests indicate the need to carry out more elaborate tests to confirm the presence or absence of the toxic effects or to further characterize or improve the reliability of the original prediction. The attractiveness of the tiered structure is that is is presumably not necessary to carry out the more expensive confirmative tests in cases where the screening tests yield negative results. Thus, in theory, a tiered testing scheme can promote cost-efficient testing.

The tests and decision rules in a tiered system can be arranged in a variety of ways, depending on the purpose of a particular testing scheme and the degree of conservatism to be built into it. In other words, a tiered system can be constructed to yield data for a comprehensive risk assessment or a preliminary risk assessment. It can address a wide range of substances and effects, or only a few.

There are a number of considerations that can influence the selection and sequencing of tests within a tiered system. For example, tests can be arranged in such a way that each effect of concern, such as acute toxicity, chronic toxicity, cancer or birth defects, has equal priority, and all effects receive adequate testing. If it is scientifically justifiable, a tiered sequence could be developed for each effect with screening tests in the first tier, and other predictive and confirmative tests in higher tiers. The latter tests would be more extensive and more costly, and would require more time to complete. They would need to be performed only when positive results from earlier tests indicated a potential for the particular effect of concern.

For certain important health and environmental effects (e.g., animal oncogenicity and chronic toxicity) there may be no validated short-term or screening tests. Therefore, tiering based on scientific criteria is not possible for all properties and effects. The lack of short-term or screening tests means that it would be necessary to perform expensive tests if one wishes to test for all significant effects. As a result the first tier of tests would be very expensive. Thus, one of the major theoretical advantages of a tiered testing system could be diminished in practice if tests for all important effects are included.

A decision to include only short-term or screening tests in the first tier, on the other hand, would mean that no testing would be conducted for some effects. Negative test results concerning those effects for which screening tests are available would mean that higher tiers would not be reached. Thus, effects represented only in the higher tiers would go untested in such cases. EPA prefers not to ignore certain toxic effects simply because inexpensive short-term screening tests are not available.

One possible tiered testing scheme is similar to, and in effect builds upon, the flexible base set approach discussed above. EPA could identify a minimum base set of tests to provide data which would be presumed necessary for every chemical substance. This set of tests, which could be designated "Tier O," might relate to important physical or chemical properies, such as vapor pressure and octanol/water partition coefficient. The Tier O tests could be used to determine which types of Tier 1 (short-term and screening) tests would be appropriate for particular chemical substances.

A tiered testing scheme could also be constructed based on economic as well as scientific considerations. Such a scheme would have the explicit objective that less expensive tests would be performed in the first tier and more expensive tests in higher tiers. This approach would result in a less costly testing program, because only the less expensive tests would be carried out routinely. More expensive tests would be carried out only when the less expensive tests yielded postitive results, or (for effects for which there are no short-term or screening tests) when other criteria for testing are met. These latter criteria could include production volume, company size, chemical profitability, and so forth.

There are two constraints associated with this approach which limit its utility for scientific risk assessment. First, since the sequencing of tests would be determined in part by their relative costs and not solely by the reliability of the first tier tests as screens for the higher tier effects, questions of the scientific adequacy of the resulting data might arise. Second, the consequence of such an approach would automatically be that effects for which inexpensive tests exist would be given priority over other effects for which there are no such tests.

Though attractive from an economic and pragmatic point of view, such a testing system may not adequately protect society from hazardous chemical substances. For example, it is arguable that long-term chronic health effects should be of greater concern to EPA under section 5 than short term acute effects. If so, performance of chronic studies should not depend on the results of short term tests which are not scientifically related to the evaluation of chronic effects.

A tiered testing system should include criteria following each tier to guide decisions concerning whether to go on to higher tiers or terminate testing. These decision criteria can be quantitative or qualitative, rigid or flexible. Various suggested testing schemes, for example, have incorpo-

rated decision criteria based upon exposure or environmental release potential, such as quantitative or qualitative estimates of production volume, discharge volume, specific uses, or estimated environmental concentrations. Other decision criteria have been suggested on the basis of indicators of environmental persistence or bioconcentration potential, such as volatility or sorption loss rates, hydrolytic half-life, BOD/COD ratios, water solubility, or octanol-water partition coefficients. Further, most schemes employ one or more decision criteria related to acute animal toxicity, in the form of LD_{50} or LC_{50} values, relationships of static to flow-through bioassay data, or other parameters. It is important to recognize that decision criteria, like the tier structure itself, can be based on both scientific and policy consideration. For example, triggers can be established that make it relatively difficult or relatively easy for a substance to exit from the testing system. Establishing decision criteria which are extreme in either direction defeats much of the purpose of the tiered system. Therefore, the nature and sensitivity of decision criteria have a great deal to do both with the expense of testing a substance and the degree of certainty that the testing system will yield a low percentage of false negative and false positive results.

EPA could sequentially develop a series of tiered testing systems on the basis of categories of chemicals or use or exposure patterns. This approach would eliminate some of the difficulties inherent in addressing the universe of new chemical substances in a single testing guidelines package. It probably would permit more detailed guidance. However, more time and resources would probably be required to develop this approach.

(2) *Testing schemes recommended to EPA.* In the course of developing testing guidelines, EPA has considered a number of tiered testing schemes developed by various interested parties, such as the Conservation Foundation, National Academy of Sciences, European Economic Community, American Institute of Biological Sciences, American Society for Testing and Materials, and several chemical manufacturers. Though the schemes have been developed by diverse groups, they have some elements in common. Generally speaking, the recommended test schemes tend to contain basic physical and chemical properties and short-term acute toxicity tests in the lower tier, and long-term, chronic effects tests in higher tiers. The acute tests are often called "screening tests," though there is often little or no scientific support for the proposition that the results of the acute tests are predictive of certain chronic effects to be tested in the higher tiers. In some cases lower tier tests appear to be placed there primarily because they are less expensive.

Some of the recommended systems, though recognizing the need for decision criteria for progressing from one tier to the next, do not contain such criteria. In those that do contain criteria, the criteria often appear to be based on subjective judgments involving economic and methodoligical concerns as well as scientific considerations. Although such judgments may be necessary to arrive at usable decision criteria, the analysis on which they are based should be explicit so that the validity and implication of the criteria can be evaluated.

3. *The Cost of Testing.* It appears that many chemicals currently in commercial production are low volume, specialty chemicals. Preliminary information derived from the inventory of chemical substances developed by EPA under section 8(b) of the Act suggests that approximately 75 percent of all chemicals in production in the United States have annual production volumes of less than 100,000 pounds. Most of these chemicals have been developed for specific uses. They compete with numerous potential substitutes and face highly price sensitive demand. Presumably, many new chemical substances will share some of these features. For a typical new substance, initial production may be low and increase as the substance penetrates the market. Making conservative assumptions about sales prices, gross margins on sales, product lives, and start-up costs, it appears that for many new chemicals it may not be economically feasible to perform very much testing for health and environmental effects or chemical fate at the premanufacture stage. For some chemicals, the manufacturer might therefore decide to forego production of the chemical rather than incur the cost of testing it. It is thus possible that premanufacture testing sufficient to produce the information needed for a reasoned risk assessment could inhibit innovation in the chemical industry. A major objective of testing guidelines is to minimize this effect by focusing testing efforts on substances which, because of anticipated exposure or preliminary indication of toxicity, are more likely to present a risk to health or the environment.

Perhaps the most difficult situation arises when a new chemical substance is expected to be produced in small quantities but for a use that will expose large segments of the population. An example would be minor component of a widely used consumer product. In this situation, the probability of widespread human exposure would indicate the need for health effects testing. However, the anticipated low production volume might mean that the anticipated profits from the chemical would be insufficient to cover the costs of the necessary health tests. In this situation, the manufacture might decide to not attempt to market the substance.

Considering the premanufacture review program as a whole, it is difficult to predict accurately the actual degree to which chemical innovation might be inhibited by testing guidelines. It would depend on the cumulative individual decisions of many manufacturers developing a variety of chemicals for diverse uses.

It is reasonable to generalize, however, that detailed guidance will encourage more testing to be carried out. Due to the cost of testing when guidance indicates the need for it, some low market potential chemicals would not be produced. However, the public would gain greater certainty that those that are produced do not present and unreasonable risk to health or the environment. Conversely, more general guidance could result in less testing. Therefore, there would be more chemical innovation but less certainty concerning risk. Finding the proper balance between information needed for public assurance of safety and societal benefits from chemical innovation is a vital part of the long term successful implementation of TSCA.

TSCA addresses this implicit policy conflict which it creates. In the Statement of Policy in Section 2, TSCA states that "authority over chemical substances and mixtures should be exercised in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation while fulfilling the primary purpose of the Act to assure that such innovation and commerce in such chemical substances and mixtures do not present an unreasonable risk of injury to health or the environment." (Section 2(b)(3)).

In the context of the premanufacture notice program, EPA especially seeks public comment on how to balance the "primary purpose" of TSCA, to assure that new chemical substances do not present an unreasonable risk, with the admonition that the Agency not "unduly" impede innovation in the chemical industry. The Agency seeks comment on how premanufacture testing guidelines can be constructed to encourage the appropriate balance between the need for test data and the cost of obtaining them.

There are several approaches to the question of guidelines for premanufacture testing which could mitigate adverse effects on innovation. Perhaps the most straightforward is the use of

"production volume cutoffs" as decision criteria in a tiered scheme. With such an approach, EPA would advise manufacturers that it would expect little or no testing for substances which will be produced under certain volume limits. This approach would remove the economic burden of testing for many low volume chemicals. However, it would be based on the implicit assumption that low production volume equates with low exposure and therefore low risk. Under this approach, low production-high exposure chemicals would probably go untested even though they might be very hazardous. Also, the assumption that low production implies low exposure does not consider particular segments of the population, such as production or processing plant workers, whose exposure might be quite high. Given EPA's responsibility for considering all types of exposure, an assumption which implicitly "averages out" a production volume over the whole of society in deciding that exposure levels will be acceptable requires close scrutiny. Thus, there are issues associated with the production volume cut-off approach which weigh against its economic merits.

Another approach which might mitigate the overall economic impact of premanufacture testing guidelines involves the selection of particular "effects of concern". Under this approach, EPA would limit its testing recommendations to those effects the Agency deems to be of greatest importance in the review of notices for new substances. Cost estimates for testing the properties and effects with which EPA could be concerned range from a few hundreds or thousands of dollars for many of the chemical fate and ecological effects tests, to tens of thousands and even hundreds of thousands of dollars for some of the health effects tests. Biodegradation tests, for example, cost in the neighborhood of $5,000-$12,000 to perform, while subchronic health tests cost $100,000 or more and chronic toxicity and oncogenicity studies cost $300,000-$700,000. By focusing on certain effects, EPA would decrease the cost of testing for particular substances. However, the Agency would do so at the expense of obtaining information about many effects. Because some of the more expensive tests relate to human health effects, it might be difficult to implement the "effects of concern" alternative in such a way as to both reduce cost and protect important public health values.

A third way to mitigate the costs of testing would be to modify the conventional test method which would be included in a base or first tier set so as to reduce the overall cost of the set. For example, less expensive test organisms could be used in 90 or 180 day subchronic testing, or the number of recommended tests in a mutagenic/oncogenic screening battery could be reduced. A problem with this approach is the loss of predictive power that might result. EPA is actively pursuing this option by seeking ways to reduce the cost of particular tests while maintaining adequate scientific predictability.

Another alternative would be to adopt a "deferred testing" approach. For certain new substances which EPA determines will present little potential risk at initial production levels and intended uses, EPA could issue significant new use rules (SNURs) under section 5(a)(2). The SNUR for a substance could identify possible future production levels and uses for the substance. Should these conditions be realized, the substance would again be subject to section 5 review in terms of its new production level and uses. At this point, the section 5 review might indicate a need for certain additional testing. Because the chemical probably would have a greater market potential than when first manufactured, it should be better able to support the costs associated with additional testing. The general effect of using SNURs in this way would be to relate levels and costs of testing to the expanding market strength and profitability of new chemicals. Such a program could result in a minimum adverse effect on production of new chemicals while ensuring that those which are successful will be subject to further EPA review.

EPA does not prefer to allow small volume chemicals, regardless of their uses, to be produced without some testing. However, it is not the Agency's intent to encourage extensive testing of all new chemicals. EPA is aware that in some cases a relatively small amount of data of certain types will be sufficient to perform an adequate risk assessment, while in other cases data from a full range of tests, including chronic toxicity and oncogenicity tests, will be needed. As EPA gains experience in performing risk assessments under TSCA, the tradeoffs between the costs of generating information and the value of that information will become better understood and incorporated into guidelines and section 4 testing rule decisions. Further, testing technology has evolved rapidly in the recent past, and EPA expects that it will continue to do so. As new tests are developed and correlations among tests are documented, EPA will revise the premanufacture testing guidelines. The goal will be to maintain state of the art cost effectiveness and scientific validity as knowledge of testing technology advances.

Finally, EPA is aware that it is operating in an area of relative uncertainty in its efforts to develop testing guideline and incorporate them into the premanufacture review program. For a number of reasons, it is difficult to perform economic assessments of alternative approaches to testing guidelines. For example, the Agency does not know for a certainty how many new substances will be introduced each year; the types of chemicals they will be; how many of them will be small volume, low profit chemicals; or what current industry practices are with respect to health and environmental testing. Equally important, the true economic cost of a particular approach to testing guidelines depends upon the extent to which manufacturers follow EPA's recommendations, a factor about which EPA cannot obtain advance knowledge.

II. Reference Tests and Methods

As discussed in Part I above, EPA plans to propose testing guidelines to support implementation of the premanufacture notification provisions of section 5 of the Toxic Substances Control Act (TSCA). As a first step in developing testing guidelines, EPA has tentatively identified a number of "reference tests" for specific physical and chemical properties and health and environmental effects of chemical substances. The reference tests will advise a manufacturer who has decided to evaluate a particular property or effect which test or tests EPA feels are most appropriate. Each reference test will be accompanied by a detailed description of the preferred method for conducting the test.

Though adherence to the reference tests is voluntary, EPA believes that publishing recommended tests and methods will encourage uniformity of testing methodology. Uniformity of testing methodology is desirable because it would facilitate risk assessment. Use of a recommended test and method would assure acceptance of the test and method as valid. It would also allow EPA to focus its assessment on the results of tests rather than on evaluation of a variety of test methods.

The reference tests will address a broad range of properties and effects. The Agency does not foresee that all reference tests would be carried out on every new chemical substance. Rather, the reference tests will provide a list of recommended tests from which a manufacturer may, if he desires, choose tests which are appropriate for his test plan.

Also, EPA is participating in two major efforts to develop multiagency agreement upon test methods. The first of these involves the Interagency Regulatory Liaison Group (IRLG),

which consists of the Occupational Safety and Health Administration, the Consumer Product Safety Commission, the Food and Drug Administration, and EPA. This group is identifying test methods which would yield data suitable for submission to any program within the four agencies.

The second effort aimed at building agreement on testing methods is an international effort sponsored by the Organization for Economic Cooperation and Development (OECD). The OECD activity seeks to identify agreed-upon test methods in order to avoid duplicative testing.

Except where specific circumstances make a particular test method inappropriate, TSCA section 4, section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (FIFRA), IRLG, or OECD agreed-upon methods will be regarded as suitable for new chemical evaluation purposes. Furthermore, section 5 testing guidance will be periodically revised and updated to reflect these approaches as appropriate.

The tests presented below are grouped into three categories (1) tests for basic chemical and physical properties and other characteristics associated with environmental transport and persistence (Fate Tests), (2) tests for health effects and (3) tests for ecological effects. Each group of tests is preceded by a discussion of the need for information of that type for risk assessment.

The tests and methods set forth below are those which EPA has tentatively identified as appropriate for testing for certain properties and effects. The Agency requests comment on the scientific adequacy of each test and method for assessing the property or effect to which it pertains.

Because there has been considerable confusion concerning EPA's reasons for considering the array of tests presented here, the Agency wishes to emphasize that it does not contemplate recommending that all the tests be performed on any substance. In fact, some of these tests logically could not be performed on the same substance (for example, tests for liquid density and particle size). Similarly, a test for aquatic toxicity would not normally be recommended for a volatile liquid which will not be discharged to water. In fact, as stressed in the discussion in Part I, EPA expects that a manufacturer will design a test plan which is appropriate for his chemical, its characteristics, and use. He will therefore select the tests which are necessary to execute his test plan. The purpose of developing these tests is to establish Agency preferences for particular tests and methods for use in assessing the potential for particular effects. Each recommended test will be available for inclusion in any testing system developed by a manufacturer. EPA will encourage a manufacturer to use recommended tests and methods, but will evaluate on a case by case basis the validity of any other test or method which might be used in premanufacture testing.

The tests and methods presented below vary in their relative degree of validation and standardization. Some have been used by a single laboratory (developed). Others have been thoroughly tested in multilaboratory comparisons (validated) and/or recommended by an appropriate body of experts (standardized). In addition, a few tests have never been performed using the recommended methods; the methods have been constructed from component parts of existing tests.

For each chemical property or effect, the test proposed by EPA is believed to be the most acceptable based on standardization or other stated criteria. In some cases, a conventional or well known test was not selected because of poor cost-effectiveness, inadequate sensitivity, or inappropriateness for assessment. In other cases, there are tests which are believed to be potentially more suitable but which were not selected because they are not yet as well validated as the recommended test. In the latter cases, the Agency will support development and validation to the extent justified by circumstances within the constraints of resource and time limitations. As this development and validation is completed, the tests presented here will be replaced or modified.

The tests are discussed in greater technical detail in a "Draft Technical Support Document" which is being prepared by EPA's Office of Toxic Substances. The "Draft Technical Support Document" will contain a rationale for the choice of each fate and ecological effects test and method and will discuss the extent to which each test has been standardized or validated.

Persons interested in submitting technical commments on the tests and methods described below are urged to first obtain a copy of the "Draft Technical Support Document." (See SUPPLEMENTARY INFORMATION at the beginning of this document.)

Relationship to Other Testing Guidelines and Standards

The development of tests for TSCA section 5 premanufacture testing guidelines relates to other ongoing EPA test development activities. Under section 4 of TSCA and section 3 of FIFRA, EPA is developing proposed testing approaches for a detailed evaluation of selected industrial chemicals and pesticides, respectively. Because the two statutes are similar in purpose, final requirements will, to the maximum extent possible, be identical for those tests common to both.

A. Chemical Fate Tests

A-1. DISCUSSION OF CHEMICAL FATE

Assessment of the fate of a chemical substance after its release into the environment is essential for the evaluation of potential risk. Fate, in this sense, is defined as the transport and transformation of a chemical by natural means after it is released to the environment from a point source (e.g., a manufacturing plant or waste treatment plant), a disposal site (e.g., landfill), or a dispersive use. Determination of the fate of a chemical in the environment helps identify:

- The nature of dispersal and ultimate distribution.
- The types of reactions in which the chemical participates during transport.
- The chemical form(s) and concentration(s) to which the environment will be exposed.
- The biological organisms exposed to the chemical.

Two categories of reference tests are recommended to support the preliminary evaluation of the potential fate of a new chemical substance in the environment: transport tests and persistence tests. The first category deals with physical and chemical characterization of substances, including key parameters to allow predictions to be made regarding how and where a substance could be transported after release into the environment. The second category deals with the susceptibility or resistance of a chemical substance to degradation by chemical, photochemical, or biological mechanisms in the environment. Environmental transport and persistence are both important elements in the estimation of potential environmental exposure of a new chemical substance.

The following is a list of chemical and physical properties and environmental fate characteristics that EPA considers potentially important for evaluating a proposed new chemical substance (except where the nature of a particular chemical or its intended use or distribution indicate that such information is unnecessary or unwarranted):

1. Spectral data, including an x-ray diffraction spectrum for inorganic substances, or a mass or alternative spectrum for most other substances.
2. Density, for liquid or solid substances.
3. Solubility in water.
4. Octanol/water partition coefficient.
5. Melting and boiling points.
6. Dissociation constant in water for substances which dissociate in water.

7. Particle size distribution for insoluble solids.

8. Degradation characteristics, noting roughly how fast such degradation occurs upon exposure to oxidants, water, sunlight, microorganisms, and the identity and characteristics of significant degradation products (see test methods in section A4).

9. Flammability, using standard flammability test(s) required by the Department of Transportation for materials in commerce.

10. Vapor Pressure.

11. Adsorption/desorption on particulate surfaces.

Many of the physical/chemical (transport) tests recommended below are reference methods that are already commonly performed by manufacturers to develop sufficient information to move from research to production status or to satisfy requirements of other regulatory agencies such as the Department of Transportation. The most cost-effective, state-of-the-art persistence testing methods were selected whenever possible. For example, biodegradation tests that require radio-labeled substrates were not included in this preliminary set of tests. In some cases, several commonly-used tests are combined into a single recommended protocol because the individual tests could not cost-effectively satisfy the information needs for premanufacture assessment. The Agency, however, has studies under way to validate less expensive experimental methods and will be substituting them as soon as they become available.

Most of the physical and chemical characterization of new chemical substances can be carried out before persistence testing is initiated. This approach provides information for determining the optimum ways to conduct persistence testing and in some cases can serve as a basis for deciding that certain persistence tests are unwarranted. Therefore prudent sequencing of tests can often reduce the time and cost for developing necessary information. This is demonstrated in the following examples:

- Water solubility should be determined early-on since the results can guide the design and conduct of most other tests.
- Boiling point determinations can serve a "range-finding" function for measuring vapor pressure, meaning that only one of the two vapor pressure tests need be conducted.
- An early measurement of hydrolytic degradation should be made, since if a substance hydrolyzes rapidly, tests of adsorption and biodegradation may not be required.
- Soil thin layer chromatography testing could serve as a "range-finding" test for adsorption isotherm tests when needed.

The chemical fate tests and methods presented below were developed to provide sufficient data for an initial evaluation of the fate of a generalized chemical. The choice of test to run for any particular chemical will be governed by the nature of the chemical and its intended use, projected volume, and distribution. Methodologies are evolving and these tests will be replaced or modified as new methods are developed or old ones improved. These tests are state-of-the-art or widely accepted. In either case, they were chosen to yield risk assessment data in the most cost-effective way.

A-2. GENERAL PROVISIONS

A-2.1 *Quality Assurance.* EPA is currently drafting Good Laboratory Practices (GCP) under section 4(b) of TSCA. When these become available, they will provide detailed guidance on proper procedures for laboratory management and the conduct of tests.

A-2.2 *General References.* The testing guidelines proposed under Part 162, Chapter I, Title 40 of the Code of Federal Regulations (Pesticide Guidelines, Subpart D, Chemistry Requirements, Federal Register 43(132): 29708-29724) are recommended as the reference for any chemical fate tests not addressed in the following discussions. As test standards are developed and published under section 4(b) of TSCA and by the Interagency Regulatory Liaison Group (IRLG), they will also serve as tests for use under section 5 of TSCA. Other suggested references are noted under the individual tests contained in these guidelines.

A-2.3 *Test Substance.* (a) Data obtained by tests conducted with the technical grade product to be marketed by the manufacturer will be most relevant for assessment purposes unless that is not the most probable formulation to which the environment will be exposed or unless indicated differently in a specific test method listed below. If the technical grade product is not tested, an explanation of the reason for the substitution would help validate the data for assessment. If possible, a description of the differences between the substance that was used and the market product, including a description of its physical state and chemical nature and how these may affect biological characteristics should be given.

(b) Test results will be more consistent if the lot of the substance tested is the same for the duration of the study, and if the sample is stored under conditions that maintain its purity and stability. If a test substance will not be stable for the duration of the study or, for other reasons, it is not possible to use the same lot throughout the test, subsequent lots of the test substance should be selected that are as nearly identical to the original lot as practicable. Chemical assays should be performed to assure this composition.

(c) Data are more easily and accurately interpreted when the composition of each lot of the test substance, including the name and quantities of contaminants and impurities, is known. An analysis of composition should include the amount of any unknowns, so that 100% ±5% of a sample is accounted for. (Ideally, the amount of any unknown should not exceed 0.5% of the total).

A-2.4 *Data: Suggested Format.* (a) *General.* The data generated by testing are most useful for assessment if submitted in a report format. Such a report should include all information necessary for a generally complete evaluation of the test procedures and results, including information on the facility performing the study, information on the test substance, a description of the test procedures, presentation of the data generated, and a summary and analysis of the test results. The following information is considered valuable for assessment:

(b) *Information on Testing Laboratory/Sponsor.* (1) Name(s) and address(es) of the facility performing the study, and of the sponsor if different from the testing facility.

(2) Laboratory study number

(c) *Information on Test Substance.* (1) Identification of the test substance, including chemical name, chemical abstract number, sponsor code number, synonyms, and molecular structure.

(2) A qualitative and quantitative determination of chemical composition (including names and quantities of known contaminants and impurities, so far as is technically feasible).

(3) Name of the manufacturer, lot number(s) of test substance, method of synthesis, date(s) when received and storage procedures.

(4) Relevant physical properties of the test substance, such as physical state, ph, stability, melting point, purity and solubility.

(5) Identification and composition of any vehicles or other materials used in testing the substance.

(d) *Description of the test procedures.* (1) Specification of test methods, including a full description of the experimental design and procedures, reference(s) to the chosen test method, the length of the study, and the dates on which the study began and ended.

(2) Methods of all chemical analyses performed for determining concentrations of test substances, impurities or degradation products, along with the

precision and accuracy of the test methods.

(3) Appropriate statistical methods used to summarize experimental data, express trends, and evaluate the significance of differences in data from individual test groups. For example, data averages or means accompanied by standard deviation allow assessment of the variability in the raw data. In addition, the standard errors of the means may also be calculated for their use in comparing means from different tests groups. However, notations of statistically significant differences along with the confidence level of probability, could substitute for standard errors.

(4) References to statistical methods for analyzing the data, and to published literature used in developing the test protocal, performing the test, making and interpreting observations, and compiling and evaluating the results.

(3) *Presentation of Data Generated.* All data which would be useful for assessment from each of the test methods.

(f) *Summary Analysis of Test Results.* A summary and analysis of the data, and a statement of the conclusions drawn from the analysis. The summary could highlight positive data or observations and deviations from control data.

A-2.5 *Miscellaneous Considerations.* (a) Since photochemical effects may influence test results, reaction mixtures should be shielded from incident light whenever practical during the experimental period.

(b) The use of trade names in the text is not intended as an endorsement by EPA but is merely intended to illustrate examples of equipment, materials and other facilities suitable for the tests described.

A-3. PHYSICAL/CHEMICAL PROPERTIES, MEASUREMENTS, AND TESTS

A-3.1 *General.* Chemicals discharged into the environment are generally released into one or more of three media: air, water and soil. [1] Discharged materials often do not reside long in one medium but are transported to other media by processes that depend upon the characteristics of chemical substances, as well as meteorological conditions, the flow of surface waters, the location and flow of groundwaters, tidal action, topographic characteristics and the physical and chemical characteristics of soils, sediments, and particulates. An analysis of the transport and fate of discharged chemicals is further complicated because the media can be divided into a variety of subtypes. Thus, water can be fresh, saline, or estuarine, surface or ground, free or bound. Similarly, soils vary widely in structure, compositions, and chemical properties.

The permutations that stem from these variables are enormous. No simple test scheme can predict absolutely how long a chemical will remain in one particular location, or by what mechanism and at what rate it will migrate. The most any test sequence can accomplish is to provide data which a skilled evaluator can integrate with other information to draw presumptive conclusions. These conclusions indicate where a particular chemical is *likely* to be distributed and a rough order-of-magnitude estimate of its concentration. Often the results of such an analysis can rule out the possibility of a chemical entering certain environments in significant concentration. Such conclusions are valuable since they markedly reduce the time, effort, and cost of subsequent testing.

A-3.2 *Water Solubility.* (a) *Objectives.* The water solubility of a chemical is an important characteristic for establishing that chemical's potential environmental movement and distribution. In general, highly-soluble chemicals are more likely to be distributed by the hydrologic cycle than poorly-soluble chemicals.

Water solubility can also affect adsorption and desorption on soils and volatility from aquatic systems. Substances which are more soluble are more likely to desorb from soils and less likely to volatilize from water. Water solubility can also affect possible transformation by hydrolysis, photolysis, oxidation, reduction, and biodegradation in water. Finally, the design of most chemical tests and many ecological and health tests requires precise knowledge of the water solubility of chemicals.

Water solubility is an important parameter for assessment of all solid or liquid chemicals. Water solubility is usually not useful for gases because their solubility in water is measured when the gas above the water is at a partial pressure of one atmosphere. Thus, solubility of gases does not generally apply to environmental assessment because the actual partial pressure of a gas in the environment is extremely low.

(b) *Rationale.* Several methods have been published for determining the saturated water solubility of chemicals. In selecting the method to use, three factors should be kept in mind when determining the *true* saturated equilibrium water solubility. First, most methods define a specific time period for immersion in a constant-temperature bath, after which it is assumed that saturation has been achieved. This is not always accurate, particularly in the case of very hydrophobic chemicals. Second, very hydrophobic solids inevitably form colloids when mixed with water. Some methods do not provide for the removal of these colloidal suspensions and result in inaccurate measurement. Third, water purity is extremely important for meaningful solubility determinations. These factors are important and were all considered in choosing the tests for water solubility recommended below.

The composition of natural waters can vary greatly. Environmental variables such as pH, water hardness, cations, anions, naturally occurring organic substances (e.g., humic and fulvic acids, hemicelluloses) and organic pollutants all affect the solubility of chemicals in water. Some bodies of water contain enough organic and inorganic impurities to significantly alter the solubility of poorly soluble chemicals. Since it is difficult, if not impossible, to define a standard natural water, very pure water should be used instead of natural water in determining the water solubility of chemicals.

When attempting to determine the true saturated equilibrium of very hydrophobic chemicals, it should be recognized that colloids can form and do not readily aggregate. Therefore, it is suggested that the sample be ultracentrifuged at two or three different G values for one half hour at constant temperature until concentration changes are small. This will remove colloidal particles (Biggar and Riggs, 1974).

A recently published method used coupled column liquid chromatography to determine the aqueous solubility of some very hydrophobic organic chemicals (polycyclic aromatic hydrocarbons) (May, et al., 1978). The method seems promising but needs more experimental work on a variety of very hydrophobic chemicals before it qualifies as state-of-the-art. No single method covers the entire range of solubilities in water. Thus, several methods are given to cover the range of water solubilities from the part-per-billion (μg/l) range to greater than approximately 500 mg/l.

(c) *Methods*—(1) *Test details.* (A) The following considerations should be taken into account when determining the solubility of chemicals in water:

(i) See Mader and Grady (1970) for a discussion of methods for determining the solubility of solutes in liquids before making measurements.

(ii) One should conduct solubility experiments in a thermostatic bath with a shaker, good temperature control, and an accurate temperature measuring device. Determine the solubility at 10, 20, and 30 ± 1° C.

(iii) When dissolving very hydrophobic chemicals in water, as little agita-

[1] Including atmospheric particulates and aquatic sediments.

tion as possible should be used to minimize agglomeration of the finely dispersed particles.

(iv) In some cases, very hydrophobic chemicals tend to adsorb to the surface of the vessels. To minimize this, all transfer vessels should be prerinsed with waterphase aliquots.

(v) The solubility of chemicals which reversibly ionize or protonate (e.g., inorganic acids and bases, carboxylic acids, phenols, and anilines) should be measured at pH 5.0, 7.0, and 9.0. Prepare buffer solutions according to the *Handbook of Chemistry and Physics* (1974–1975).

(vi) Very pure water (e.g., water comparable to reagent grade water from a millipore Milli-Q-System) should be used.

(B) The principal method for determining the solubility of a chemical at saturation is to analyze the solution by some suitable physical or chemical method. Whenever possible, an analytical procedure should be used having a precision within ±5%.

(C) Solubility measurements should be made on analytically pure chemical (greater than 99% by weight pure), if possible. If the chemical contains some impurities, the nature and amount (%) of each impurity should be specified.

(D) *To determine the solubility of solids and liquids in water at concentrations greater than approximately 100 mg/l.* Mader and Grady (1970) described a method to determine the solubility of solids in liquids. The apparatus designed by Lombardo (1967) should be used, with very pure water as the solvent. Equilibrium is approached by undersaturation and oversaturation. When duplicate determinations with both approaches yield concentrations within ±5%, the true saturated equilibrium solubility has been reached.

In addition, Mader and Grady (1970) described a method to determine the solubility of liquids in liquids. Very pure water should be used as the solvent. Equilibrium is approached by undersaturation and oversaturation. When duplicate determinations with both approaches give concentrations within ±5%, the true saturated equilibrium solubility has been reached.

If the concentration of the solute exceeds 10 gm/l, the density of the solution can be determined by weighing known volumes of the solution at the same temperature as the constant-temperature bath. Duplicate determinations should agree to within ±5%. If the concentration of the solute is less than 10 gm/l, the density of the solution does not have to be measured and can be assumed to be the same as the density of water at the temperature of the constant-temperature bath. See the *Handbook of Chemistry and Physics* (1974–1975) for the density of water as a function of temperature.

(E) *To determine the solubility of solids in water from 1 mg/l to approximately 500 mg/l.* The Pesticide Guidelines described a nephelometric method to determine the solubility of solids in water from one to a few hundred ppm (EPA, 1975). For further details on carrying out nephelometric (turbidity) measurements see *Methods of Chemical Analysis of Water and Wastes* (EPA, 1974). Special sonicators should be used to form stable suspensions (Riggs and Biggar, 1965). Very pure water should be used and the experiments conducted in duplicate.

(F) *To determine the solubility of very hydrophobic solids in water.* For very hydrophobic organic chemicals which form colloids, the following method can be used. The chemical should be dissolved in a suitable volatile organic solvent and coated on the walls of a vessel. One should avoid coating the bottom of the vessel. A teflon-coated magnetic stirrer should be carefully placed in the bottom, very pure water added, and the mixture slowly stirred. Concentration-time studies should be conducted to make sure that true saturated equilibrium solubility has been reached. When the concentration reaches a plateau, this indicates true saturated equilibrium solubility. When determining the concentration of chemical in the aqueous phase, the suspension should be centrifuged at two or three different G values for one-half hour at constant temperature until concentration changes are small (Biggar and Riggs, 1974). For several pesticides, centrifugation at approximately 39,000 G removed the colloidal particles corresponding to 0.01 μ particle size (private communication with Biggar). Centrifuge tubes which can be tightly sealed should be used. Solubility experiments should be conducted in duplicate.

(G) *To determine the solubility of hydrophobic liquids in water.* For hydrophobic liquids, the method of McAuliffe (1966) is recommended, with the following modifications: (1) Very pure water should be used; (2) Concentration-time studies should be conducted to make certain that true saturated equilibrium solubility is reached. When the concentration reaches a plateau, this indicates true saturated equilibrium solubility. To make sure that no emulsions persist, the aqueous phase should be checked with a Hach 2100 Turbidimeter (or an equivalent instrument). If the emulsions persist for a long time, high speed centrifugation in tightly sealed tubes is suggested to break the emulsion. Solubility determinations should be conducted in duplicate.

(2) *Calculations and Information Which Should be Recorded.* The method used for determining the saturated water solubility should be given. In describing the analytical method used, an outline of the detailed procedure and the calibration data are considered important, as are the mean solubility and the standard deviation. In addition, if extraction methods were used to separate the solute from the aqueous phase, a description of the method of extraction and recovery data should be provided.

For the nephelometric method, a plot of the turbidity vs. concentration should give a straight line. The best equation for the straight line should be calculated by linear regression analysis and the solubility determined from this equation at the point of zero turbidity. The slope, intercept, correlation coefficient (R^2), and the solubility of each set of experiments should be recorded. The mean solubility and standard deviation should be recorded.

(d) *References.*

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McAuliffe, C. 1966. Solubility in water of paraffin, cycloparaffin, olefin, acetylene, cycloolefin, and aromatic hydrocarbons. *J. Phys. Chem.* 70:1267.

Riggs, R.L., and J. W. Biggar. 1965. Ultrasonic suspension of chlorinated pesticides in aqueous media. *Soil Sci. Soc. of Amer. Proc. 29:629.*

A-3.3 *Octanol/Water Partition Coefficient.* (a) *Objectives.* When a chemical enters a living organism, its accumulation and transport are governed by polarity, water solubility, affinity for fatty tissues, and the nature of potential binding to biological receptors.

The octanol/water partition coefficient is an indicator of bioconcentration potential in fatty tissues in aquatic and other living organisms. The partition coefficient is one factor in determining whether to conduct fish bio-

concentration studies. Its relationship to molecular structure and in some cases toxicity also makes it useful in the assessment of all organic chemicals.

(b) *Rationale.* The octanol/water partition coefficient, P, the ratio of the equilibrium molar concentrations of the chemical in octanol and water, was introduced by Hansch and coworkers to correlate biological activity and chemical structure (Hansch, 1969; Hansch and Fujita, 1964). Hansch and coworkers published many papers on the conventional determination of, and correlations involving, P. The octanol/water partition coefficient is related to the bioconcentration potential of organic chemicals in fish (Neely, et al., 1974). Based on Neely's publication, the partition coefficient has been widely used as a measure of bioconcentration potential in fatty tissues in aquatic and other living organisms.

There are published alternatives to the conventional method of determining the octanol/water partition coefficient used by Chiou, et al. (1977), Hansch, et al. (1967) and Leo, et al. (1971). For example, more rapid methods based on high-pressure liquid chromatography have been developed (Mirrless, et al., 1976; Yamana, et al., 1977; Carlson, et al., 1975; Veith, et al., 1978). In addition, a correlation between the partition coefficient P and the water solubility of some chemicals has been demonstrated (Chiou, et al., 1977). However, these methods are based on a limited number of experiments and none qualifies as state-of-the-art.

The published literature concerning the conventional method for determining the octanol/water partition coefficient indicates that numerous factors, which are discussed in the following section, should be considered. The reasons for choosing very pure water to determine P are discussed in Section A-3.2(b).

(c) *Test Description.* The octanol/water partition coefficient is defined as the ratio of the equilibrium molar concentrations of chemical in octanol and water. It is determined by simultaneously exposing a chemical substance to water and octanol and then measuring the amount of chemical in each phase after equilibration.

(d) *Methods*—(1)*Test Details.* The following brief discussions and test procedures can be used as guidelines to determine the partition coefficient of organic chemicals.

(A) The partition coefficient P, derived using thermodynamic theory (Glasstone, 1946), indicates that in dilute solution

$$P = \frac{C_{octanol}}{C_{H_2O}} \quad . \qquad (1)$$

That is, the solute (organic chemical) distributes between octanol and water in such a way that at equilibrium the ratio of the molar concentrations of the solute in the two layers is a constant at a given temperature. Because equation 1 is applicable only in dilute solution, all partition coefficients should be determined at a concentration $C<0.01M$. Since most physical properties of chemicals are reported at 25°C, P should be determined at this temperature. P is an equilibrium constant and can vary to some extent with temperature. Hence, the temperature should be controlled to ± 1°C.

(B) Equation 1 applies only to individual molecular species in solution. If a molecule associates or dissociates in octanol and water, then equation 1 needs to be modified to take into account such speciation changes as ionization, aggregation, and hydration, (Leo, et al., 1971; Glasstone, 1946).

(C) The purity of the solute can affect solubility in octanol and water and may affect the determination of its concentration. Thus, in determining the partition coefficient of a solute, analytically pure material (greater than 99% pure by weight), should be used, if possible. If the chemical contains some impurities, the nature and amount (%) of each impurity should be noted.

(D) Very pure water (e.g., water comparable to reagent grade water from a Millipore Milli-Q-system) should be used. Pure n-octanol (e.g., n-octanol comparable to Eastman Kodak White Label, minimum 98% pure) should be washed sequentially with 0.1N H_2SO_4, with 0.1N NaOH, then with very pure water until neutral. The n-octanol should be dried with calcium chloride and distilled twice in a good distillation column under reduced pressure. This should produce 99.9% pure n-octanol.

(E) In order to insure that equilibrium has been established, gently shake the two-phase system for one hour.

(F) The ratio of the volumes of the two solvents should be adjusted as appropriate for the relative solubility of the solute in octanol and water. By adjusting the volumes, concentration errors are minimized and errors resulting from dividing large numbers by small numbers are kept to a minimum (Hansch and Anderson, 1967; Leo, et al., 1971). Leo, et al. (1971) give an example to illustrate this point.

(G) In determining the P value for any given solute, the octanol and water phases should be analyzed for the solute. Whenever possible, an analytical procedure with a precision within ±5% should be used.

(H) When measuring the partition coefficient of chemicals which reversibly ionize or protonate (e.g., carboxylic acids, phenols, or anilines) pure water at pH 5, 7, and 9 should be used with buffers prepared according to *Handbook of Chemistry and Physics* (1974-1975).

(I) Gentle shaking should be used to minimize the formation of emulsions. Since centrifuging is necessary to separate troublesome emulsions, equilibration should be conducted in ground-glass stoppered centrifuge tubes. Volatile compounds are thus easily handled and a transfer step is eliminated. For volatile compounds, enough solvent should be used so tubes are almost full. In this way, partitioning with air can be neglected (Hansch and Anderson, 1967). Centrifuging at 37,000G at 25°C for 20 minutes should be performed (Chiou, et al., 1977).

(J) Very hydrophobic chemicals (with P in the order of 10^6) require relatively large volumes of the aqueous phase. These solutions should be equilibrated in a large ground-glass stoppered flask, and for the final phase separation transferred to centrifuge tubes that are prerinsed with some of the aqueous phase. After centrifugation, aliquots should be withdrawn from each tube (the transfer vessel should be prerinsed with the water phase) and recombined for analysis.

The methods outlined by Leo, et al. (1971), Hansch, et al. (1967), and Chiou, et al. (1977) are useful as general guidelines to the determination of the partition coefficient of organic liquids and solids. For determination of the partition coefficient of gases, the method of Hansch, et al. (1975) is recommended. The partition coefficient should be determined in duplicate at concentrations $C<0.01M$ and $C_1=0.1C$.

(2) *Calculations and Information Which Should be Recorded.* (A) A description of the procedure of analysis, calibration data and the method used to separate and sample the water and n-octanol phases are considered important. In addition, if extraction methods were used to separate the solute from the n-octanol and the aqueous phases, a description of the extraction method and recovery data should be provided.

(B) Calculations of the partition coefficient using equation 1 for each separate determination at concentrations C and C_1 should be made. The mean value of P and the standard deviation for each concentration C and C_1 should be recorded. If P is not constant at C and C_1, association and dissociation should be considered in determining the true value of P (Leo, et al., 1971; Glasstone, 1946).

(e) *References.*

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A-3.4 *Vapor Pressure.* (a) *Objectives.* Volatilization, the evaporative loss of a chemical, depends upon the vapor pressure of the chemical and on environmental conditions which influence diffusion from the evaporative surface. Volatilization is an important source of material for airborne transport and may lead to the distribution of a chemical over wide areas and into bodies of water (e.g. in rainfall), far from the site of release. Vapor pressure values provide indications of the tendency of pure substances to vaporize in an unperturbed situation, and thus provide a method for ranking the relative volatilities of chemicals. Vapor pressure data combined with solubility data permit calculations of rates of evaporation of dissolved organics from water using Henry's Law constants, as discussed by MacKay and Leinonen (1975) and Dilling (1977).

Chemicals with relatively low vapor pressures, high adsorptivity onto solids, or high solubility in water are less likely to vaporize and become airborne than chemicals with high vapor pressures or with less affinity for solution in water or adsorption to solids and sediments. In addition, chemicals that are likely to be gases at ambient temperatures and which have low water solubility and low adsorptive tendencies are less likely to transport and persist in soils and water. Such chemicals are less likely to biodegrade or hydrolyze, but are prime candidates for photolysis and for involvement in adverse atmospheric effects (e.g., smog formation, or stratospheric alterations). On the other hand, nonvolatile chemicals are less frequently involved in significant atmospheric transport, so concerns regarding them should focus on soils and water.

Knowledge of the vapor pressure is important for assessment of all chemicals except those with a standard boiling point of 30°C or less, and those whose vapor pressure at ambient temperatures is less than 10^{-7} torr. Compounds with a low boiling point, if free in the environment, would readily vaporize under ambient conditions, and thus would be classified as highly volatile. For such materials, the boiling point at standard atmospheric pressure would confirm high volatility.

(b) *Rationale.* Since no single vapor pressure procedure applies to the entire range of vapor pressures at ambient temperatures, more than one method is needed to measure vapor pressures from 10^{-7} to 760 torr. A standardized method, ASTM D-2879-70 (ASTM, 1974), is used for pure liquids to determine vapor pressures from 1 to 760 torr. A gas saturation method is proposed to determine vapor pressures of compounds from 10^{-7} to 10 torr. This method is the best technique available to measure low vapor pressures.

Most of the alternative methods for measuring vapor pressure are unsuitable because they cover only a limited vapor pressure range, are complex, are limited to very precise measurements, or apply only to specific chemicals.

Boiling point methods, such as the one using the Ramsey and Young apparatus, were rejected because the accuracy is very poor below 10 torr (Thomson and Douslin, 1971).

Effusion techniques, particularly those employing the Knudsen effusion apparatus, measure vapor pressures from 10^{-7} to 10^{-2} torr and provide some good data (Hamaker and Kerlinger, 1969). These methods were rejected due to the great difficulty of working with a system under vacuum and the need to keep the capsule space saturated with vapor during measurement. The lack of equilibrium saturation may have caused inaccurate published vapor pressure data (Spencer and Cliath, 1970).

The isoteniscope method is a standardized method for determining the vapor pressure of certain liquid hydrocarbons. The procedure is relatively simple, and the sample may be purified within the equipment by removing dissolved and absorbed gases until the measured vapor pressure is constant. These procedures do not remove higher-boiling impurities, decomposition products, or compounds that boil close to, or form azeotropes with, the material being tested.

Gas saturation procedures described by Spencer and Cliath (1969) use relatively simple equipment and yield precise and readily obtained results. The same methods also apply to laboratory environmental simulations. The vapor pressure is computed by assuming that the total pressure of a mixture of gases equals the sum of the pressures of the component gases. The partial pressure of the vapor under study may be computed from the total gas volume and the weight of vaporized material. Direct vapor density measurements by gas saturation techniques apply more directly to practical problems related to the volatilization of chemicals than other techniques (Spencer and Cliath, 1970). Where applicable, use this method for determining the vapor pressure of compounds and the effective vapor pressure of compounds in soil or water.

(c) *Test Description.* Vapor pressure is measured by gas saturation or with an isoteniscope. The gas saturation method, which applies from 10^{-7} to 10 torr measures the vapor concentration of the test compound in a flowing, inert gas under equilibrium conditions. The isoteniscope method, which applies to vapor pressures from 1 to 760 torr, involves placing a liquid sample in a thermostated bulb connected with a mercury manometer and a vacuum pump. Enough liquid is evaporated, repeatedly, to drive out all other gases, until further evacuation gives no lowering of the vapor pressure.

(d) *Methods*—(1) *Test Details.* The vapor pressure of compounds can be determined by one of the following procedures:

- The isoteniscope method for vapor pressures of liquids with vapor pressures of 1 to 760 torr. A description of this method appears as ASTM method D-2879-70 (ASTM, 1974).

- The gas saturation method for vapor pressures of 10^{-7} to 10 torr. Spencer and Cliath (1969) gives a description of the apparatus, procedures, and calculation. The amount (in grams) of test material evaporated per unit time should be calculated at each of three or more gas flow rates and the grams vs. flow rate should be plotted. If equilibrium conditions were established, the plot is a straight line. If a straight line is not obtained, the experimental conditions should be adjusted until equilibrium is achieved.

Determinations with the sample should be made in triplicate at each of three temperatures (10°, 20° and 30°C) unless a change of state (solid to liquid or solid to vapor) or a transition point (a change from one crystalline form to another) occurs in that temperature range. If a change of state or transition point occurs in the temperature range 10°C to 30°C, the following information is considered important:

- Nature of change.
- Temperature at which the change occurs at atmospheric pressure.
- Vapor pressure at 10° and 20°C below the temperature at which the transition or change of state is noted, and at 10° and 20°C above that temperature (unless the transition is from solid to gas).

Determine vapor pressure at 10°, 20°, and 30°C for a standard reference material suitable to the method. Calculate the vapor pressure and plot the log (base 10) of the vapor pressure vs. the reciprocal of the temperature in °K. The plot should be a straight line.

(2) *Calculations and Information which should be Recorded.* The average calculated vapor pressure for the test material and the calculated vapor pressure for the reference material at each temperature are considered important, as is a plot of log p vs 1/T for the test material and for the reference material.

A description of the experimental method, including details on difficulties experienced, and any other pertinent information should be provided.

(e) *References.*

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A-3.5 *Adsorption.* (a) *Objectives.* The affinity of a chemical substance for particulate surfaces is an important factor affecting its environmental movement and ultimate fate. Chemicals that adsorb tightly may be less subject to environmental transport in the gaseous phase or in solution. However, chemicals that adsorb tightly to soil particles may accumulate in that compartment. Substances which are not tightly adsorbed can transport through soils, aquatic systems and the atmosphere.

For some substances, results of adsorption testing hold little value in assessment. If, for example, a substance is a water insoluble gas at atmospheric preasure and ambient temperature, other chemical fate properties such as volatility might far outweigh the effects of adsorption into soil or sediment particles in determining environmental fate.

(b) *Rational.* A number of laboratory tests consider the effects of soil and sediment adsorption on mobility. The two tests recommended for use are the adsorption isotherm (soils and sediments) and soil thin layer chromatography (soils only). These tests were selected for their relatively low cost, uncomplicated test procedures, wide usage and acceptance, and low labor requirements. Both tests are recommended for use by the Pesticide Guidelines (EPA, 1978).

The use of soil columns was considered but was not recommended because of the following problems: (a) the difficulty of standardizing column packing, (b) the large amounts of soil and chemical required, and (c) the excessive time and labor requirements.

The octanol/water partition coefficient was not considered as a preliminary test for adsorption because the colloid and soil chemistry literature does not conclusively indicate its applicability for predicting movement and persistence of a wide range of chemicals for a wide spectrum of soils and sediments.

Efforts to identify a method for measuring the adsorption of chemicals to atmospherically-transported particles are being made. However, no method is presently recommended.

(c) *Test Description.* Soil, the unconsolidated mineral material on the immediate surface of the earth, and sediment, the unconsolidated material deposited at the bottom of natural waters, are used as adsorbents in these tests. Two test methods, the adsorption isotherm and thin layer chromatography (TLC), are recommended to predict chemical mobility as a function of adsorption on particulate surfaces. Either the adsorption isotherm or the soil TLC method can be used to determine the test chemical's affinity for soil, but only the adsorption isotherm method is suitable for determining the test chemical's affinity for sediment.

A mobility class is assigned to the test compound based upon the compound's interaction with the adsorbents. For preliminary tests, mobility classes are assigned using a limited number of adsorbents. Therefore, extrapolation to a wider spectrum of absorbents which the test chemical may ultimately encounter in the environment cannot be made without further testing.

An adsorption isotherm is a partition diagram which describes the distribution of the test chemical between a solid absorbent and the solution in equilibrium with it. The "batch" technique is the typical method for determining and adsorption isotherm. A series of solutions containing various concentrations of the chemical are equilibrated with the adsorbent. Either the amount of chemical initially added or the amount of chemical adsorbed by the adsorbent is plotted as a function of the equilibrium solution concentration of the chemical. The resulting curve or plot is the adsorption isotherm.

Soil TLC has a fundamental analogy in conventional chromatography. Movement in soil TLC is usually measured as the frontal R_f of a spot or streak (the test chemical) which results from water movement up a thin layer chromatography plate using soil as the adsorbent. This method should be used only with test chemicals that can be analytically determined on the TLC plate in the presence of soil colloids and soluble soil organic components.

(d) *Methods*—(1) *Test Details*—(A) *Adsorption Isotherm.* A typical method of conducting an isotherm determination is described in Weber (1971). The Pesticide Guidelines (EPA, 1978) also list references to procedures for adsorption studies (Aharonson and Kafkafi, 1975; Harvey, 1974; Murray, et al., 1975; Saltzman, et al., 1972; Wu, et al. 1975). This protocol is based upon these references, with certain modifications to minimize the disparity in materials, laboratory methodology, data presentation and data interpretation.

(i) One sediment and one soil should be used in this study. The soil selected for this study should have a pH between 4 and 8, an organic matter content between 1 and 8%, a cation exchange capacity greater than 7 MEQ/100 GM, and a sand composition of less than 70%.

(ii) Duplicate samples with a 1:5 adsorbent:solution ratio should be used (for example, a 10 ml solution with 2 gms of oven-dry soil (dry at 90°C for 24 hours)). Soils should be sieved with a 100 mesh stainless steel or brass screen before testing. Sediments should be air dried.

(iii) Distilled-deionized H_2O, adjusted to pH 7 by boiling to remove CO_2, should be used as the solvent.

(iv) Containers composed of materials that adsorb negligible amounts of

the test chemical should be used. Other details of container design are not critical, except that the liners of screw caps should be teflon. The six concentrations listed below should be added to the containers and equilibrated without sediment or soil for 48 hours. The amount of adsorption by container walls should be measured and recorded.

(v) Six initial concentrations, 0.00, 0.05, 0.25, 1.25, 6.25 and 31.25 micrograms/ml, should be equilibrated with each adsorbent. If low solubility of the test chemical prohibits the use of some of these concentrations, the adsorption isotherm will have a high and a low equilibrium solution concentration at least one order of magnitude apart. The experiment should be run with a minimum of six different equilibrium solution concentrations at 20°C.

(vi) Immediately after addition of the solution the container should be vigorously agitated with a vortex mixer or similar device. The container should be shaken for 5 minutes once every hour for 48 hours at a rate to keep the adsorbent in suspension during the shaking period. After equilibration the suspensions should be centrifuged at a high speed (at least 20,000 g) for 10 minutes. The aqueous equilibrium solution should be stored at 5°C.

(vii) The chemical adsorbed on the colloidal surface should be extracted with an organic solvent in which the test chemical is soluble (minimum 1 gm/liter) and a mass balance performed. A volume of organic solvent equal to the original volume of aqueous solution (used to attain equilibrium) should be added to the adsorbent and the container shaken vigorously for 10 minutes. The mixture should then be centrifuged at a minimum of 20,000 g for 10 minutes. This extraction procedure should be performed three times. The aqueous phase and the organic solvent extracts should be analyzed for the parent chemical.

(viii) The chemical remaining in the aqueous phase and the organic solvent extracts should be characterized and measured by UV absorbance. GC retention time, mass spectrometry or other methods appropriate and specific for the particular chemical.

(B) *Soil Thin Layer Chromatography.* The typical method of conducting a soil thin layer chromatography (TLC) study is described by Helling (1971a, 1971b, 1971c), and Helling and Turner (1968). The following protocol is based upon these references.

(i) One soil with a pH between 4 and 8, an organic matter content between 1 and 8%, a cation exchange capacity greater than 7 meg/100 gm and which is less than 70% sand should be used.

(ii) Soils should be prepared by sieving to remove stones, coarser sand fractions, and large plant fragments. Any crushing or grinding involved should reduce soil aggregate size but should not create more fine particles (silt and clay) than originally present. Soils should be sieved at 250 μm to remove coarse (500–2,000 μm) and medium (250–500 μm) sand fractions. Earlier testing showed that removal of a portion of the sand did not affect mobility of a test compound but did aid in achieving a more uniform soil layer.

(iii) Distilled-deionized H_2O adjusted to pH 7 by boiling to remove CO_2 should be used.

(iv) Water should be added to a sieved soil until a smooth, moderately fluid slurry is attained. Approximately 0.75 ml H_2O added for each gram of soil will provide a moderately fluid slurry. The soil slurry should be applied to clean glass plates quickly to prevent particle size segregation.

(v) The soil slurry should be spread evenly across the plate by (1) use of a variable thickness plate spreader or (2) use of a glass rod. If a glass rod is used, the layer thickness should be controlled by affixing multiple layers of masking tape along the plate edges. Soil layer thickness should be 500–750 micrometers.

(vi) The plates should be air dried for a minimum of 24 hours after slurry application.

(vii) The purest grade of test chemical available should be used in this study. Impurities cannot be distinguished from degradation products and may indicate the need for degradation product identification when in fact, none exists.

(viii) At least three replicate plates for each soil should be used. A horizontal line should be scribed through the soil layer 11.5 cm above the base. The test chemical should be spotted 1.5 cm from the edge and the amount recorded. Approximately the same quantity should be used for each plate. For radio labeled materials, 0.5–5 μg containing .01–.03 μCi of ^{14}C labeled compound is appropriate.

(ix) The plate should be immersed vertically in a closed chromatographic chamber containing 0.5 cm H_2O. The plate should be removed from the chamber when the solvent front has migrated to the 11.5 cm line.

(x) R_f values should be determined by visualization, zonal extraction, plate scanning or other methods suitable for detecting the test chemical and the techniques for R_f measurement should be described.

(2) *Calculations and Information Which Should be Recorded*—(a) *Adsorption Isotherm.* The average value of the adsorbed chemical, x/m, as a function of equilibrium concentration, C_e, should be plotted for each soil according to the equation $(x/m)=KC_e^{1/n}$. The quantity x refers to the amount of adsorbed chemical per unit amount of adsorbent m (usually expressed as μg/g soil). The adsorbed chemical is defined as the difference between the initial concentration of the chemical added to the soil-solution system and the equilibrium solution concentration of chemical. The quantities K and n are constants. The Freundlich adsorption coefficient can be obtained by plotting log (x/m) vs. log C_e, yielding a linear slope of 1/n. The Freundlich constant K and the constant 1/n should be recorded along with all raw data (see Table 2).

A mass balance for the parent compound should be developed by subtracting the combined concentrations of the parent chemical in the aqueous phase and in the organic solvent extracts from the initial concentration of parent compound and recording the difference. A reasonable hypothesis should be submitted to account for any discrepancy greater than 5% between the initial concentration and the concentration found after adsorption, along with any appropriate supportive data.

The following information on the selected soil is considered important: soil order, soil series, classification, sample location, horizon, particle size analysis, percent organic matter, pH, percent carbonate as $CaCO_3$ (for soils with basic pH), cation exchange capacity, extractable cations, and clay fraction mineralogy. The following information on the selected sediment is considered important: location, particle size analysis, percent organic matter, pH, cation exchange capacity and clay fraction mineralogy. Black (1965), Hesse (1971) and Jackson (1969) describe methods of analysis. Soils with widely differing physical and chemical properties, but representative of most of the soil orders in the United States, are listed in Table 1 and are suggested for use in this test.

If reference compounds with known adsorption isotherms are used, record their adsorption isotherms.

(B) *Soil Thin Layer Chromatography.* The following information should be recorded: (i) approximate concentration of the test chemical applied to the plates, (ii) detailed description of the analytical technique used in R_f determination, (iii) the mean frontal R_f value with the standard deviation for each soil tested. (iv) a photograph or diagram of the TLC plate and showing the entire leaching pattern (from 1.5 to 11.5 cm) (see Table 2); and (v) the physical/chemical properties of the soil as described in (d)(1)(B)(i).

(C) *Use of the Data.* The Freundlich constant K and the R_f will help place

the chemical into a generalized mobility class. Table 3 summarizes the general relationship between the soil/solution partition coefficient K, R_f and soil mobility. The chemical will have a mobility class for each soil tested.

(e) *References.*

Aharonson, N., and U. Kafkafi. 1975. Adsorption, mobility and persistence of thiabendazole and methyl 2-benzimidazole carbamate in soils. *J. Agr. Food Chem.* 23:720-724.

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Helling, C. S. 1971b. Pesticide mobility in soils II. Applications of soil thin layer chromatography. *Soil Sci. Soc. Am. Proc.* 35:737-743.

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[6560-01-C]

Table I

Physical and Chemical Properties[1] of Soils
Suggested for Use in Conjunction With Protocol

For Adsorption Tests[2]

SOIL ORDER:	Alfisol	Aridisol
SOIL SERIES:	Crider	-
CLASSIFICATION:	Typic Paleudalf fine-silty, mixed, mesic	Salorthid
LOCATION:	Gallatin County, Ill.	California
HORIZON:	A	
% SAND:	1.2	
% SILT:	86.6	
% CLAY:	12.2	
% ORGANIC MATTER:	1.74	
CARBONATE AS $CaCO_3$:	-	
pH (1:1 H_2O):	7.2	
CATION EXCHANGE CAP. (MEQ/100GMS)	13.5	
EXTRACTABLE CATIONS (MEQ/100GMS)		
Ca	8.4	
Mg	2.8	
Na	-	
K	0.7	
H	1.6	
SPECIAL CHEMICAL/MINERALOGICAL FEATURE:		
CLAY FRACTION MINERALOGY:	>50% Montomorillonite 5-20% Mica <5% Kaolinjte (36-120 cm depth)	Saline
SOIL ORDER:	Histosol	Inceptisol
SOIL SERIES:	Rifle	Maile
CLASSIFICATION:	Typic Borohemist	Hydric Drystrandept, Thixotropic, isomestic
LOCATION:	Michigan	Tallamook County, Ore.
HORIZON:		A
% SAND:		15
% SILT:		53.6
% CLAY:		31.4
% ORGANIC MATTER:		15.4
pH (1:1 H_2O):		5.3
CATION EXCHANGE CAP. (MEQ/100GMS)		103.6
EXTRACTABLE CATIONS (MEQ/100GMS)		
Ca		6.7
Mg		1.2
Na		0.4
K		0.4
H		94.9
SPECIAL CHEMICAL/MINERALOGICAL FEATURE:	Histic Epipedon	Allophane
CLAY FRACTION MINERALOGY:		33-50% Vermiculite 20-33% Kaolinite 5-20% Quartz 34% Allophane (68-125 cm depth)

[1] Those physical and chemical properties not listed will be published when available.

[2] Soils listed here will be distributed by the National Bureau of Standards.

Table I (continued)

SOIL ORDER:	Inceptisol	Mollisol	Mollisol
SOIL SERIES:	Toledo		Walla Walla
CLASSIFICATION:	Mollic Haplaquept fine, illitic, nonacid, mesic	Natriboroll	Typic Haploxeroll coarse-silty, mixed mesic
LOCATION:	Ohio	North Dakota	Salt Lake County, Ut.
HORIZON:			A
% SAND			30.4
% SILT:			46.5
% CLAY:			23.1
% ORGANIC MATTER:			2.99
CARBONATE AS $CaCO_3$:			-
pH (1:1 H_2O):			7.3 (Saturated Paste)
CATION EXCHANGE CAP (MEQ/100GMS)			26.7
EXTRACTABLE CATIONS (MEQ/100GMS)			
Ca			15.4
Mg			5.1
Na			0.2
K			0.9
H			4.0
SPECIAL CHEMICAL/MINERALOGICAL FEATURE:	Illitic Dolomitic		-
CLAY FRACTION MINERALOGY:			33-50% Kaolinite 20-33% Mica 5-21% Montmorillonite (0-41 cm depth)

SOIL ORDER:	Mollisol	Ultisol	Ultisol
SOIL SERIES:	Sharpsburg	Bladen	Malbis
CLASSIFICATION:	Typic Argiudoll fine, montmorillonitic mesic	Typic Albaquult, clayey, mixed, thermic	Plinthic Plaeudult fine-loamy, siliceous, thermic
LOCATION:	Tama County, IA	Liberty County, GA	Johnston County, NC
HORIZON:	A	A	A
% SAND:	2.2	55.6	64.1
% SILT:	69.2	37.5	27.2
% CLAY:	28.6	6.9	8.7
% ORGANIC MATTER:	2.35	2.2	0.89
CARBONATE AS $CaCO_3$	-	-	-
pH (1:1 H_2O):	5.7	4.1	4.9
CATION EXCHANGE CAP. (MEQ/100GMS)	27.2	14.6	7.4
EXTRACTABLE CATIONS (MEQ/100GMS)			
Ca	13.9	1.80	1.40
Mg	3.4	0.90	0.24
Na	-	0.10	0.01
K	0.5	0.10	0.22
H	9.3	11.70	5.50
SPECIAL CHEMICAL/MINERALOGICAL FEATURE:	Montmorillonite	High Aluminum	Vermiculite Chlorite Kaolinite Gibbsite
CLAY FRACTION MINERALOGY:			Vermiculite Chlorite Intergrade 20-33% <5% Vermiculite Kaolinite 35% Gibbsite 12% Quartz 7% (0-51 cm depth)

Table I (continued)

SOIL ORDER:		Vertisol
SOIL SERIES:		Houston Black
CLASSIFICATION:		Udic Pellustert Fine, Montmorillonitic thermic
LOCATION:		Collin County, TX
HORIZON:		A
% SAND:		23.1
% SILT:		40.7
% CLAY:		36.2
% ORGANIC MATTER:		1.05
CARBONATE AS $CaCO_3$:		-
pH (1:1 H_2O):		6.4
CATION EXCHANGE CAP.:		28.4
EXTRACTABLE CATIONS (MEQ/100GMS)		
	Ca	23.0
	Mg	4.3
	Na	0.3
	K	0.8
	H	4.5
SPECIAL CHEMICAL/MINERALOGICAL FEATURE:		-
CLAY FRACTION MINERALOGY:		Montmorillonite

Table II

Suggested Format For Data Submission For Adsorption Isotherm Protocol

Soil	Sediment
	SAMPLE LOCATION:
SOIL ORDER:	
SOIL SERIES: CLASSIFICATION	
LOCATION:	
HORIZON:	
% SAND:	% SAND:
% SILT:	% SILT:
% CLAY:	% CLAY:
% ORGANIC MATTER:	% ORGANIC MATTER:
CARBONATE AS $CaCO_3$	
pH (1:1 H_2O):	pH:
CATION EXCHANGE CAP. (MEQ/100GMS)	% INSOLUBLE CARBONATES:
EXTRACTABLE CATIONS (MEQ/100GMS)	CATION EXCHANGE CAPACITY:
Ca	
Mg	
Na	
K	
H	
SPECIAL CHEMICAL/MINERALOGICAL FEATURE:	
CLAY FRACTION MINERALOGY:	CLAY FRACTION MINERALOGY:

Table II (continued) Soil TLC Data Format

SOIL:

AMOUNT OF CHEMICAL APPLIED:

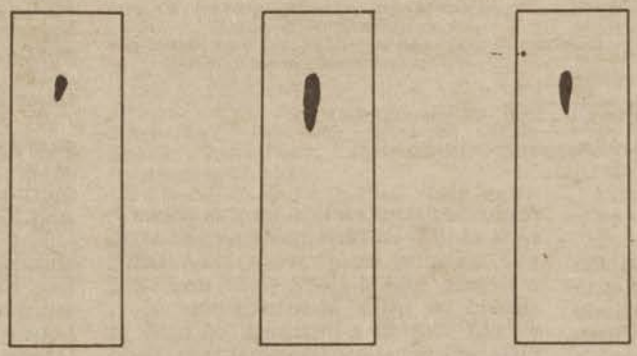


PLATE 1
R_F=

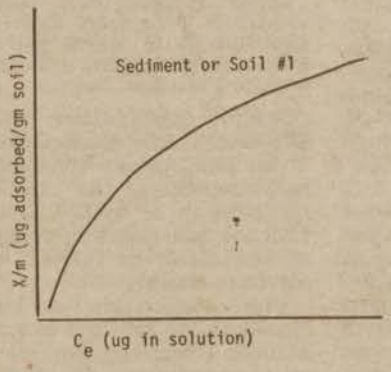
PLATE 2
R_F=

PLATE 3
R_F=

Mean R_F:

Standard Deviation:

Table II (continued)

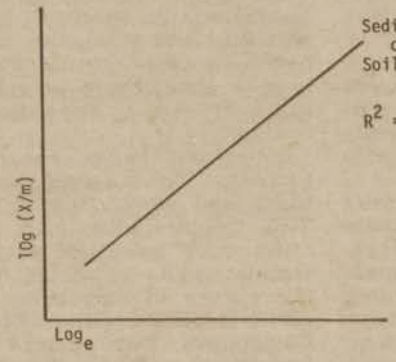


Adsorption Isotherm Data Format

X/m	C_e

log (X/m)	log C_e

K=
1/n=



Mass Balance

initial ug/gm soil added	ug/gm not accounted for	% not accounted for.

TABLE III.—*The General Relationship Between the Soil/Solution Partition Coefficient K, R_f and Soil Mobility*

K_{oc}	R_f	Mobility class	Distance surface applied chemical may leach [1]
0.1	0.95	Very mobile	
1	0.60		Much of chemical leaches through top 20 cm soil into subsoil.
10	0.25	Mobile	Much of chemical leached into soil, but peak concentration in top 20 cm soil.
10^2	0.10	Low mobility	Only small amount of leaching and peak concentration normally in top 5 cm soil.
$10^{2.5}$	0.00		
10^3	0.00		
10^4	0.00	Immobile	No significant leaching.

[1] If rain exceeds evapotranspiration by 10 inches assuming no degradation.

[6560-01-M]

A-3.6 *Other Physical/Chemical Parameters*

A-3.61 *Boiling / Melting / Sublimation Points.* (a) *Objectives.*—The boiling point of a liquid is the temperature at which its vapor pressure equals the pressure of its surrounding environment. The melting point (and/or freezing point) of a chemical is the temperature at which the solid and liquid forms of the chemical are in equilibrium. The sublimation point is the temperature below the melting point at which the vapor pressure of the solid equals atmospheric pressure.

These measurements could provide the information necessary to determine the likely physical state of a chemical at ambient temperatures. A boiling point near ambient temperatures would indicate the likelihood of significant exposure via inhalation to persons in close proximity to the uncontained chemical, and such data may indicate the extent of environmental release through vaporization. Sublimation point determinations could provide a quality assurance check on vapor pressure determinations.

The lowest temperatures commonly occurring in the winter in the United States are approximately minus 30°C. Many compounds that boil between 150 and 200°C have significant vapor pressures ($>10^{-1}$ Torr) at ambient temperatures. Therefore, the boiling point should be determined on compounds that boil between minus 30° and +200° at atmospheric pressure.

(b) *Rationale.* Several methods are offered as examples for boiling/melting/sublimation point determinations. The exact method used is not very important, but it should be properly conducted. The single most important consideration in most of these methods is the use of a slow rate of heating. The following tests are the only methods that were considered; none were rejected.

(c) *Methods*—(1) *Test details.* Some examples of procedures that may be used are those found in ASTM E324, D1078-70, D3451, CIPAC MT 2, the vapor pressure section of this package (A-3.4). For differential thermal analysis/scanning calorimetry (DTA/DSC) methods, ASTM E487, E472, and E537 should be used. Measurements of % weight loss as a function of time at different constant temperatures (thermogravimetry) could provide useful sublimation data. Vapor pressure data and DTA-DSC data are only relevant if phase changes have been noted.

(2) *Calculations and Information Which Should be Recorded.* For vapor pressure determinations, the data as described in the vapor pressure section of this package (A-3.4) should be submitted. For DTA/DSC determinations, a very brief description of the method used should be submitted along with the pertinent data obtained. If an ASTM or CIPAC method is used, the method should be cited and the pertinent data included.

(d) *References.*

ASTM. *1974 Annual ASTM Standards.* Philadelphia, PA.

CIPAC Handbook. 1970. *Analysis of Technical and Formulated Pesticides,* Vol. I. Compiled by R. De B. Ashworth, et al. Edited by G. R. Raw. CIPAC, Ltd., Hertfordshire, England, Chapter 7.

A-3.62 *Density/Specific Gravity*—(a) *Objectives.* Density is the mass per unit volume of a chemical substance at a specified temperature. Specific gravity is the ratio of the mass of a given volume of a substance at a specified temperature to the mass of the same volume of water at a specified temperature.

Measurements of the density of solids and the specific gravity of liquids indicates whether immiscible, low-reactivity chemicals will sink or float in a body of water. The density of gases indicates whether the gas will be transported along the ground, possibly subjecting surrounding populations to high exposure, or whether it will disperse rapidly.

(b) *Rationale.* The choice of method is not critical, but should be suitable for the chemical. The accuracy required for density data in risk assessments is approximately ± 0.1 g/cm³. Accuracy is especially critical for numbers near the density of water (1.0 g/cm³ at 20°C). The air (or helium) comparison pycnometer method is the only method suggested that has not been standardized by ASTM or CIPAC. The method is easy, reproducible, quick, and accurate. The density of gases will be calculated by EPA staff assuming ideal gas behavior unless actual gas density measurements are made.

The only methods considered were those listed below.

(c) *Methods.*—(1) *Test details.* The density of solids should be determined at 20 ± 3°C, by one of the following methods: CIPAC MT3 (for solids) or ASTM (35) D792-66.

The specific gravity for liquids should be determined at 20 ± 3°C relative to water at 20°C. The following methods are suitable: CIPAC MT3 (for liquids), ASTM (23) D941-55, (23) D1480-62 or (23) D1481-62.

In addition, the air (helium) comparison pycnometer can be used at 20 ± 3°C, following manufacturer's recommendations.

(2) *Calculations and Information Which Should be Recorded.* The method used should be very briefly described. If an ASTM or CIPAC method was used, merely cite the method. Density data should be recorded in units of g/cm³ and the specific gravity reported relative to water at 20°C.

(d) *References.*

ASTM. *1974 Annual ASTM Standards.* Philadelphia, PA.

CIPAC Handbook. 1970. *Analysis of Technical and Formulated Pesticides.* Vol. I. Compiled by R. De B. Ashworth, et al. Edited by G. R. Raw. CIPAC, Ltd., Hertfordshire, England, Chapter 7.

A-3.63 *Dissociation Constant*—(a) *Objectives.* The dissociation constant is an equilibrium constant and is a measurement of the extent to which an ionizable substance breaks up into charged constituents, usually because of the effect of solvent on the dissolved chemical.

The dissociation constant of a chemical can be used in assessing the aquatic, terrestrial, and metabolic fate of the chemical. Dissociated species may precipitate in water depending on certain factors, such as water hardness. The ionic charge of a compound also affects its ability to bind to certain soils and sediments. In addition, metabolism and partitioning (between lipid or octanol and water) of chemicals is affected by the extent of dissociation.

Solids and liquids that have structures that indicate a pK value between three and eleven should be tested. This includes pKa, pKb, and other "first order" solvolysis reactions. Pure samples (99.9+%) should be used, or the nature of impurities and their effect on pK value should be assessed. Compounds with water solubilities below that necessary for the method

discussed (below 10^{-5} M) need not be tested.

(b) *Rationale.* The three methods cited are potentiometric titration, spectrometry (relative absorbances), and conductivity. Each is a classic, well established method, and were the only methods considered. These methods can be used at solubilities from 10^{-5} to 0.5 M, are reproducible and can be performed by most competent chemical laboratory technicians.

(c) *Methods*—(1) *Test details.* The dissociation constant of Brönsted acids and bases should be measured by potentiometry (a pH meter titration with strong acid or base) or by the method of relative absorbances from the relationship:

$$pH = pK - \log \frac{[H_xA]}{[(H_{x-1}A)^-]}$$

The dissociation constant should be determined at 25 ± 1°C, to ± 0.1 pK unit.

For salts and organic compounds that contain functional groups that may be solvolyzed and acids and bases of low water solubility, a conductivity cell should be used. Successive dilutions with the concentration of the ionizing species below 0.01 M should be used, since higher concentrations may cause the dissociation "constant" to vary (MacInnes and Shedlovsky, 1932). The temperature should be held at 25 ± 1°C.

(2) *Reference Compounds.* The dissociation constant of one of the following compounds should be measured at the same time and at the same facility as the new chemical. The appropriate reference compound should be selected based on structural and pK similarities with the new chemical.

acetic acid	phosphoric acid (step 2 pKa)
benzoic acid	ammonium hydroxide
o-, m-, or p-nitrophenol	cyclohexylamine

(3) *Calculations and Information Which Should be Recorded.* For pH titrations, a plot of pH vs volume of standard acid or base should be provided, with accompanying data, including the temperature and pH of buffers used to standardize the pH meter.

For spectroscopic methods, the molar absorptivities of the acid and base forms of the chemical, tabulated data of

$$\log \frac{[HA]}{[A^-]}$$

at various pH values, calculations of pK and the type and model number of the spectrometer should be recorded.

For conductivity measurements, the cell constant and the solution conductivity of the instrument, conductance data (in units of μmhos/cm) and calculations of pK should be recorded.

(d) *References.*

For pH Titrations

ASTM. 1975. *Annual ASTM Standards.* Philadelphia, PA. D1293.

APHA/AWWA/WPCF. 1978. *Standard Methods for the Examination of Water and Wastewater.* 14th ed. American Public Health Association, Washington, D.C. Standard Method 424.

Nelson, H.H., and S.D. Faust, 1969. Acidic dissociation constants of selected aquatic herbicides. *Eviron. Sci. Techno.* 3(11): 1186-1188.

For Conductometry

ASTM. 1974. *Annual ASTM Standard.* Philadelphia, PA. D1125.

APHA/AWWA/WPCF. 1976. *Standards Methods for the Examination of Waste and Wastewater.* 14th ed. American Public Health Association, Washington, D.C. Standard Method 205.

Albert, A., and E.P. Serjeant, 1962. *Ionization Constants of Acids and Bases,* John Wiley & Sons, Inc., New York, NY. pp. 93-105.

MacInnes, D.A., and T. Shedlovsky 1932. The ionization constant of acetic acid. *J. Amer. Chem. Soc.* 54:1429.

For Absorbance

Albert & Serjeant, 1962. op cit. pp. 69-92.

A-3.64 *Flammability / Explodability.*—(a) *Objectives.* The tests in this section include flash point, flammable limits for gases, autoignition temperature, thermal explodability, and shock explodabilty. The flash point is the temperature at which a liquid or volatile solid gives off a vapor sufficient to form an ignitable mixture with the air near the surface of the liquid or within the test vessel (National Fire Protection Association (NFPA), 1969). "Flammable limits for gases" are the maximum and minimum concentrations of gas and air mixtures that will ignite. The autoignition temperature is the temperature at which a substance will spontaneously ignite in the absence of a spark or flame source. Explodability is the capability of a substance to undergo an uncontrolled, fast, violent chemical reaction resulting in a sudden increase in pressure.

Knowledge about the explosion and fire potential of new chemicals is important for assessing the acute risk they may pose to human health. Information from a flash point determination could indicate what controls, if any, are necessary on the chemical's thermal environment, and possible ignition sources. Information from a gas flammability test could indicate what concentrations of gas in air are likely to pose a fire hazard. Autoignition data could be useful in assessing the potential of new chemicals to spontaneously ignite upon contact with a hot surface or because of heating from some other source. The impact explodability affects the risk of handling large quantities of chemical (the force of a falling container is proportional to mass). Thermal explosion data could be a useful parameter for assessing the risk posed by handling or using various quantities of a chemical. The probabilties of thermally-induced explosion occurring are independent of the weight of the chemical present except as this may affect the rate of heating.

Flash points are appropriate for chemicals that are liquid below 60°C. Gas flammability is appropriate for chemicals that are gaseous under conditions of intended use, unless the chemical has a totally oxidized structure (e.g., BF_3, CO_2). Autoignition is appropriate for chemicals that come into direct contact with hot surfaces (100°C or more). Shock and thermal explodability testing is potentially applicable to all solid and liquid chemicals. (The intended use of a new chemical will be especially important in determining applicability for these tests).

(b) *Rationale.* The flash point methods cited are all closed cup methods. Open cup methods generally give higher results, and reaction conditions are not as well controlled. Also regulations of the Department of Transportation (DOT), Department of Labor (OSHA) and EPA (Office of Pesticide Programs and Office of Solid Waste) all require closed cup methods. However, it has been suggested that open cup methods may be more appropriate in certain cases.

The method for flammable gases is that required by DOT. None other was considered.

The autoignition method was also recommended by NFPA, and was evaluated in part by Affens and Carhart (1974). The method used for autoignition measurements is critical since a variability in results between methods can be great (100°C or more).

The thermal explodability method recommended (differential thermal analysis/scanning calorimetry (DTA/DSC), is a classic, simple chemistry technique yielding results that are easily interpreted. ASTM method E-474 is an apparatus calibration method that should be performed to assure the quality of the submitted DTA/DSC data. The impact explodability method for solids is that recommended by DOT and EPA (Offices of Pesticide Programs and Solid Waste). The impact explodability method for liquids was based on a critical review by DOT (1973).

(c) *Methods*—(1) *Test details.* For flash point (closed cup), ASTM D93-73, D56-75, D3278-73, D1437-64, E502-74, and CIPAC MT 12 (1970) should be

used. Cleveland or other open cup methods may be appropriate in rare situations.

For gas flammability (DOT), CFR 49, 173-300 (b) should be used.

For autoignition ASTM D2155-66 should be used. For thermal explodability (DTA/DSC), ASTM E487 should be used. For data recording E472 should be used. For calibration E537, E474 should be used.

For impact explodability, the Bureau of Explosives impact apparatus (CFR 49, 173.53 Note 4) should be used for solids. Bureau of Mines or Naval Ordnance Laboratory impact testers should be used for liquids.

(2) *Calculations and Information Which Should Be Recorded.* If the method is not one of the above, it should be described.

The flash point ±2°C should be recorded along with the atmospheric pressure.

For gas flammability, the upper and lower limits (v/v%) should be recorded.

For autoignition, the autoignition temperature (±3°C), the time lag before ignition, and the atmospheric pressure should be recorded.

For thermal explodability, a graph of ΔT(°C) or ΔE cal vs. T or t (sec. or min.) should be attached, the heating rate and calibration determination recorded, and the instrument (make and model) described.

For impact explodability, the results for the different heights and weights used should be recorded.

(d) *References.*

ASTM. 1974. *Annual ASTM Standards.* Philadelphia, PA.

Dept. of Transportation. Definition of class A explosives, CFR 49 173-53. Note 4. 1976.

A. H. Lasseigne. 1973. *Hazard Classification of Explosives for Transportation Evaluation of Test Methods,* U.S. Department of Transportation. Report # TES-20-73-2.

CIPAC Handbook. 1970. *Analysis of Technical and Formulated Pesticides.* Compiled by R. De B. Ashworth, et al. Edited by G. R. Raw. CIPAC, Ltd., Hertfordshire, England, Chapter 7, Vol. I.

National Fire Protection Association (NFPA). 1969. *Properties of Flammable Liquids and Gases.* Manual No. 325M, Boston, MA.

Proposed Resource Conservation and Recovery Act (RCRA) Hazardous Waste Criteria, Appendix B, 1978.

A-3.65 *Particle Size.* (a) *Objectives.* Particle size is quantitative measurement of the size of the crystalline or fibrous powder forms of new chemical substances. In the context of this document "particle diameter" or "particle size" refers to the effective spherical diameter of a particle (from Stokes' Law).

Particle size affects the probability of human inspiration through direct exposure, the likely point of deposition in the respiratory tract (if inhaled), and the distribution of the particle in the environment through widespread or large-volume uses (Corn, 1977).

Particles of lengths greater than 200 μm have been found in lung tissue that had been lavaged (Morgan, et al., 1978). Particles of diameter 5 μm or less are likely to be deposited in the broncheolar and alveolar regions. Therefore, particle size determinations are appropriate for compounds that are likely to form particles of 500 μm or less in length under conditions of expected use and handling.

(b) *Rationale.* The methods cited cover a wide range of sensitivities. All but one are ASTM methods. The non-ASTM method using the Sedigraph 5000 D particle size analyzer, was included because EPA has had favorable experience with it. The methods involve use of dry sieves, light microscopy, the Coulter counter, and sedimentation techniques. These methods are relatively inexpensive to perform. Electron microscopy data, of course, will be accepted. The Andreason Pipet method was considered and rejected because of disruption of the sedimentation medium caused by sampling (Irani & Callis, 1963, p. 70).

(c) *Methods*—(1) *Test details.* ASTM C690, E20-68, D1705, or D422 should be used for measuring particle size. D1366 should be used for data recording. The manufacturer's procedure for using the Sedigraph 5000 D analyzer should be used.

(2) *Calculations and Information Which Should Be Recorded.* If the method used is not one cited above, it should be described.

A graph of cumulative mass percent or percent of particles of stated size vs. log diameter (in microns) should be attached.

(d) *References.*

ASTM *Annual Book of Standards.*

Corn, Morton. 1977. Aerosols and the Primary Air Pollutants—Nonviable Particles. *Air Pollution,* A. C. Stern (ed.) pp. 77-99.

Irani, R. R., and C. F. Callis. 1963. *Particle Size: Measurement, Interpretation and Application.* John Wiley & Sons, Inc., New York, NY.

Morgan, A., et al. 1978. Significance of fiber length in the clearance of asbestos fibers from the lung. *British J. Indust. Med.* 35: 146-153.

A-3.66 *pH Measurement.* (a) *Objectives.* Knowledge of the pH of a chemical solution is useful primarily for assessing the risk of acute hazards for health and ecological effects. Data on pH is useful for estimating eye and dermal irritation for pH values less than 3 or greater than 12. This data will also indicate possible pH changes in an aquatic system at the point of effluent discharge or in the event of a spill. Depending on the buffering capacity of the ambient waters, the effects on local aquatic life could be significant.

(b) *Rationale.* The method involves measuring the pH of chemicals in a 1% v/v concentration of chemical in water, which is estimated to be the greatest concentration in the vicinity of a large discharge. More chemicals are soluble at this concentration than at a higher concentration. For health effects assessments, the pH value so obtained can be extrapolated linearly to higher concentrations (i.e., an estimate of the pH of a 50% solution would equal pH at 1% + log 50). For compounds not soluble at 1% concentration, dioxane was chosen as a cosolvent because empirical correction factors have been determined for various concentrations of dioxane/water solutions (Irving and Mahnot, 1968). Because dioxane is a suspect human carcinogen, it should be handled in accord with "good industrial hygiene practices and procedures." One should consult D.H.E.W. (NIOSH) Pub. #77-226 *NIOSH Criteria for Recommended Standard Occupational Exposure to Dioxane.* Other organic solvent systems with pH correction factors are suitable.

Data on pH should be submitted for all solid and liquid chemicals expected to form nonneutral solutions with water or water/dioxane.

(c) *Methods*—(1) *Test details.* The pH should be measured using a 1% v/v aqueous solution of the chemical in CO_2-free distilled water. If the compound is not soluble at that concentration, a solution of purified dioxane in water may be used, with up to 80% dioxane/water (v/v). Other solvents may be used if they have an empirical correction factor for pH, such as the one for dioxane (Irving and Mahnot, 1968):

$$-\log[H^+] = B + \log U^*_H + \log \delta$$

where B = apparent pH, $\log U^*_H$ is an empirical correction factor at zero ionic strength, and $\log \delta$ is the logarithm of the mean activity coefficient of hydrochloric acid in the solvent mixture at the same temperature and ionic strength.

Glass electrode pH meters (either combination, or reference and standard pair) should be used. Standard buffer solutions at two or three pH values which bracket the expected pH of the test solution should be used for calibration. Indicator paper is not suitable.

It is not necessary to prepare fresh buffer solutions before each series of measurements, as implied by the recommended protocols: Method 144 (APHA, 1976) and ASTM E70-74. (1974).

(2) *Calculations and Information Which Should Be Recorded.* A brief description of the procedure used (if not

the same as above) should be provided, noting the pH and the temperature.

(d) *References.*

Irving, H. H., and U. S. Mahnot, 1968. pH-meter corrections for titrations in mixtures of water and dioxane. *J. Inorg. Nucl. Chem.* 30: 1215-1220.

American Public Health Association. 1974. *Standard Methods for the Examination of Water and Wastewater.* 13th ed. Washington, D.C., pp. 274-76.

A-3.67 *Chemical Incompatibility.* (a) *Objectives.* Chemical incompatibility determines the likelihood of violent reactions occurring when the new chemical is mixed or comes into contact with other substances. Thus, dangerous contact during its chemical life (manufacturing, processing, distribution, use, and disposal) can be avoided. Significant temperature increases, evolution of gases, noxious fumes, splattering, and evolution of flame are possible dangers. As used here, "significant temperature increases" is defined as an increase of 5°C or more. As with flammability/explodability properties, testing might be replaced by structure/activity analyses.

(b) *Rationale.* These tests will indicate hazardous reactions which can occur resulting from contact of the chemical with common oxidizing and reducing agents, common fire extinguishing agents, and common solvents.

(c) *Methods*—(1) *Test details.* This qualitative assessment will vary from chemical to chemical depending on physical state and intended uses. Subjective judgments by a chemist familiar with the chemical and its intended uses are needed in selecting appropriate tests. The following is only an example of an appropriate set of tests for a hypothetical chemical. All temperature increases of greater than 5°C should be noted. Tests should be conducted at temperatures expected during the normal use of the chemical. Generally, the ratio of the mass of the new chemical to the mass of the chosen reactant should be high, simulating maximum exposure situations.

(A) The chemical should be placed in contact with water for 24 hours and visual observations recorded.

(B) The chemical should be placed in contact with carbon dioxide and/or monoammonium phosphate for 24 hours, and visual observations recorded. Both of these compounds are widely used fire extinguishing agents.

(C) The chemical should be placed in contact with zinc or iron for 24 hours and observations recorded. Elemental zinc and iron are both moderately strong reducing agents. Data from corrosion tests may be suitable in lieu of this test.

(D) The chemical should be placed in contact with a moderately strong oxidizing agent, one which the chemical may contact in its intended use. The electrochemical series should be used as a guide (CRC *Handbook of Chemistry and Physics,* for example). A dilute, neutral, aqueous solution of potassium permanganate may be appropriate.

(E) If the chemical is intended for use in households, it should be placed in contact with a household organic solvent, such as kerosene, turpentine, or gasoline, for 24 hours and observation recorded.

(2) *Calculations and Information Which Should Be Recorded.* Descriptions and results of all tests should be provided.

(d) *References.*

National Fire Protection Association 1976. Extinguishing agents, *Fire Protection Handbook,* 14th ed. NFPA, Boston, MA.

A-3.68 *Vapor Phase UV Spectrum for Halocarbons.* (a) *Objectives.* In recent years a great deal of work has been done demonstrating the potential for depletion of stratospheric ozone by halogenated organic compounds (Molina and Rowland, 1974; National Academy of Sciences, 1976). This measurement may be used to make qualitative assessments of the risk posed by halogenated hydrocarbons to stratospheric ozone concentrations. Absorption cross sections can be calculated for different wavelengths based on absorbance, cell path length, and gas density of the cell. Based on this information, known structure-activity relationships, and an assumed quantum yield of 1, tropospheric half-lives can be calculated. Tropospheric half-lives of greater than several years will indicate that the chemical is likely to be transported to the stratosphere. Rowland and Molina (1975) and Chou, et al. (1978), indicate that a large fraction of chlorinated organic compounds transported to the stratosphere will release chlorine atoms either via reaction with $O(^1D)$ or via photodissociation. Therefore, any halocarbons in the stratosphere may pose a threat of reduction in ozone concentration.

This measurement is appropriate for solids, liquids, and gases that contain chlorine or bromine, and have a vapor pressure equal to or greater than 0.5 Torr at 25°C.

(b) *Rationale.* The method is a standard, simple, reproducible laboratory technique.

(c) *Methods*—(1) *Test details.* Evacuated spectral cells should be filled to predetermined gas concentrations (pressures). The spectrum should be recorded as the absorbance or molar absorptivity as a function of wavelength compared to a matched cuvette blank.

Vapor phase absorption spectra should be measured at three different pressures, between the wavelengths 275 nm and 700 nm, and at room temperature (e.g. Chou, et al., 1978; Tsubomura, et al., 1964; Gordus and Bernstein, 1954; and Lacher, et al., 1950). Calibrate the cell path length of 10 cm cells using a reference compound with an accurately known molar absorptivity and Beer's Law.

(2) *Calculations and Information Which Should Be Recorded.*

The absorbance or molar absorptivity as a function of wavelength for each concentration (gas density) should be recorded. For tabular data, wavelength intervals of two or five nanometers should be used.

The cell pathlength and the spectrophotometer model name and number, the temperature of the cell, and cell calibration data (for 10 cm cells) should be recorded.

(d) *References.*

Chou, C. C., et al. 1978. Stratospheric photodissociation of several saturated perhalochloroflurocarbon compounds in current technological use (Fluorocarbons 13, 113, 114, and 115). *J. Physical Chem.* 82: 1.

Gordus, A. A., and Bernstein, R. B. 1954. Isotope effect in continuous ultraviolet absorption spectra: Methyl bromide d, and chloroform d, *J. Chemical Phys.* 22(5): 290-295.

Lacher, J. R., et al. 1950. The near ultraviolet absorption spectra of some fluorinated derivatives of methane and ethylene. *J. American Chemical Soc.* 72: 5486-5489.

Molina, M. J., and F. S. Rowland. 1974. Stratospheric sink for chlorofluoromethanes: Chlorine atom catalysed destruction of ozone. *Nature* 249: 810-812.

National Academy of Sciences. 1976. *Halocarbons Effects on Stratospheric Ozone,* Washington, D.C.

Rowland, F. S., and M. J. Molina. 1974. Chlorofluoromethanes in the environment. *Reviews Geophysics Space Physics* 13: 1.

Tsubomura, H., et al. 1964. Vacuum ultraviolet absorption spectra of saturated organic compounds with non-bonding electrons. *Bull. Chem. Soc. Japan* 37: 417-423.

A-3.69 *Ultraviolet and Visible Absorption Spectra in Aqueous Solution.* (a) *Objectives.* The ultraviolet and visible absorption spectra of chemicals in solution are important physical properties that are characteristic of molecular structure. Since water covers most of the earth's surface, water is the obvious choice as the solvent. The ultraviolet and visible absorption spectra of chemicals in aqueous solution are also useful as an aid in carrying out and interpreting the photochemical transformation of chemicals in aqueous solution.

It may be necessary in the assessment process to obtain the ultraviolet and visible absorption spectra for chemicals that are liquids or solids at 25° C.

(b) *Rationale.* The test method outlined in Section (c) is the conventional method for determining the ultraviolet an visible absorption spectra of chemicals in aqueous solution.

(c) *Methods*—(1) *Test Details.* The following general discussion and test procedures can be used as guidelines to determine the ultraviolet and visible absorption spectra in aqueous solution.

(A) Very pure water should be used (e.g., water comparable to reagent grade water from a Millipore Milli-Q System).

(B) Spectrograde methanol or acetonitrile should be used as a cosolvent.

(C) Analytically-pure chemical should be used.

(D) If possible, the ultraviolet and visible absorption spectra of the chemical should be determined in water. However, this task is sometimes difficult, if not impossible, because the solubility of many organic chemicals in water is very low. As an alternative, mixtures of water and acetonitrile or methanol can be used as the solvent. These organic solvents have refractive indices which are very close to that of water, so the absorption spectra of nonpolar compounds will be very similar in mixtures of water and acetonitrile or methanol as in water (Zepp, 1978). The minimum amount of cosolvent required to achieve a concentration which will give a good spectrum should be used.

(E) Particular care should be used to obtain a good spectrum in the absorption "tail", since tailing absorptions may contribute significantly to the light absorption by the chemical in sunlight.

(F) When measuring the absorption spectra, a solvent vs. solvent baseline should be established, and replicates run to ensure that no instrumental or cell effects introduce artifacts into the absorption data. It is desirable to obtain molar absorption coefficients from the spectra.

(G) In some cases, cells of longer pathlength (e.g., 10 cm cells) can be used to obtain the spectrum, but must be a matched set, and must be accurately calibrated. The pathlength of these cells can be determined as follows: The Beer-Lambert equation is given by $A_\lambda = \epsilon_\lambda lC$, where A_λ is the absorbance at wavelength λ, l is the cell pathlength in cm, C is the molar concentration, and ϵ_λ is the molar absorption coefficient at wavelength λ. An analytically pure reference compound with an accurately known value of ϵ_λ should be chosen. A solution should be prepared at a molar concentration C which will give a reasonable value of A_λ in a given solvent. Before measuring A_λ, solvent vs. solvent in the two cells should be run to establish the baseline. The sample cell should be filled with the reference solution and the reference cell with the solvent. The absorbance should be measured in duplicate at the wavelength λ corresponding to the known value of ϵ_λ. The pathlength l can then be calculated using A_λ, C and ϵ_λ in the Beer-Lambert equation. The procedure should be repeated to calibrate the reference cell. Since the cells are a matched set, the pathlengths should be essentially the same.

(H) The ultraviolet and visible absorption spectra should be obtained at pH 5, 7 and 9 for chemicals which reversibly ionize or protonate (e.g., inorganic acids and bases, carboxylic acids, phenols, and anilines). Buffer solutions should be prepared according to the *Handbook of Chemistry and Physics* (1974–75).

(I) The molar absorption coefficient will be very useful in the interpretation of the data on photochemical transformation of chemicals in water. The molar absorption coefficient should be determined from the two absorption spectra at sufficient wavelengths to define the absorption band, including "tailing". Determining the absorption coefficient in the "tail" is difficult since it will have a low value. At wavelengths where the absorbance is indistinguishable from the baseline noise, the value of ϵ_λ should be recorded as zero.

(2) *Calculations and Information Which Should be Recorded.*

(A) The Ultraviolet and visible spectra of the chemical in aqueous solution, or in water plus methanol, or in water plus acentonitrile should be determined.

(B) The concentration of the solution and the cell pathlength.

(C) If 10 cm cells are used, submit all data on the determination of the cell pathlength.

(D) The name, structure, and purity of the reference chemical.

(E) Extinction coefficients ϵ_λ should be recorded as a function of the wavelength.

(F) The manufacturer and model number of the spectrophotometer should be recorded.

(d) *References.*

Handbook of Chemistry and Physics. 1974–1975. 55th Edition. CRC Press, Cleveland, Ohio.

Zepp, R.G. 1978. Quantum yields for reactions of pollutants in dilute aqueous solution. *Environ. Sci. and Tech.* 12:327.

A-4 Persistence Tests

A-4.1 *General.* Chemical persistence is defined here as the property of a compound to retain its physical, chemical and functional characteristics in the environments through which it is transported and distributed for a certain period of time following its environmental release. Persistence is an important aspect of a discharged chemical in the overall evaluation of the potential risk posed by the chemical to the environment.

In testing for health and ecological effects of chemicals, the range of concentrations or dosages usually employed has, as an upper limit, the minimum concentration which produces a deleterious effect. In the assessment of potential chemical risk, the allowable use of persistent chemicals must be based on an exposure safety factor derived from the dose giving a minimal effect and production data. If a chemical persists in an ecosystem and is continuously or periodically deposited there, it could accumulate to levels that exceed acceptable limits.

Chemical transformation can be considered the inverse of persistence. Transformation products can be hazardous in their own right. The fate of chemicals in the environment depends upon various chemical, physical and biological interactions. Few of these have been studied in enough detail to predict dominant pathways or rates of change in concentration. However, one intent of these Guidelines is to focus attention on persistence testing so that these deficiencies can be systematically corrected in the future.

A-4.2 *Chemical Transformation: Hydrolysis.* (a) *Objectives.* Chemicals introduced into aqueous media in the environment could undergo hydrolysis and be transformed into new chemicals with properties different from their precursors. In addition, processes other than nucleophilic displacement by water may occur (e.g., elimination or isomerization). The importance of these transformations of chemicals as dominant pathways in aqueous media can be determined quantitatively from data on hydrolysis rate constants and half-lives.

Hydrolysis data will generally be important in assessing risks from organic chemicals that have hydrolyzable functional groups (e.g., esters, amides, alkyl halides, epoxides, and phosphoric esters).

(b) *Rationale.* Hydrolysis refers to the reaction of an organic chemical (RX) with water with the resultant net exchange of the group X for the OH group from the water at the reaction center. Therefore,

$$RX + HOH \longrightarrow ROH + HX \quad . \quad (1)$$

In the environment, hydrolysis of organic chemicals occurs in dilute solution. Under these conditions, water is present in a large excess and the concentration of water is essentially constant during hydrolysis. Hence, the kinetics of hydrolysis are pseudo-first-order at a fixed pH.

Processes other than nucleophilic displacement by water can take place. For example, X can be lost from RX via an elimination reaction. These

elimination reactions exhibit kinetic behavior (i.e., pH independent or first-order acid or base dependent) similar to those reactions where OH substitution occurs. Elimination reactions are also covered in this hydrolysis protocol.

The hydrolysis reaction can be catalyzed by acidic or basic species, including OH^- and H_3O^+ (H^+). The promotion of hydrolysis by H^+ or OH^- is known as specific acid or specific base catalysis, as contrasted to general acid or base catalysis encountered with other cationic or anionic species. So far, the published laboratory data (e.g., Smith, et al., 1977, 1978; Wolfe, et al., 1977; Zepp, et al., 1975) indicate that hydrolysis rates are the same in sterile natural freshwaters and in buffered distilled water at the same temperature and pH. Thus, only specific acid or base catalysis together with neutral water reaction need be considered. Although other chemical species may catalyze hydrolysis reactions, the available concentrations of these species in the environment are usually too low to have an effect and are not expected to contribute significantly to the rate of hydrolysis (Mabey and Mill, 1978).

An extensive amount of information has been published on the hydrolysis of a wide variety of organic chemicals. However, most of the literature relating to environmental hydrolysis of chemicals pertains to pesticides. Much of this data is incomplete for the range of pH and temperature of environmental concern. Effects of buffer salts are often unrecognized. At present, no published screening test exists for determining the hydrolysis rate constant at relevant environmental pHs and temperatures. Such a test is being developed. In the interim, the general discussion and test procedures described herein can be used as guidelines. These procedures take into account (1) the fundamentals of the kinetics of hydrolysis; (2) the need for quantitative data in the pH and temperature ranges of environmental concern; (3) the effects of buffer salts on the rates of hydrolysis; and (4) the need to assure that only hydrolysis takes place. For example, the experiments should be designed to prevent biodegradation, loss by volatilization, or photolysis (for chemicals that absorb in the visible region).

(c) *Methods*—(1) *Test Details.* The following general discussion and test procedures can be used as guidelines for determining the hydrolysis of organic chemicals.

(A) Hydrolysis experiments should be conducted in a thermostatic bath with good temperature control (±1°C) and with accurate temperature measurement.

(B) Hydrolysis experiments should be performed using analytically-pure material (greater than 99% by weight pure), if available. However, if the chemical contains some impurities, note the nature and amount (%) of each impurity.

(C) Very pure, sterile water should be used (e.g., water comparable to reagent grade water from a Millipore Milli-Q-System).

(D) All glassware should be sterilized in an autoclave or by some other suitable method.

(E) Buffer solutions should be prepared using reagent grade chemicals and very pure water, as follows:

pH 5.0: 0.01M sodium acetate adjusted to pH 5.0 with 0.1M acetic acid.
pH 7.0: 30 ml of 0.067M NaH_2PO_4 mixed with 61 ml of 0.067M K_2HPO_4 and diluted tenfold.
pH 9.0: 0.025M $Na_2B_4O_7$ adjusted to pH 9.0 with 0.1M acetic acid.

The pH of each buffer solution should be checked with a pH meter at 25°C and adjusted to pH 5.0, 7.0, or 9.0, if necessary. These solutions should be used to prepare reaction solutions of the chemical.

(F) Test solutions should be prepared as follows:

(i) If the chemical is readily soluble in water, an aqueous solution of chemical in very pure water should be prepared, with buffer solution added to on aliquot of this aqueous solution. The chemical concentration in the final solution should be less than one-half its solubility in water and less than 10^{-3}M.

(ii) For chemicals which are too insoluble in pure water to permit reasonable handling and analytical procedures, pure chemical should be dissolved in reagent grade acetonitrile and buffer solution should be added to an aliquot of the acetonitrile solution. The chemical concentration in the final solution should be less than one-half its solubility in water and less than 10^{-3}M. The concentration of acetonitrile should be one volume-percent or less, in the final solution.

(G) The solution absorption spectrum, as measured by the method described in Section A-3.69, can be used to determine whether the hydrolysis experiments should be carried out in the dark to eliminate photolytic transformations. For chemicals that absorb in the visible region, the experiments should be conducted using amber or red safelights, amber or red glassware, or some other suitable method.

(H) Stoppered volumetric flasks (no grease) should be used for carrying out the hydrolysis reaction. If the chemical is volatile, the tubes should be sealed. Tubes should be filled almost completely, sealed, and submerged in the constant-temperature bath.

(I) Any suitable analytical procedure can be used for the determination of the concentration of chemical at various times during the course of the hydrolysis reaction. Whenever possible, an analytical procedure that provides a precision within ± 5% should be used.

(J) Complications can be encountered when measuring the rate of hydrolysis of compounds that reversibly ionize or protonate in the pH range 5 to 9. Rates of hydrolysis of these compounds often show unusual pH-rate profiles, often with a maximum or minimum, owing to competition between charged and uncharged forms. Mabey and Mill (1978) depict typical log k_h vs pH plots for chemicals which undergo acid, water, and base promoted hydrolysis (Figure 1). Should there be any question about the importance of this effect on the hydrolysis of compounds that reversibly ionize or protonate in the pH range 5-9, additional measurements should be made to define the pH-rate profile.

(K) In general, with low concentrations of chemicals, buffers may be used at 0.01M concentrations to hold pH constant without introducing buffer effects (Mabey and Mill, 1978). The buffers outlined in (E) should be adequate. However, for some chemicals, it is possible that buffer catalysis could affect the rate of hydrolysis. If there is any reason to suspect buffer catalysis, hydrolysis experiments can be carried out at two buffer concentrations using the buffers in (E) and the same buffers at a lower concentration. If the rates of hydrolysis are the same, then buffer catalysis has been eliminated. A good discussion of general acid and base catalysis is given by Jencks (1969).

(L) As a general guideline to carrying out hydrolysis experiments, the methods of Wolfe et al. (1976); Wolfe et al. (1977); Smith et al. (1977) (1978); Barrow (1966); and Frost and Pearson (1961) should be followed. All experiments should be conducted in duplicate by one of the following procedures.

Reaction solutions of the chemical should be prepared as described above at 25°C at pH 5.0, 7.0, and 9.0. The initial concentration (C_o) should be determined at t=0.

Procedure 1: Each reaction mixture should be analyzed at regular time intervals to provide a minimum of six time points (in hours) with hydrolysis between 20-70%. Rates should be fast enough so that 60-70% of the chemical is hydrolyzed in four weeks (672 hours).

Procedure 2: If hydrolysis is too slow at 25°C to conveniently follow the reaction to high conversion in four weeks but still rapid enough to measure 20-30% conversion, the accuracy

of the data will be impoved if more data points are taken between 10 and 30% conversion. Fifteen to twenty time points are preferable.

Procedure 3: If the chemical hydrolyzes less than 20% in four weeks, the concentration (C) should be determined after four weeks (t=672 hours).

(2) *Calculations and Information Which Should Be Recorded.*

(A) A description of the analytical procedure and data on calibration should be recorded.

(B) A description of the method of extraction and data on recovery should be recorded if an extraction method is used to separate the chemical from the aqueous phase.

(C) The initial concentration of the chemical should be recorded for each set of experiments.

(D) The pH for each set of experiments should be recorded.

(E) Hydrolysis calculations should be carried out in the following manner. Since the kinetics of hydrolysis is pseudo-first-order, the integrated equation can be put in the form

$$\log_{10}C = -\left[\frac{k_h}{2.30}\right] t + \log_{10}C_o \quad . \quad (2)$$

C_o is the initial concentration of the chemical, C is the concentration of chemical at t (in hours) and k_h is the hydrolysis rate constant (in hours $^{-1}$) at a fixed temperature and pH. Using the experimental data from Procedures 1 or 2 and linear regression analysis, k_h can be accurately determined at 25° C. k_h and the correlation coefficient (R^2) for each set of experiments should be calcluated and recorded. The mean value of k_h and the standard deviation should be calculated and recorded. From the mean value of k_h at pH 5.0, 7.0, and 9.0 at 25° C, the half-life $t_{1/2}$ can be calculated using the following equation:

$$t_{1/2} = \frac{0.693}{k_h} \quad (3)$$

The values of $t_{1/2}$ at pH 5, 7, and 9 should be calculated and recorded. For Procedure 3, the initial concentration C_o and the concentration of chemical C remaining at t=672 hours should be used in equation 2 and k_h calculated at 25° C for each set of experiments. The mean value of k_h and the standard deviation at pH 5, 7, and 9 should be calculated and recorded. From the mean value of k_h at pH 5.0, 7.0, and 9.0 at 25° C, the half-life, $t_{1/2}$ should be calculated and recorded. If after 672 hours, C is essentially equal to C_o, then k_h cannot be calculated and the chemical would then be considered persistent.

(d) *References.*

Barrow, G. M. 1966. *Physical Chemistry,* McGraw-Hill, New York, N.Y.

Frost, A. A. and R. G. Pearson. 1961. *Kinetics and Mechanism.* Second Edition. John Wiley & Sons. New York, N.Y.

Jencks, W. T. 1969. *Catalysis in Chemistry and Enzymology.* Chapter 3. McGraw-Hill. New York, N.Y.

Mabey, W. and T. Mill. 1978. Critical review of hydrolysis of organic compounds in water under environmental conditions. *J. Phys. and Chem. Ref. Data* 7:383.

Smith, J. H. et al. 1977. *Environmental Pathways of Selected Chemicals in Freshwater Systems. Part I. Background and Experimental Procedures.* EPA-600/7-77-113.

Smith, J. H. et al. 1978. *Environmental Pathways of Selected Chemicals in Freshwater Systems. Part II. Laboratory Studies.* EPA-600/7-78-074.

Wolfe, N. L. et al. 1976. *Chemical and Photochemical transformation of Selected Pesticides in Aquatic Systems.* EPA-600/3-76-067.

Wolfe, N. L. et al. 1977. Kinetics of chemical degradation of malathion in water. *Environ. Sci. Technol.* 9:88.

Zepp, R. G. et al. 1975. Dynamics of 2,4-D esters in surface waters: Hydrolysis, photolysis, and vaporization. *Environ. Sci. Technol.* 9:1144.

A-4.3 *Chemical Degradation: Oxidation.* (a) *Objectives.* For many organic chemicals which are gases at ambient temperatures or which have appreciable volatility, atmospheric oxidation undoubtedly is a major degradative pathway. A number of studies of these reactions, principally in air pollution research, make predictions possible on the fate of a variety of organic compounds in the atmosphere. Oxidants produced *in situ* in the air through photochemical oxidation include ozone, hydroxy radicals, peroxides, hydroperoxides and peroxy nitrates. The most important oxidants of organic vapors are the hydroxy radicals and ozone.

Chemical oxidation occurs in aquatic environments as a consequence of photochemical processes that generate free radicals. The concentrations and reactivities of oxy free radicals are such that only alkyl-peroxy radicals and singlet molecular oxygen are likely to act as important oxidants in natural waters (T. Mill, 1978).

Data from free radical oxidation studies will permit the calculation of estimated half-lives and degradation rates and the assessment of oxidation as a factor in the environmental persistence of the test chemical.

Chemicals subject to rapid atmospheric oxidation are less likely to persist and be transported from the point of release. On the other hand, a chemical not likely to be rapidly oxidized or degraded by other mechanisms is more likely to have an effect on various life forms.

There are some indications that free radical oxidations may be important only for certain types of organic chemicals, but this needs more study. Until applicability can be limited on the basis of structure-activity relationships, the free radical oxidation methods apply as follows:

(1) For atmospheric oxidations, testing with hydroxy radical and with ozone for all organic chemicals except those with vapor pressures of less than 10 torr at 30°C.

(2) Oxidation testing in water for all organic chemicals except those with a water solubility of less than 0.1 mg/l at 20°C.

(b) *Rationale.* Free radical oxidations are important degradative mechanisms for many organic compounds in the atmosphere and such reactions may be important for some organic chemicals in water and soil. However, there are at present no simple procedures for evaluating the potential for free radical oxidations in the environment. Thus, selected references will be cited that describe typical methods currently used to measure the oxidation of organic compounds at environmentally realistic concentrations. Development and validation of procedures acceptable to EPA will be based on these methods.

Appropriate studies of free radical oxidation in air include enclosure of the reactants—an oxidant species and the organic compound—in a container at appropriate concentrations. Analytical procedures are used to follow the change in concentrations of one or both of the reactants.

Some technology is being developed for determining the free-radical oxidation potential in water (Smith, et al., 1977). In this method alkylperoxy radicals are generated at a known concentration in water and the disappearance of an organic test compound is followed. The procedures need further development and refinement, and methods need to be developed for testing for oxidation by singlet oxygen. It also appears that only selected classes of chemicals will be sufficiently reactive with free-radical oxidants to justify testing. Those classes need clearer definition.

There is no technology for the study of free-radical oxidations in soil.

The referenced procedures are the best state-of-the-art methods for determining free-radical oxidation under environmental conditions.

(c) *Methods.* The cited procedures measure the potential for a chemical to undergo free-radical oxidation in airborne or aqueous environments, but they require modifications. Until test details are developed and validated, the following references should be used as guidelines.

(1) *Atmospheric Studies.* The important oxidant species in the air appear to be ozone and hydroxy radical. Tests with ozone may be performed as described by Doyle et al. (1975), Japer et

al. (1974) or Walter et al. (1977). An example of good studies of hydroxy radical reactions is described by Niki et al. (1978).

(2) *Oxidation in Water.* Methodology currently under development is described by Smith et al. (1977).

(3) *Calculations and Information Which Should be Recorded.* (A) A written description of the method used (or equivalent literature reference) should be prepared, including details on equipment, analytical techniques, reactant species and concentrations, and reaction conditions (temperature, light, etc.).

(B) The half-life calculations and results for the organic test compound should be recorded.

(C) A written discussion of any difficulties experienced should be included along with any other pertinent information.

(d) *References.*

Doyle, G.J. et al., 1975. Gas phase kinetic study of relative rates of reaction of selected aromatic compounds with hydroxyl radicals in an environmental chamber. *Env. Sci. Tech.* 9:237-241.

Hill, James IV, et al., 1976. Dynamic behavior of vinyl chloride in aquatic ecosystems. A report for the Office of Research and Development, U.S. EPA, Athens, GA. EPA-600/3-76-001.

Japer, S.M., et al., 1974. Rate constants for the reaction of ozone with olefins in the gas phase. *J. Phys. Chem.* 78:2318-2320.

Mill, R. Unpublished.

Niki, H. et al., 1978. Relative rate constants for the reaction of hydroxyl radical with aldehydes. *J. Phys. Chem.* 82:132-134.

Smith, J.H., et al., 1977. Environmental pathways of selected chemical in freshwater systems. A report for EPA, Office of Research and Development, Athens, GA. EPA Report No. 600/7-77-113.

Walter, T.A., et al., 1977. Mechanism for olefin-ozone reactions. *Env. Sci. Tech.* 11:382-386.

A-4.4 *Photochemical Transformation in Water.* (a) *Objectives.* Chemicals introduced into aqueous media in the environment can undergo transformation by direct photolysis in sunlight into new chemicals with different properties than their precursors. Data on direct photolysis rate constants and half-lives establish the importance of direct photolysis in sunlight as a dominant transformation of chemical in aqueous media. Therefore, risk assessment may demand photolysis data on chemicals that are liquids or solids at 25°C. except aliphatic hydrocarbons including alkanes, alkenes, and alkynes.

(b) *Rationale.* Although numerous papers have been published on the photolysis of chemicals in solution, rate constants for direct photolysis of chemicals in water under environmental conditions (i.e., in sunlight) have emerged only in the last three years. Zepp and Cline (1977) published a paper on photolysis in aquatic environments with equations for direct photolysis rates in sunlight. These equations translate readily obtained laboratory data into rate constants and half-lives for photolysis in sunlight. Rate constants and half-lives can be calculated as a function of season, latitude, time-of-day, depth in water bodies, and the ozone layer. Several published papers concerning the photolysis of chemicals in the presence of sunlight verify this method (Zepp, et al., 1977; Wolfe, et al., 1976; Zepp, et al., 1976; Zepp, et al., 1975; Smith, et al. 1977, 1978).

This preliminary test is based on the following criteria: (1) the basic fundamentals of photochemistry; (2) the need for quantitative data on direct photolysis rates of organic chemicals in aqueous media; (3) the use of sunlight as the irradiation source because of its relevance and low cost in comparison to artificial light sources; and (4) the experimental design so that only photolysis occurs. For example, the experiments should be designed to eliminate biodegradation and volatilization. However, the test method fails to measure sunlight intensities on the sample during photolysis. Reference compounds (i.e., sunlight actinometers) will be developed through EPA contract to evaluate sunlight intensities. The test will then be modified to use simultaneous photolysis of a chemical and actinometer to evaluate sunlight intensities on the sample. The mofidied procedure will quantify sunlight photolysis of a chemical at a specific time of year and latitude and gives a less accurate but still useful measure of seasonal variation of photolysis.

Substances present in natural fresh waters may accelerate or retard the photolysis of chemicals in sunlight. How these substances affect photolysis is not completely understood. Research is needed to determine what effects substances present in natural waters may have on photolysis rates, with emphasis on the role of various sensitized and photo-initiated free radical processes in accelerating photolysis. Research is also needed on the effect natural substances may have on quenching or retarding photochemical processes. Therefore, only very pure air-saturated water is recommended for use in the screening tests.

(c) *Methods*—(1) *Test details.* Use the following discussion and test procedures as guidelines for determining the photolysis of chemicals in aqueous solution.

(A) conduct photolysis experiments on an analytically pure chemical (greater than 99% by weight pure), if available. If the chemical contains some impurities, specify the nature and amount (%) of each impurity.

(B) Use very pure, sterile, air-saturated water (e.g., water comparable to reagent grade water from a Millipore Milli-Q-System).

(C) Sterilze glassware in an autoclave or by another suitable method.

(D) Prepare solutions with the chemical (1) at less than one-half its solubility in water, (2) at less than 10^{-5} M, and (3) at a concentration such that the absorbance is less than 0.02 in the reaction cell at wavelengths greater than 290 nm. Since the reaction cell is approximately 1 cm, the absorbance of the solution should be less than 0.02 as measured spectrophotometrically in a 1 cm cell. For chemicals which are too insoluble in pure water to permit reasonable handling and analytical procedures, prepare reaction solutions from pure chemical dissolved in reagent grade acetonitrile, an aliquot of which is added to very pure water. Do not exceed one volume-percent of acetonitrile in the final solution.

(E) Carry out photochemical studies at pH 5, 7, and 9 with chemicals which reversibly ionize or protonate (e.g., inorganic acids and bases, carboxylic acids, phenols, and anilines). Prepare buffer solutions by procedures given in the hydrolysis protocol.

(F) The absorption spectrum, as measured by the method described in Section A-3.69, will determine what type of reaction cell can be used in the photolysis experiments. For chemicals that absorb below 340 nm, use approximatly 11 mm i.d. quartz ground-glass stoppered tubes (no-grease). Chemicals that absorb at wavelengths greater than 340 nm can be tested in borosilicate tubes. Cylindrical borosilicate reaction tubes with an i.d. of 11 mm are acceptable. Tubes comparable to Corning Glass, Inc., disposable culture tubes (13 X 100mm) are convenient because they have screw caps for easy sealing. Fill almost completly either tube type with the reaction solution.

(G) Use any suitable analytical method for the determination of the concentration of chemical at various times during the course of the photolysis. Whenever possible, use an analytical procedure that provides a precision within ±5%.

(H) Zepp and Cline (1977) published a paper on determining the rates of direct photolysis in aquatic environments, where the rate of decrease of the concentration of the chemical (C) with time was given by equation 1:

$$-\frac{dC}{dt} = \phi k_a C = k_p C \qquad (1)$$

$$k_p = k_a \phi \quad , \qquad (2)$$

where ϕ is the reaction quantum yield of the chemical in dilute aqueous solution, and $k_a = \Sigma k_{a\lambda}$, the sum of $k_{a\lambda}$ values of all wavelengths of sunlight that are absorbed by the chemical. The term k_p represents the photolysis rate constant in sunlight. Integrating equation 1 yields:

$$\log_{10} \frac{C_o}{C} = \frac{k_p t}{2.30} \quad , \quad (3)$$

where C is the molar concentration of chemical at time t during photolysis and C_o is the initial molar concentration.

By measuring the concentration of chemical C as a function of t during photolysis in sunlight, k_p can be determined using equation 3. Because equation 1 is a first-order rate equation, the half-life for direct photolysis in sunlight is given by equation 4:

$$t_{1/2} = \frac{0.693}{k_p} \quad (4)$$

Zepp and Cline (1977) compute (by computer) direct photolysis rate constants in sunlight (k_p) using a series of equations and laboratory data. Zepp (1978) also determined the quantum yield ϕ by laboratory methods.

(I) For details on conducting photolysis experiments in water, consult the reports by Smith, et al. (1977, 1978) and Wolfe, et al. (1976). The following procedure is a general guideline for determining k_p in sunlight, as an average value for a 24-hour day (expressed in units of day $^{-1}$). For all experiments, prepare an aqueous solution of the chemical and a series of samples in quartz tubes or in sealed 11 mm i.d. borosilicate tubes, as described above in duplicate. Prepare two control samples by wrapping the tubes with aluminum foil. These are analyzed for chemical immediately after completion of the experiment to make sure no decomposition occurred. Place the samples, including the controls, outdoors in an area free of shade and reflections of sunlight from windows and buildings on a black background and inclined at approximately 30° from the vertical. Conduct the photolysis experiments during a warm time of year (i.e., June, July, August) and begin before sunrise. Record the date begun and completed and the latitude of the site. Use one of the following four procedures, depending on how fast the chemical photolyzes:

(i) *Procedure 1:* If the chemical photolyzes 60–80% in 28 days, measure the concentration of chemical at time t = 0 and periodically at 12 o'clock noon.

(ii) *Procedure 2:* If the chemical photolyzes in the range 20–50% in 28 days, determine the concentration after 28 days of photolysis. If less than 20% of the chemical photolyzes after 28 days of exposure, the chemical has a half-life in water greater than 3 months.

(iii) *Procedure 3:* For chemicals that photolyze 60–80% in sunlight within 7 days, determine the concentration at time t=0 and at 12 o'clock noon each day.

(iv) *Procedure 4:* For chemicals that photolyze in sunlight 60–80% within one or two days, place the samples outside before sunrise and measure the concentration of chemical at t=0 and after sunset the first day and after sunset the second day. The above experiment will be carried out on cloudless days a total of three times.

(2) *Calculations and Information Which Should be Reported.* In describing the analytical method used, give the detailed procedure and all the calibration data. In addition, if an extraction method is used to separate the chemical from the aqueous phase, report the detailed method of extraction and recovery data.

For chemicals that photolyze 60–80% in 28 days, use one concentration C which corresponds to less than 40% remaining and the corresponding time in days along with the initial concentration C_o in equation 3 and calculate k_p in days^{-1}. From the analysis of duplicate samples, calculate two values of k_p. Report the mean value of k_p and the standard deviation. Calculate the half-life $t_{1/2}$ using the mean value of k_p in equation 4.

For chemicals that photolyze, 20–50% in 28 days, use the concentration C remaining at t=28 days long with C_o to calculate k_p. Use the same procedure as described above to calculate and report a mean value of k_p, the standard deviation, and $t_{1/2}$.

For chemicals that photolyze in the time period described in Procedure 3, use one concentration C which corresponds to less than 40% of chemical remaining and the corresponding time in days in equation 3 along with C_o to calculate k_p in days $^{-1}$. Calculate two values of k_p from the analysis of duplicate sample and report the mean value and standard deviation of k_p. Use the mean value of k_p in equation 4 to calculate $t_{1/2}$.

For Procedures 1, 2, and 3, if exposure has been intermittent, submit the dates and times of actual exposure. Also report latitude, site of photolysis, and unusual weather conditions.

For chemicals that photolyze rapidly as described in Procedure 4, calculate a full-day k_p value, using the concentration of chemical remaining after sunset along with C_o in equation 3. Calulate two values of k_p from the analysis of duplicate samples and report the mean and standard deviation of k_p. Repeat these calculations for the three separate full-day photolysis experiments. Calculate, and report, the half-life $t_{1/2}$ using the mean value of k_p in equation 4. Also report the dates of photolysis, the latitude, and the site.

(d) *References.*

Smith, J.H., et al. 1977. *Environmental Pathways of Selected Chemicals in Freshwater Systems. Part. I Background and Experimental Procedures.* EPA-600/7-77-113.

Smith, J.H., et al. 1978. *Environmental Pathways of Selected Chemicals in Freshwater Systems. Part II. Laboratory Studies.* EPA-600/7-78-074.

Wolfe, N. L., et al. 1976. *Chemical and Photochemical Transformations of Selected Pesticides in Aquatic Systems.* EPA-600/3-76-067.

Zepp, R. G. and D. M. Cline. 1977. Rates of direct photolysis in aquatic environment. *Environ. Sci. and Tech.* 1:359.

Zepp, R. G. 1978. Quantum yields for reactions of pollutants in dilute aqueous solution. *Environ. Sci. and Tech. 12:327.*

Zepp, R. G., et al. 1977. Photochemical transformation of the DDT and methoxychlor degradation products, DDE and DMDE, by sunlight. *Arch. Environ. Contam. Toxicol.*, 6:305.

Zepp, R. G., et al. 1976. Light-induced transformations of methoxychlor in aquatic systems. *J. Agri. Food Chem.*, 24:727.

Zepp, R. G., et al. 1975. Dynamics of 2,4-D esters in surface waters. Hydrolysis, photolysis, and vaporization. *Environmental Science and Technology*, 9:1145.

A-4.5 *Biodegradation.* (a) *Objectives.* The major use of data on biodegradation is for assessing the persistence of a chemical substance in a natural environment. The natural environment, for the purpose of such tests, is natural waters and various soils (including hydrosoils). If the compound does not persist, information is needed on whether the compound degrades to innocuous molecules or to relatively persistent and toxic intermediates. Secondary concerns for environmental persistence are the possibilities that (1) toxic substances may interfere with the normal operation of biological waste treatment units or (2) toxic substances not substantially degraded within a treatment plant may be released to the natural environment.

The test procedures for biodegradation give an estimate of the relative importance of biodegradability as a persistence factor. The data will be used to evaluate biodegradation rates in comparison with standard reference compounds.

The reference tests described below provide opportunities for biodegradation with relatively dense microbial populations which have been allowed to adapt to the test compound. Those compounds which degrade rapidly (in comparison with reference compounds) and extensively (as judged by such evidence as CO_2 evolution and loss of dissolved organic carbon) are

likely to biodegrade rapidly in a variety of environmental situations.

Such compounds may persist in specialized environments and under circumstances which are poorly represented by these preliminary tests. Further testing may be necessary which focuses on those circumstances. Compounds which produce little indication of biodegradation in these tests may be relatively persistent in a wide variety of environments. In such cases, assessment should focus on other degradation routes, transport and effects.

Reliable conclusions about biodegradation are not generally possible on the basis of structure alone. Biodegradation is the most important degradative mechanism for organic compounds in nature, in terms of mass of material transformed and extent of degradation. Therefore, information on biodegradability is very important in any evaluation of persistence and is generally needed on organic compounds that can be solubilized or dispersed in or on water. Highly insoluble compounds are not testable at present without the use of radioisotopes or complex analytical measurements, nor are there methods to study biodegradation with very low substrate concentrations. Research is needed in these areas to assure more comprehensive and representative assessment.

These types of tests do not differentiate all chemical compounds as relatively nonbiodegradable or rapidly and extensively biodegradable. Results for many materials lead to intermediate conclusions. A more complete understanding of the biodegradability of such compounds would result from advanced tests, such as those employing radiolabelled substrates. Any decision to proceed with such advanced testing would depend upon other factors, such as other transformations and adverse effects of the compound and its degradation products.

(b) *Rationale.* Relatively expensive procedures, such as the use of radiolabelled compounds or instrumental analysis for parent compound and degradation products, are avoided by using methods which follow degradation by indirect methods. These methods include measuring the production of CO_2 and/or methane, the uptake of oxygen and the disappearance of dissolved organic carbon (DOC). Among the methods are a shake flask procedure and CO_2 and BOD measurement. The procedure described by Gledhill (1975) may be substituted for these tests. Other tests are an activated sludge test and an anaerobic test. The proposed tests are based on widely used methods and are being considered as models for standard procedures. They represent the best current state-of-the-art, although each has problems which research might resolve.

The shake flask method is conducted in a mineral salts basal medium with a weak inoculum and relatively low test substrate concentration. This serves as a simple model of surface water. Significant loss of DOC during the test indicates degradation of parent compound but does not prove complete conversion of the organic molecule to CO_2, inorganic salts, and compounds involved in the normal metabolic processes of microorganisms. Loss of DOC could result from cellular uptake, sorption or loss by evaporation.

The CO_2 evolution and standard BOD tests also simulate surface water and provide an indirect measure of biodegradation. When an organic compound is degraded by microorganisms in the presence of molecular oxygen, it may be converted completely to CO_2 and inorganic salts. The theoretical maximum utilization of O_2 and evolution of CO_2 can be calculated if the carbon atoms of an organic compound are completely oxidized to CO_2. In practice, the complete mineralization of the organic substrate is seldom observed because microorganisms generally assimilate from 5 to 40% of the substrate carbon and only 60 to 95% is converted to CO_2. Thus, CO_2 evolution values (or O_2 uptakes) which exceed 60% of the theoretical maximum may indicate substantial degradation of the parent compound.

The activated sludge method simulates conditions in an activated sludge waste treatment plant with moderate to heavy concentration of activated sludge organisms and test compound. The compound to be studied is used at concentrations of 50 to 100 mg/l as DOC. These concentrations allow for analytical reliablity (more easily measured) and for blank organic carbon values which make up only a small part of the total analytical value.

Anaerobic microbial degradation of organic compounds is an important mechanism for degrading waste materials in both the natural environment and in waste treatment plants. However, there are few relatively simple state-of-the-art methods at present for evaluating the potential for anaerobic biodegradations. The types of methods most frequently cited employ microcosms such as flooded soils in flasks and require the use of radiolabelled substrate. Methane from fermentation of organic substrates is the end of a food chain process involving a wide variety or anaerobic bacteria (Mink and Dugan, 1977). The anaerobic digestion test compares the production of methane and CO_2 by anaerobic bacteria in sludge samples with and without added test material.

A desirable goal of degradation testing is to obtain some estimate of the rate at which a compound will degrade in the environment. It is relatively easy to estimate reaction rates for such degradation processes as hydrolysis, photolysis and free-radical oxidations. Environmentally realistic reaction rates for biodegradation are much more difficult to obtain. Among the more important environmental variables which can effect the rate and the extent of biodegradation are (1) temperature, (2) pH, (3) salinity, (4) dissolved oxygen, (5) concentration of test substance, (6) concentration of viable microorganisms, (7) quantity and quality of nutrients (other than test substances), trace metals, and vitamins, (8) time and (9) microbial species. The screening tests proposed in these guidelines do not attempt to deal with all of these variables and the data will not yield quantifiable information on reaction rates. The methods cited will provide indirect evidence for biodegradation, as opposed to the direct analysis for the parent compound and any intermediates that might be formed. The methods cited will provide a means to identify those compounds which are likely to biodegrade rapidly and extensively under conditions that are generally optimal for biodegradation and, also, those compounds which do not biodegrade significantly under those conditions. The methods cited will provide some means for estimating the environmental biodegradability of the test compound by including, in each test, a well-characterized reference compound. If suitable analytical methods are available for the analysis of the parent compound, those methods also may be used to follow the persistence or disappearance of that compound. The rate of disappearance of the parent compound and/or the rate of production of microbial biomass may be followed, in the shake flask test or the CO_2-evolution test, to provide some quantification of the biodegradation process. However, it is believed that such quantification is best left for subsequent tests employing radiolabelled compounds or other suitable analytical techniques which allow the use of substrate concentrations, microbial densities and the like which are more realistic representations of the environment than are the screening tests. The need for subsequent testing should be based on other factors besides biodegradability, such as other degradation/transformation possibilities and indications of adverse effects of the compound and its degradation products.

The investigator may choose to substitute more complex procedures, or procedures using appropriately radiolabelled compound (for example, the

procedures cited in the EPA Pesticides Guidelines) for the procedures described here. Such substitution is acceptable if the methods employed are commensurate with the intended conditions of chemical use and release to the environment and if the same broad environmental circumstances (aerobic aquatic, anaerobic, and activated sludge) are investigated.

There are dozens of alternative methods which could have been specified, many described in a review by Howard, et al. (1975). The proposed methods were preferred over the alternatives because of wider acceptability in the scientific community, simplicity and low cost. These methods represent the best state-of-the-art methods for biodegradability and are being considered as models for standard procedures. However, none is completely acceptable and each should use standard reference compounds concurrently with the test compound. Any problems which appear to be associated with toxicity to the microbial populations, volatility of the test compound, or nonbiological transformations should be recorded.

Sparingly soluble and insoluble materials present special problems in biodegradability tests. Solids should be pulverized or ground to powder or fine particles, if possible, and dispersed into the systems using a minimal volume of organic solvent, if absolutely necessary. When a solvent must be used, a solvent blank (a duplicate setup with everything except the test compound) should be included in the test.

(c) *Test Description.* Descriptions of tests are given at the beginning of each section on specific methods.

A-4.51 *Shake Flask Method.* (a) *Test Description.* The shake flask procedure for biodegradability is based on the Presumptive Test of the Soap and Detergent Association (1966) and the Modified OECD Screening Test (1971).

Microorganisms are inoculated into flasks that contain a defined microbial growth medium (basal medium) and the test compound. Aeration is accomplished by continous shaking of the flask. Following four adaptive transfers, biodegradation is determined by measuring the reduction (if any) in dissolved organic carbon (DOC) during the test period.

The investigator may choose to combine the shake flask method (method A-4.51) with the CO_2 evolution test (method A-4.54) using the apparatus and procedures described by Gledhill (1975). If this option is chosen, the same information should be reported with respect to DOC loss and CO_2 evolution as wouuld be the case of those measurements were made using separate procedures. The microbial inoculum source and acclimation period should be the same as for the shake flask method.

(b) *Basal Medium.* The following basal medium should be used:

(1) Water: high quality water (ASTM Type II or better, ASTM, 1974) containing less than 1 mg/l total organic carbon (TOC), from a block tin or all glass still.

(2) Phospate Buffer Solution: Dissolve 8.5 g KH_2PO_4; 21.75 g K_2HPO_4; 33.4 g $Na_2HPO_4 \cdot 7H_2$; and 15.0 g NH_4Cl, in about 500 ml of distilled water and dilute to 1 liter.

(3) Magnesium sulfate Solution: Dissolve 22.5 g $MgSO_4 \cdot 7H_2O$ in distilled water and dilute to 1 liter.

(4) Calcium Chloride Solution: Dissolve 27.5 g anhydrous $CaCl_2$ in distilled water and dilute to 1 liter.

(5) Ferric Chloride Solution: Dissolve 0.25 g $FeCl_3 \cdot 6H_2O$ in distilled water and dilute to 1 liter.

(6) Trace Element solution: Dissolve 39.9 mg $MnSO_4 \cdot 4H_2O$, 57.2 mg H_3BO_3, 42.8 mg $ZnSO_4 \cdot 7H_2O$ and 34.7 mg $(NH_4)_6Mo_7O_{24}$ in distilled water and dilute to 1 liter.

(7) yeast Extract Solution: Dissolve 15 mg of Difco yeast extract in 100 ml distilled water. Prepare immediately before use.

(8) To each liter of water, 1 ml of each solution above should be added except the yeast extract solution. The solution should be dispensed in 500 ml or 1000 ml portions into 1-liter or 2-liter narrow mouth Erlenmeyer flasks. The flasks should be stoppered with cotton plugs or the equivalent to reduce evaporation and contamination. The flasks should be sterilized if not used on the day of preparation, by autoclaving at 120°C for 20 minutes. Immediately before use, 1 ml of yeast extract per liter of solution should be added to each flask.

(c) *Microbial Culture.* The microbial culture used as the initial inoculum should be prepared as follows:

(1) Secondary Effluent Culture: A sample of secondary effluent of good quality should be obtained from a sewage treatment plant dealing with a predominantly domestic sewage, and filtered through a glass wool pad. The filtrate should be retained.

(2) Soil Culture: 100 g of garden soil (not sterile) should be obtained and suspended in 1 liter of chlorine-free tap water. Soils that are largely clay, sand, or humus should not be used. The suspension should be stirred to thoroughly mix the contents and to break up any clumps. The solids should be allowed to settle for 30 minutes. The supernatant should be filtered through a glass wool pad, and the filtrate retained.

(3) Mixed Culture Inoculum: 100 ml of secondary effluent filtrate should be mixed with 50 ml of soil suspension filtrate and used to inoculate the shake flasks within 24 hours of the time of collection of the secondary effluent and soil. Up to 25 ml of any other mixed culture suspension may be added to the 150 ml of sewage and soil organism suspension. If this is done, information on source of organisms, handling prior to use, and rationale for addition should be recorded.

(d) *Linear Alkylate Sulfonate (LAS).* A sample of LAS (Standard LAS may be obtained from the U.S. Environmental Protection Agency, Environmental Monitoring and Support Laboratory, Cincinnati, Ohio 45268.) should be obtained. The quantity containing 10 mg of organic carbon should be calculated based on the percent of active LAS in the sample.

(e) *Test Compound.* The quantity of test compound which will supply 10 mg of organic carbon should be calculated. If the compound is readily soluble in water, a solution containing 10 mg per ml of organic carbon in distilled water should be prepared.

(f) *Procedure.* (1) Test compound at 10 mg of organic carbon per liter of basal medium should be added in a test flask.

(2) LAS at 10 mg of organic carbon per liter of basal medium should be added in a control flask.

(3) One flask containing basal medium and containing no added test material or LAS should be selected and appropriately labeled as a blank flask.

(4) Each flask should be innoculated with 1 ml of mixed microbial inoculum per liter of basal medium.

(5) The flasks should be placed on a reciprocating shaker or gyratory shaker operating at sufficient speed to assure good aeration (dissolved oxygen 2.0 mg/l or higher) but not so fast as to cause spilling or wetting of the plugs, and then incubated in dark at $22 \pm 3°$ C.

(6) Adaptation: Adaptive transfers should be made at 48 to 72 hour intervals with the final adaptive transfer on the 10th day following the start of the adaptation period. On each transfer day, 1 ml of the 48- to 72-hour culture should be transferred into each liter of fresh basal medium, basal medium plus test compound, and basal medium plus reference compound. Transfers should be from test compound flask to test compound flask, from blank to blank, and from control to control.

(7) Growth of cultures within each flask is indicated by an increasingly hazy or cloudy appearance in the liquid medium and by the deposit of cellular matter on the upper walls of the flasks. If the medium stays clear in the test flask, the test substance might be toxic or inhibitory. In this case, the test procedures should be repeated with the substance at a lower

concentration. If the control flask also remains unclouded, defective inoculum is possible.

(8) Test Period: On the thirteenth day following the initial inoculation, 72 hours after the final adaptive transfer, another transfer into test flasks should be made. The procedure is the same as for the adaptive transfer, except for duplicate preparations for blanks, controls, and test flasks, and two flasks with basal medium plus test compound but without inoculum. The contents of the latter two flasks should be kept sterile throughout the test period.

(9) Following transfers, the first samples should be taken from each flask, the height of the liquid marked with a water-insoluble marker, and the samples incubated as before.

(10) Samples should be taken over a period of 21 days on 0, 1, 2, 3, 4, 7, 10, 15, and 21 or by some other schedule appropriate to the rate of degradation for the test chemical. Only the necessary volume of culture medium necessary for each DOC analysis should be withdrawn, mixing well to dissolve or resuspend material adhering to flask walls before sampling. Evaporation losses should be made up between samplings with distilled water. Following each removal of sample, the liquid level should be marked before returning the flask to the shaker. Unless analyses are run immediately, samples should be preserved by acidifying to pH 2 or less with concentrated H_2SO_4, HCl, or HNO_3 (note: choice of acid may depend on compatibility with the organic carbon apparatus). Preservation can be done before or after filtration.

(11) Within three hours of sampling, each sample should be filtered through a 0.2 μm pore-size membrane until there is sufficient filtrate for the organic carbon analysis. Filters should be pretreated in boiling water for one hour and then stored (for up to one week) at room-temperature in distilled water.

(12) A total organic carbon analysis (TOC) of the filtrate measures dissolved organic carbon (DOC). TOC instruments suitable for the DOC determinations in the range of 1 to 10 mg C/l include products from Beckman Instruments, Dohrman-Envirotech, Ionics Corp., and Oceanography International. Each sample should be analyzed at least twice and the average value reported as mg C/l, using the format shown below.

(13) If suitable methods are available, analysis of the test compound can be used to follow disappearance of that compound. A complete description of the test method and results should be provided.

The % removal at time t should be calculated for each replicate and for each sampling time using the equation

$$\%\ \text{Removal}_t = \frac{[(C_o - B_o) - (C_t - B_t)]\ 100}{(C_o - B_o)}$$

where $\%\ \text{removal}_t$ = % removal at time t

C_o = Concentration of organic carbon in test or reference flask at time 0

B_o = Concentration of organic carbon in blank flask at time 0

C_t = Concentration of organic carbon in test or reference flask at time t

B_t = organic carbon in blank flask at time t.

The % removal values should be averaged for each pair of duplicate flasks and plotted against the time in days.

(g) *Calculations and Information to be Recorded.* (1) The Shake Flask Test data sheet (Table 1) is offered as the preferred format for recording test data, with DOC values expressed as mg C/l to the nearest whole number.

(2) The % removal values vs. time should be calculated and recorded.

(3) A plot of % removal vs. time should be recorded.

(4) Analytical data (for example, if there are analyses of the parent compound) with a description of the method and results should be recorded.

Table 1. Data Sheet for Shake Flask Test: DOC Analysis

Test Material: Starting Date: _____

Name: _____ Type of Carbon Analyzer:

Initial Conc. (mg/l): _____ _____

Reference Material

Name: _____

Initial Conc. (mg/l): _____

Culture medium	Replicate	Average mg C/l on day								
		0	1	2	3	4	7	10	15	21
Basal medium with inoculum only	1									
	2									
Basal medium with test cmpd + inoculum	1									
	2									
Basal medium with reference cmpd + inoculum	1									
	2									
Basal medium with test cmpd only	1									
	2									

A-4.52 *Activated Sludge Test.* (a) *Test Description.* The activated sludge test is based on the semicontinuous activated sludge test of the Soap and Detergent Association (1965) and on the static activated sludge method of Zahn and Wellens (1974) and Zahn and Huber (1975).

Following a period of adaptation to synthetic sewage and gradually increasing concentrations of test compound, an activated sludge should be exposed to a mineral salts medium plus test compound in a well aerated chamber for up to 20 days. Biodegradation is followed by comparing dissolved organic carbon (DOC) at the start with DOC in the mixed liquor on the test day.

(b) *Aeration Chambers.* Polyethylene or glass 3 to 4 l. percolators (or other suitable vessels with cone shaped lower ends) should be fitted with an

aeration stone (gas diffuser) secured at the inside of the narrow end of each percolator. Each percolator should be suspended vertically in a ring or by a bale holder and clean (oil-free) compressed air should be provided to the aeration stone by means of tubing passed through the small, cone shaped end of the percolator. The small end of the percolator should be sealed to make it watertight and 2 l. of water should be added to each chamber. The outside of each chamber should be marked indelibly at the 2 l. liquid level and the water discarded.

(c) *Activated Sludge.* Activated sludge should be collected from a sewage treatment plant that principally treats domestic wastes. The suspended solids concentration (APHA, 1975) should be determined and then adjusted to 2500 mg/l by adding tap water or by decanting supernatant, as appropriate.

(d) *Synthetic Sewage Stock Solution.*

Glucose	30.0 g
Nutrient broth	20.0 g
Dipotassium hydrogen phosphate	13.0 g
Ammonium sulfate	2.5 g

Tap water should be added to make 1 liter and the ingredients dissolved by heating just below the boiling point. The solution should be stored in a refrigerator at less than 7°C. The stock solution should be discarded if evidence of biological growth appears.

(e) *Mineral Nutrient Solution.* (1) 109.55 g $CaCl_2 \cdot 6H_2O$ should be dissolved in distilled water and made up to 1 liter.

(2) 123.25 g of $MgSO_4 \cdot 7H_2O$ should be dissolved in distilled water and made up to 1 liter.

(3) Nutrient solution: 38.5 g of NH_4Cl, and 9.0 g of $NaH_2PO_4 \cdot H_2O$ should be dissolved in distilled water and made up to 1 liter.

(4) Mineral nutrient solution: For each liter of Mineral Nutrient Solution, 4.8 ml of $CaCl_2$ solution, 0.6 ml of $MgSO_4$ solution, and 2.5 ml of the Nutrient Solution should be used and diluted to 1 liter with distilled water.

(f) *Acclimation Procedures.* (1) 200 ml of the solids-adjusted activated sludge should be placed into each chamber and aerated at a rate of about 500 ml/minute.

(2) A daily "fill and draw" routine should be done as follows:

(i) Chamber walls should be scraped and/or brushed down to remove accumulated solids and to return them to the aerated liquor.

(ii) The mixed liquor suspended solids (MLSS) concentration should be determined and, if necessary, sufficient mixed liquor removed to maintain MLSS at 2000 to 3000 mg/l.

(iii) Aeration should be stopped and the solids allowed to settle for 30 minutes.

(iv) The upper 1500 ml of supernatant should be discarded, leaving 500 ml of settled sludge and liquor in the aeration chamber.

(v) Aeration should then be resumed.

(vi) 15 ml of synthetic sewage stock should be added to each chamber, and the chambers then filled to the 2000 ml mark with tap water.

(vii) The pH should be checked daily and maintained in the range 6.5 to 8.0 by adding H_2SO_4 or NaOH solution, as necessary.

(viii) The dissolved oxygen concentration of the mixed liquor should be checked daily and, if necessary, the air flow should be increased to maintain at least 2.0 mg/l D.O. in each unit.

(3) With each run, one blank unit should be maintained which is fed synthetic sewage stock only.

(4) With each run, one reference compound unit should be maintained which is fed 15 ml of synthetic sewage stock daily plus diethylene glycol, according to the following schedule:

Acclimation day	Diethylene glycol, mg/unit	Total mg as organic carbon
0	0	0
1, 2, 3	88	40
4, 5, 6	177	80
7, 8, 9	265	120
10, 11	354	160
12, and daily to end of acclimation period	442	200

(5) With each run, four test compound units should be maintained which are fed 15 ml of synthetic sewage stock daily plus test compound, using the following schedule:

Acclimation day	Test compound, total mg as organic C	
	Units 1 and 2	Units 3 and 4
0	0	0
1, 2, 3	20	40
4, 5, 6	40	80
7, 8, 9	60	120
10, 11	80	160
12, and daily to end of acclimation period	100	200

Test compound should be added on the basis of its calculated organic carbon content. The test compound may be added as a solution in water (if sufficiently soluble) or as aliquots weighed to the nearest 0.1 mg.

(6) All units should be maintained at 22°±3°C.

(7) Beginning on the fourteenth day, following the sludge settling step, a portion of the supernatant should be retained for DOC analysis. Simulated influent samples should be prepared as follows:

(i) Blank influent: 1.5 ml synthetic sewage feed + distilled water to 200 ml.

(ii) Referencce unit influent: 1.5 ml synthetic sewage feed + 44.2 mg diethylene glycol + distilled water to 200 ml.

(iii) Test units influents: 1.5 ml synthetic sewage feed + test compound at 10 or 20 mg as organic carbon + distilled water to 200 ml.

Each sample of supernatant and simulated influent is then filtered through a 0.2 μm pore-size membrane until there is sufficient filtrate for the organic carbon analysis. If filtration proves difficult, the sludge solids can be partially removed by centrifugation prior to filtration. The filtrate should be preserved for later analysis, by acidification to pH 2 or less with concentrated H_2SO_4, HCl, or HNO_3 (the choice of acid depends on compatibility with the specific TOC apparatus).

(8) This procedure should be continued for at least three days (days 14 through 16 of the acclimation period) with the same feeding schedule and daily sampling and analysis.

(9) The daily % removal of dissolved organic carbon (DOC) should then be calculated:

$$\% \text{ Removal} = \frac{I - S}{I} 100$$

where

I=DOC of simulated influent
S=DOC of supernatant sample

(10) The daily data should be plotted and the acclimation program continued until the DOC removal efficiency remains at a high (>70%) and consistent (±10%) level for 3 consecutive days or until the thirtieth day of the acclimation period. If the acclimation period continues for 30 days without achieving high DOC removal consistently for 3 consecutive days, the test should be concluded at that time.

(g) *Test Procedures.* (1) Following the three-day period of consistently high DOC removal in the acclimation procedures, and approximately 24 hours after the last addition of synthetic sewage, sufficient mixed liquor should be discarded to reduce the suspended solids to 1000 mg in each unit (500 mg/l). Aeration should be stopped and the remaining solids allowed to settle for 30 minutes. All of the clarified supernatant above the settled sludge solids should be discarded. Aeration should then be resumed and material added to each chamber, as follows:

(i) Blank unit: Mineral nutrient solution to the 2000 ml mark.

(ii) Reference compound unit: 442 mg of diethylene glycol plus mineral nutrient solution to the 2000 ml mark.

(iii) Low concentration test units: 100 mg of test compound, as organic carbon, plus mineral nutrient solution to the 2000 ml mark.

(iv) High concentration test units: 200 mg of test compound, as organic carbon, plus mineral nutrient solution to the 2000 ml mark.

(2) Test unit temperatures should be maintained at 22±3°C, pH at 6.5 to 8.0, and D.O. at 2.0 mg/l or higher. Aeration should be continued throughout the test period.

(3) Losses from evaporation and sampling should be made up before each sampling with nutrient solution (the solution given in (e)(5)(C)) diluted 1:500 with distilled water. A total volume of 2000 ml should be maintained to the conclusion of the run. The volume removed for sampling is taken into account in the evaluative calculations.

(4) The removal of dissolved organic matter should be determined by DOC measurements at regular intervals. Samples from the test, reference, and blank units should be filtered through pre-washed 0.2 μm pore-size membranes. If filtration proves difficult, the sludge can be partially removed by centrifugation prior to filtration. The filtrate should be preserved by acidification for later analysis.

(5) The first samples should be taken 30 minutes after beginning the test to detect adsorption of test compound on the activated sludge. Subsequent samples should be taken at 3, 6, and 24 hours and on days 2, 3, 4, 6, 8, 10, 13, 16, and 19 at approximately the same time of day.

(6) The percentage removal of DOC is given by:

$$\% \text{ removal} = \frac{[DOC_A-(DOC_T-DOC_K)]\ 100}{DOC_A}$$

where

DOC_A=initial DOC value based on amount of compound added. DOC_A will be 100 mg/l for diethylene glycol and either 50 or 100 mg/l for test compound at the start of the test. These values should be corrected for sample volumes as described below.

DOC_T=value at time of sampling.

DOC_K=value of blank unit sample.

(7) Decline in concentration due to the removal of samples is calculated as in the following example:

A sample of 20 ml. removes 1/100th of the DOC in a total volume of 2000 ml. The initial DOC value (DOC_A) needs to be corrected for this removal, as shown below. This results in DOC_A values that become progressively smaller as the run proceeds.

Time	DOC_A MgC/L	Correction for next DOC_A	Measured DOC - DOC_k mgC/L	% Removal
0.5 hr.	100	$\frac{(80)(20)}{2000} = 0.8$	80	$\frac{(100-80)(100)}{100} = 20$
3 hrs.	100-0.8 = 99.2	$\frac{(70)(20)}{2000} = 0.7$	70	$\frac{(99.2-70)100}{99.2} = 29$
6 hrs.	99.2-.7 = 98.5	$\frac{(45)(20)}{2000} = 0.45$	45	$\frac{(98.5-45)100}{98.5} = 54$
24 hrs.	98.5-.45 = 98.05	$\frac{(32)(20)}{2000} = 0.32$	32	$\frac{(98.0-32)100}{98.0} = 67$

NOTE: Correction for next DOC_A = measured DOC $\times \frac{\text{sample volume}}{\text{total volume}}$

(8) The test period should last no more than 19 days. If 90% removal is attained before the end of 19 days and is confirmed by a second analysis on the following day, the trial can end. The test may also be discontinued if the percent removal values do not appear likely to reach 90% and remain consistent (±10%) for 3 or more consecutive days.

(9) If suitable analytical methods are available, the disappearance of the test compound may be followed.

(h) *Calculations and Information to be Recorded.* (1) Daily % removal during acclimation period, including calculations and a plot of % removal vs. time should be recorded.

(2) The data for each sample during the test period should be recorded.

(3) The % removal values for each unit at each sampling time during the test period, including calculations, should be recorded.

(4) The average % removal for each duplicate at each sampling time should be recorded.

(5) A plot of % removal vs time should be recorded.

(6) Any additional analytical data (for example, analyses of the parent compound), with a description of the test method and the results should be recorded.

A-4.53 *Methane and Carbon Dioxide Production in Anaerobic Digestion.* (a) *Test Description.* The anaerobic digestion test is based on the procedures of Nottingham and Hungate (1969). Approaches that might be followed, and acceptable methods for conducting anaerobic aquatic biodegration studies are cited below.

An anaerobic sludge is obtained from a municipal treatment plant. Portions of this stock culture are transferred to stoppered containers and allowed to equilibrate. Selected containers receive the test material. The amount of gas produced in each container is measured periodically and the collected gas is analyzed for its methane and carbon dioxide content. Methane production in units receiving test material compared to controls (no supplement) provides information on the biodegradeability of the substrate under anaerobic conditions.

(b) *Procedures.* An anaerobic digestor sludge should be obtained from a municipal waste treatment plant and portions placed in each of several closed containers. The containers may be butyl-rubber stoppered test tubes (16 × 150 mm) as described by Nottingham and Hungate (1969) or larger tubes or flasks (100 to 500 ml capacity). The 16 × 150 mm test tubes should receive about 5 ml of sludge. Other types of containers should receive sludge at about 25 ml of sludge per 100 ml of capacity. Prior to closing the units, air should be displaced with O_2-free carbon dioxide gas. If small tubes are used, evolved gas may be collected and analyzed using the procedures of Nottingham and Hungate (1969). If larger vessels and larger quantities of sludge are employed, it may be necessry to trap evolved gases in a displacement type gasometer, such as that shown by Mueller, et al. (1959) and by Weng and Jeris (1976).

The units should be maintained at 35°C to 37°C. Evolved gas should be collected and the volume produced should be measured daily, until the daily gas production volume becomes relatively constant (±10%) for 3 or more consecutive days.

When the sludge-containing units reach equilibrium with respect to gas production, test material should be added according to the following schedule:

Unit No.	Test material (mg/l)
1, 2	0
3, 4	10
5, 6	20
7, 8	40
9, 10	100
11, 12	200

Until reference compounds are identified, another pair of units, numbered 13 and 14, should be provided with a single dose of the NYG medium described by Nottingham and Hungate (1969) at the rate of 1 ml of NYG medium per 100 ml of sludge.

The cultures should be incubated at 35° to 37°C for at least 28 days. Gas production is measured periodically (as convenient) and the evolved gas is analyzed for methane and carbon dioxide (Nottingham and Hungate, 1974). At the end of the test period, 5 *N* HCl is added to each unit at the rate of 10 ml of HCl per 100 ml of sludge. This will convert bicarbonate to CO_2. The evolved gas should be measured and analyzed for methane and CO_2 to end the test. If a suitable method is readily available for analysis of the test compound, the vessel contents should be analyzed at the completion of the test period.

As discussed by Nottingham and Hungate (1969), it is possible to calculate the theoretical maximum production of methane and carbon dioxide derived from anaerobic degradation of the test compound. Excess gas production in the units receiving test compound, as compared to units which were unfed, may be related to anaerobic digestion of the test compound. The excess methane and CO_2 (as mg of carbon) produced during the test period is compared to the total theoretical maximum and the percent of theoretical production then calculated as shown.

$$\% \text{ of theoretical} = \frac{(G_T - G_M)\ 100}{G_T}$$

where

G_T=total mg of organic carbon in sample
G_M=mg of carbon in excess CH_4+CO_2 (excess compared to units 1 and 2)

(c) *Calculations and Information Which Should be Recorded*

(1) The source of sewage sludge and date of sampling should be recorded.

(2) Total gas production for each culture unit at each measurement time should be recorded.

(3) Methane and carbon dioxide content of the gas at each measurement time from each unit should be recorded.

(4) The calculated % of theoretical CH_4 and CO_2 production for the test period at each substrate concentration should be recorded.

(5) Repression (if any) of gas production in the presence of test material should be recorded.

A-4.54 *Carbon Dioxide Evolution.*—(a) *Test Description.* The procedures suggested for use in screening for ultimate biodegradability potential (CO_2 evolution and BOD measurement) are based on the method described by Sturm (1973) and on the standard biochemical oxygen demand (BOD) test (APHA, 1975). Those investigators who conduct biodegradability tests should choose to run only one of these methods. The carbon dioxide evolution method is preferred over the long-term BOD test.

(b) *Acclimated culture.* The CO_2 evolution test should be preceded by a thirteen-day acclimation period, using the same materials and procedures described for the shake flask method, with the following exceptions:

(1) The reference compound should be glucose instead of LAS. A concentration of 10 mg C/l of glucose should be made by using 25 mg/l in the basal medium.

(2) Organisms may be acclimated to more than one test compound simultaneously by setting up separate shake flasks for each compound.

(3) On the thirteenth day, equal volumes (500 ml or more) from each shake flask culture should be combined, including the blank and control flasks, to form a composite inoculum culture.

(c) *Procedures.* The procedures should be as follows:

(1) A reaction unit of about 41. volume should be set up and air trains attached as described by Sturm (1973), with air passing through a rotameter, a drying tube (Ascarite), and a CO_2 check (100 ml of 0.05 N $Ba(OH)_2$) before entering the carboy and passing through three CO_2 absorbers (100 ml of 0.05 N $Ba(OH)_2$ in each) arranged in a series, after leaving the reaction chamber.

(2) 250 ml of composite inoculum and 2750 ml of mineral salts medium (basal medium without the yeast) should be placed into each reaction unit. A separate unit and air train apparatus should be set up for a blank, for the reference compound (glucose), and for each test compound concentration.

Each unit containing inoculum and mineral salts medium should be aerated with CO_2-free air for 24 hours prior to adding test compound.

(3) Each test material should be added to its respective reaction unit to concentrations of 5 and 10 mg C/l.

(4) The mixtures should be incubated in the dark at 22±3° C.

(5) CO_2-free air should be bubbled through each setup and the effluent air from each unit passed through three CO_2 absorbers (in series), each containing 100 ml of 0.05 N $Ba(OH)_2$. Periodically, the CO_2 absorber most proximal to the carboy should be removed for titration. The remaining two absorbers should each be moved one place closer to the carboy and a new absorber unit placed at the distal end. The air flow should be low enough that entrainment of aerosols is avoided and evaporation of trapping solution is prevented.

(6) The proximal absorber should be removed for titration on days 1, 2, 3, 4, 5, 8, 10, 15, 21 and 28 following addition of the test compound. The analysis schedule may be varied by the investigator as deemed appropriate to match the degradation rate of rapidly degraded or relatively resistant material.

(7) CO_2 produced during the test and trapped as barium carbonate should be quantitated by titrating the $Ba(OH)_2$ remaining in solution to the phenolphthalein end point with 0.1 N HCl. It generally is more convenient to titrate a portion of the absorber solution, e.g. 25 ml, and to calculate CO_2 production from that data. The procedures and data for each of the absorbers—blank, control, and test units should be recorded.

(8) Calculations: The calculations should be as follows: The ml of 0.1 N HCl required to titrate the residual $Ba(OH)_2$ in the absorber from the blank unit should be recorded. The ml of 0.1 N HCl required to titrate the residual $Ba(OH)_2$ in the absorber from the test unit should be recorded. The test value should be subtracted from the blank value to determine the ml of 0.1 N HCl required to titrate the $Ba(OH)_2$ not converted to $BaCO_3$ by CO_2 derived from the test or control compound. This value multiplied by the normality of the HCl equals the milliequivalents (meq) of HCl required and also is equal to the meq of CO_2 produced from the substrate. Note that 1 meq of CO_2 =the gram molecular weight of CO_2 divided by 2000=44/2000=0.022g=22mg.

As an example:

0.1 N HCl to titrate 25 ml of blank unit = 6.3 ml
0.1 N HCl to titrate 25 ml of test unit = 5.4 ml
difference = 0.9 ml

(0.9 ml) (0.1 N)=0.09 meq HCl=0.09 meq CO_2 produced
0.09 meq CO_2 =(0.09) (22)=1.98 mg CO_2 in 25 ml of absorber solution
(1.98) (4)=7.9 mg CO_2 in 100 ml of absorber solution

Overall equation:

$$\text{mg of } CO_2 \text{ produced from substrate} = \frac{(T_b - T_x)\ (0.1)\ (22)\ (100)}{V} = \frac{(T_b - T_x)\ (220)}{V}$$

where,

T_b = ml of 0.1 N HCl required to titrate aliquot from blank absorber

T_x = ml of 0.1 N HCl required to titrate aliquot from test compound absorber

V = ml of aliquot used in titration

CO_2 production should be calculated for each time period preceding the collection of each absorber unit.

The maximum theoretical CO_2 production from each test or control unit (due to substrate oxidation) is 55 mg for test compound at 5 mg C/l and 110 mg for test compound at 10 mg C/l and for reference compound.

The accumulative % of theoretical CO_2 actually produced at each sampling time should be calculated. For example:

$$\%\ \text{theoretical } CO_2 = \frac{\Sigma[CO_2]_1^n\ (100)}{110} = \frac{\Sigma[CO_2]_1^n}{1.1}$$

where $\Sigma[CO_2]_1^n$ = the sum of CO_2 production values from the absorber samples taken on day 1 though day n.

(9) The % of theoretical CO_2 vs. time in days should be plotted.

(d) *Calculations and Information Which Should be Recorded.*

(1) The calculated CO_2 production for each time period and the accumulative total CO_2 production at each sampling time should be recorded, for each experimental unit.

(2) The calculated % theoretical CO_2 production values should be recorded for each unit at each sampling time.

(3) A plot of % theoretical CO_2 production vs. time should be developed and recorded.

A-4.55 *Biochemical Oxygen Demand (BOD).* (a) *Test Description.* See A-4.5(g)(1).

(b) *Acclimated Culture.* The procedures for obtaining acclimated culture should be the same as for the CO_2 evolution test.

(c) *Dilution Water.* The dilution water should be the mineral salts medium used for the CO_2 evolution test. The dilution water should be prepared one day or more before use and stored in the dark at 20°C in a loosely stoppered container until just before use. One to two hours before use, the dilution water should be inoculated with 0.1 to 0.5 ml of mixed microbial inoculum per liter of dilution water and the water gently aerated for 15 minutes with oil-free compressed air (an aquarium pump is convenient for this purpose).

(d) *Procedures.* (1) If the test compound is sufficiently soluble in water, a solution containing 0.3 mg per ml of test compound should be prepared. If the pH of this solution is less than 6.5 or greater than 8.0, the pH should be adjusted to the 6.5 to 8.0 range, as appropriate, with H_2SO_4 or NaOH solution.

(2) A standard reference solution should be prepared containing 150 mg/l each of reagent grade glucose and glutamic acid that have been dried at 103°C for one hour before weighing.

(3) Eighteen 300 ml BOD bottles should be filled about half full with inoculated dilution water, and additions of standard reference solution or test compound made as shown below.

BOD bottle No.	Organic compound additions
1, 2	None.
3, 4	5 ml of standard reference solution.
5, 6	10 ml of standard reference solution.
7, 8	0.3 mg of test compound.
9, 10	0.6 mg of test compound.
11, 12	1.2 mg of test compound.
13, 14	2.4 mg of test compound.
15, 16	4.8 mg of test compound.
17, 18	None.

The test compound may be added as a water solution if sufficiently soluble or as aliquots weighed to the nearest 0.1 mg. Each bottle should be filled to the top with inoculated dilution water and the dissolved oxygen immediately determined. During this and all subsequent D.O. determinations, the D.O. in the bottles should be measured in numerical order with two blanks first and the other two blanks always last.

(4) Each bottle should be stoppered and incubated in the dark at 20°C.

(5) The dissolved oxygen in each bottle should be measured on days 1, 2, 3, 4, 5, 8, 10, 15, 21, and 28, following addition of test compound. The contents of each bottle should be topped off with distilled water, as necessary, to maintain a water seal. To minimize evaporation of the water seal during incubation, the bottle tops may be covered with small caps or pliable film.

(6) The analysis schedule may be varied by the investigator as deemed appropriate to match the biodegradation rate of rapidly degraded or relatively recalcitrant material.

(7) The D.O. readings for each day should be subtracted from the D.O. readings for the same bottle on day zero. This gives the D.O. depletion value. From this the average depletion value for the blanks should be subtracted to obtain a "depletion less blank" value. This figure should then be multiplied by the inverse of the dilution factor to obtain the BOD value. Those cases where there is a residual D.O. of at least 1 mg/l and a depletion of at least 2 mg/l should be considered the most reliable values. An example is shown:

Bottle No. and dilution	D.O. values			Depletion less avg. blank	Con'n factor	BOD
	Day 0	Day 4	Depletion			
1 Blank	7.6	7.3	0.3			
2 Blank	7.7	7.2	0.5			
7 1/10 [6]	7.7	7.2	0.5	0.1	10^6	
8 1/10 [6]	7.7	7.2	0.5	0.1	10^6	
9 3/10 [6]	7.6	6.1	1.5	1.1	5×10^5	
10 3/10 [6]	7.7	6.1	1.6	1.2	5×10^5	
11 1/10 [5]	7.6	5.1	2.5	2.1	2.5×10^5	5.3×10^5
12 1/10 [5]	7.5	4.9	2.6	2.2	2.5×10^5	5.5×10^5
13 3/10 [5]	7.5	2.8	4.7	4.3	12.5×10^4	5.4×10^5
14 3/10 [5]	7.5	2.9	4.6	4.2	12.5×10^4	5.3×10^5
15 1.5/10 [5]	7.4	0.9			62.5×10^3	
16 1.5/10 [5]	7.3	0.8			62.5×10^3	
17 Blank	7.7	7.3	0.4			
18 Blank	7.8	7.4	0.4			

The more reliable calculated BOD values should be averaged to provide, for this example, a four-day BOD for the organic compound of 538,000 mg of O_2 per 10^6 mg of compound.

(8) Given the molecular structure of the test compound, it is possible to calculate the amount of oxygen required to completely oxidize the molecule to carbon dioxide, water, and other inorganic molecules. Comparing this value with the BOD results for any given day provides a measure of the % of the theoretical O_2 uptake:

$$\%\ \text{of theoretical} = \frac{[BOD_T - BOD_M]\ 100}{BOD_T}$$

where

BOD_T = theoretical O_2 requirement for complete oxidation

BOD_M = measured BOD.

(e) *Calculations and Information Which Should be Recorded*

(1) The calculated BOD values for each day, complete with the data on which the calculations were based should be recorded.

(2) The average BOD values for test and reference samples each test day should be recorded.

(3) The calculated % of theoretical O_2 uptake for each day for the test compound should be recorded.

(4) A plot % of theoretical O_2 uptake vs time should be developed and recorded.

A-4.56 *References.*

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Water and Wastewater, 14th ed., Washington, D.C. pp. 543-550 and p. 94.

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B. Health Effects Testing

There has been considerably more research and experience in the field of health effects testing than in environmental effects or chemical fate testing. As a result, reasonably well-established tests exist for acute toxic effects, subchronic effects, mutagenicity, teratogenicity, reproductive effects, oncogenicity, and chronic toxicity.

The National Academy of Sciences (1977) has issued a recent report on methods for evaluating toxic health effects,* as has the World Health Organization** (1978) and the Food Safety Council (1978).*** Also, EPA has proposed health effects testing guidelines under section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).**** In general, EPA regards any health effects test performed as described in any of these sources to be appropriate for TSCA section 5 premanufacture notification purposes. With respect to EPA's preferred testing methods, this spring the Agency will propose test standards under section 4 of TSCA for a number of health effects tests. These test methods will be incorporated, as appropriate, into section 5 testing guidelines. In preparing proposed section 5 guidelines for health effects testing, EPA will consider previous comments on the section 4 test standards as well as the FIFRA guidelines. However, the Agency welcomes comments at this time on the construction of and the applicability of these references guidelines for the development of health effects information related to section 5 assessment needs.

C. Ecological Effects Tests

C-1 *Discussion of Ecological Effects.* Releases of hazardous chemical substances into the environment during manufacturing, processing, distribution, use, or disposal, whether accidental or planned, can have an adverse impact on both natural and man-modified ecosystems and their components. The societal costs may include degradation of the environment, losses in sport and commercial fisheries, shellfish, populations and wildlife resources, losses in agriculture, losses in tourism and property values, and other adverse impacts.

The chemical fate and health effects tests described in sections A and B above will often provide data helpful in evaluating the potential ecological effects of chemical substances. However, such effects are exerted differently on diverse life forms, as well as at various levels of biological organization.[1] Testing for such effects requires the selection of indicators (i.e., indicative parameters) that provide for wide taxonomic representation and include a range of biological processes.

Ideally, testing at levels of ecological organization above the individual species would provide information more directly related to ecological consequences of the release of a hazardous chemical. However, the development and standardization of such tests is difficult due to the complexity of the species interactions that characterize ecosystems. A major thrust for the future therefore will be the development of test methods that address interactions such as those which occur between predator and prey, among competitors for habitat or food, and between disease and host organisms. As methods such as microcosm studies and other laboratory model systems are developed, they may help to address these ecological testing needs.

Laboratory testing below the level of the organism is also potentially useful. It is generally rapid and readily amenable to standardization, but most such testing has not yet been shown to be useable for ecological impact assessment. Since many cellular and subcellular functions are common to a wide range or organisms, they have the potential of being applicable to many sets of ecological circumstances. Therefore, there are a number of subcellular tests which are also being considered for future inclusion in testing and assessment strategies.

However, most ecological effects tests currently in use employ single species test populations of vertebrates, invertebrates or plants. Individual species represent an intermediate level of biological organization between subcellular functions and community/ecosystem interactions. Many single species tests are considered to be state-of-the-art and have correlated well with actual ecological effects of chemicals. As a consequence, the ecological effects tests included in these guidelines are all single species tests. As subcellular and ecosystem level tests are developed and validated they will be added to the guidelines.

The tests included in this section are those to which a manufacturer may refer when a case-by-case analysis indicates that preliminary data on ecological effects will be needed for assessment of a chemical substance. These guidelines do not provide criteria for making such a chemical-specific decision, nor for selection of specific tests when ecological testing is warranted, nor for the design of advanced tests (which must also be determined on a case-by-case basis). The specification of standardized test methods always rests on the current state of the methodology. Standardized tests

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*Committee for the Revision of NAS Publication 1138, Committee on Tox., Nat. Res. Council, 1977. Principles and Procedures for Evaluating the Toxicity of Household Substances. Prepared for the Consumer Product Safety Commission. National Academy of Sciences: Washington, D.C.

**Principles and Methods for Evaluating the Toxicity of Chemicals. Part I. World Health Organization. Geneva, 1978.

***Proposed System for Food Safety Assessment. Report of the Scientific Committee of the Food Safety Council (1978). Food Safety Council, 221 Teachers Building, Columbia, Maryland, 21044.

****Proposed Guidelines for Registering Pesticides in the U.S.; Hazard Evaluation: Humans and Domestic Animals. Federal Register Volume 43, No. 163, Tuesday, August 22, 1978, Part II, pp. 37336-37403.

[1] Subcellular, cellular, organismal, population, community and ecosystem levels.

are therefore subject to modification, revision, or replacement as improved methods and assessment strategies become available. This section will address some of the uncertainties inherent in preliminary testing for ecological effects, some of the areas in which future improvement might occur, and the general importance of ecological effects testing.

Generally, the following criteria were used to select tests for recommendation in these guidelines:

- The test is in standard use, generally acceptable to the scientific community, or considered to represent a state-of-the-art methodology.
- The test results are significant and useful for risk assessment.
- The test applies to a wide range of chemical substances or categories of chemical substances.
- The test is cost-effective in terms of personnel, time and facilities.
- The test is adequately sensitive for detection of the subject effect.

Confidence in extrapolation from simple tests to ecologically-significant impacts depends not only on the appropriate kinds of tests but also on selection of appropriate organisms to be used in those tests. Organisms useful for assessment testing should have characteristics such as the following:

- The organism is representative of an ecologically important group (in terms of taxonomy, trophic level, or realized niche).
- The organism occupies a position within a food chain leading to man or other important species.
- The organism is widely available, is amenable to laboratory testing, easily maintained, and genetically stable so uniform populations can be tested.
- There is adequate background data on the organism (i.e., its physiology, genetics, taxonomy, and role in the natural environment are well understood) so data from these tests can be adequately interpreted in terms of actual environmental impacts.

C-2 *General Provisions*—C-2.1 *Quality Assurance.* EPA is currently drafting Good Laboratory Practices (GLP) under section 4(b) of TSCA. When these become available, they will provide detailed guidance on proper procedures for laboratory management and the conduct of tests for ecological effects.

C-2.2 *General References.* The Pesticide Guidelines proposed under Part 162, Chapter 1, Title 40 of the Code of Federal Regulations (Pesticide Guidelines Subpart E, Hazard Evaluation: Wildlife and Aquatic Organisms. FEDERAL REGISTER 43(132): 29724-29727) are recommended as the main reference for any ecological effects tests not addressed in the following discussions. As test standards are developed and published under section 4(b) of TSCA, and by the Interagency Regulatory Liaison Group (IRLG), they will also serve as generally recommended tests for use under section 5 of TSCA. Other suggested references are noted under the individual tests contained in these guidelines.

C-2.3 *Reporting on Test Substance.* (a) Data obtained by tests conducted with the technical grade product to be marketed by the manufacturer will be most relevant for assessment purposes, unless that is not the most probable formulation to which organisms will be exposed or unless indicated differently in a specific test method listed below. If the technical grade product is not tested, an explanation of the reason for the substitute would help validate the data for assessment. If possible, a description of the differences between the substance that was used and the market product, including a description of the physical state and chemical nature and how these may affect biological characteristics should be given.

(b) Test results will be more consistent if the lot of the substance tested is the same throughout the duration of the study, and if the sample is stored under conditions that maintain its purity and stability. If a test substance will not be stable for the duration of the study or if, for other reasons, it is not possible to use the same lot throughout the test, subsequent lots of the test substance should be selected that are as nearly identical to the original lot as practicable. Chemical assays should be performed to assure this composition.

C-2.4 *Calculations and Data Which Should be Recorded.* (a) *General:* The data generated by testing are most useful for assessment if submitted in a report format. Such a report should include all information necessary for a generally complete evaluation of the test procedures and results, including information on the facility performing the study, information on the test substance, a description of the test procedures, presentation of the data generated, and a summary and analysis of the test results. The following information is considered valuable for assessment:

(b) *Information on Testing Laboratory/Sponsor.* (1) Name(s) and address(es) of the facility performing the study, and of the sponsor, if different from the testing facility.

(2) Laboratory study number.

(c) *Information on Test Substance.* (1) identification of the test substance, including chemical name, chemical abstract number, sponsor code number, synonyms, and molecular structure.

(2) A qualitative and quantitative determination of chemical composition (including names and quantities of known contaminants and impurities, so far as is technically feasible).

(3) Name of the manufacturer, lot number(s) of test substance, method of synthesis, date(s) when received and storage procedures.

(4) Relevant physical properties of the test substance, such as physical state, pH, stability, melting point, purity and solubility.

(5) Identification and composition of any vehicles or other materials used in testing the substance.

(d) *Description of Test Procedures.* (1) Specification of test methods, including a full description of the experimental design and procedures, reference(s) to the chosen test method, the length of the study, and the dates on which the study began and ended.

(2) Methods of all chemical analyses performed for determining concentrations of test substances, impurities or degradation products, along with the precision and accuracy of the test methods.

(3) Appropriate statistical methods used to summarize experimental data, express trends, and evaluate the significance of differences in data from individual test groups. For example, data averages or means accompanied by standard deviation allow assessment of the variability in the raw data. In addition, standard errors of the means may be used to compare means from different test groups. However, notations of statistically significant differences, along with the confidence level of probability, could substitute for standard errors.

(4) References to statistical methods for analyzing the data, and to published literature used in developing the test protocols, performing the test, making and interpreting observations, and compiling and evaluating the results.

(e) *Description of Organisms.* (1) Community type, species, strain(s) and/or subline(s) used, and rationale for their selection, if different from those recommended by EPA.

(2) Source of organisms, populations, or communities.

(3) Breeding history or breeding type (inbred, hybrid, outbred, as appropriate).

(4) Description of any pretest conditioning or acclimation, including diet and quarantine.

(5) Initial number of each sex, size, and weight in each test group and control group, as appropriate.

(6) Age and condition of each organism, population or community at beginning of study.

(7) Method of randomizing organisms, populations or communities into test groups and control groups.

(f) *Environmental Conditions.* (1) Source of water, its chemical characteristics, and description of any pretreatment, if applicable.

(2) The photoperiod, type of bulb and intensity when light sources are used.

(3) Source, composition, and amount of feed or nutrients made available to organisms.

(4) Temperature and humidity of test environment, if applicable (e.g., humidity is not relevant for aquatic tests).

(5) Description of test chambers including height, width, depth and volume of chamber and contained test environment.

(g) *Preparation of Test Mixture.* Data on preparation of test mixtures which would be useful include name of chemical(s), name of carrier(s), carrier concentration, method(s) of preparation of test mixture, frequency of preparation, physical state, pH, stability and decomposition, storage, and date(s) prepared. If it is known that the test chemical undergoes significant change or loss in the test mixture over the time required for a test, the test mixture should be prepared fresh before each application.

(h) *Exposure.* (1) Dosage or concentration.

(2) Method, route, and frequency of exposure and rationale for selecting each.

(3) Total volume of material (i.e., test substance plus carrier) contained in individual exposures.

(4) The method of randomization used in selecting samples to assay, the assay method used to determine the stability and homogeneity of the test substance in the testing environment, and the results of these assays.

(5) For each exposure level, the mean total amount of test substance administered per organism, population or community.

(6) The reason for selection of the carrier.

(i) *Treatment for infectious disease.* A description of the treatment(s) used to prevent or control infectious diseases if such treatment was undertaken during a test or shortly before a test was begun.

(j) *Observations.* (1) A description of the method(s) of observation.

(2) A description of the frequency of observation, such as when individual organisms are weighed or cultures checked.

(k) *Summary and analysis of test results.* A summary and analysis of the data, and a statement of the conclusions drawn from the analysis. The summary could highlight positive data or observations, and deviations from control data which may be indicative of ecological effects.

C-2.5 *Miscellaneous Considerations.* (a) There are a number of incidental effects which may influence test results; photochemical degradation is one example. Whenever practical, such reactions should be avoided. For example, photochemical degradation can be minimized by shielding reaction mixtures from incident light during the experimental period for animal and bacterial tests. When such reactions are known and cannot be avoided, they should be recorded.

(b) The use of trade names in the text is not intended as an endorsement by EPA, but merely serves as an example of the kind of equipment and facilities that may be used to carry out the tests described.

C-3 *Microbial Effects Tests*—C-3.1 *General.* Microbial activities discussed in these guidelines are associated with three major biogechemical cycles (i.e., carbon, nitrogen, and sulfur cycling) and with decomposition of organic matter. These biogeochemical tests are models which integrate physical components of the environment with biotic processes and indicate not only possible toxic activity, but also effects on the primary mediators of the cycles, the microbes. Data obtained will provide preliminary indications of possible effects of the test chemical on the cycling of elements and nutrients in ecosystems. In addition, the tests will aid in the formation of hypotheses about the ecological effects of chemicals, hypotheses which can be used in the selection of higher level tests when appropriate.

Data on the effects of chemicals on microbial populations and functions can be obtained from laboratory studies employing nonradioisotopic analytical techniques. Studies of effects on microbial functions constitute a more direct approach and are preferred to studies of effects on populations. The activities to be observed are:

- Organic matter (cellulose) decomposition by following CO_2 evolved from organically bound carbon.
- Nitrogen transformations by following the release of organically bound nitrogen (in urea) and the formation of ammonia.
- Sulfur transformation by following the reduction of sulfate to sulfide by *Desulovibrio.*

Two of these tests employ pure cultures of microorganisms for ease of performance and better reproducibility. Additional testing, if suggested by adverse effects near expected environmental concentrations, should employ mixed populations from natural sources. Other functions, such as nitrogen fixation, dehydrogenase activity, invertase activity, nitrification, and pectin or protein degradation, should be considered when additional testing is indicated.

The principal objective of preliminary microbial effects tests is to indicate whether or not the test chemical may cause undesirable changes in microbial populations or in the functions of microbial communities. Such changes might result in a reduction in plant growth or quality through nutritional disturbances, or they might interfere with the natural degradative functions of microorganisms which play a dominant role in transformations of biotic and xenobiotic wastes.

The investigator may choose to substitute more complex procedures, such as those contained in the Pesticides Guidelines (1978), for the methods described here, if the methods employed are commensurate with the intended conditions of chemical use and release to the environment and if the same microbial functions (cellulose degradation, ammonification and sulfate reduction) are investigated.

REFERENCE

Environmental Protection Agency. 1978. Guidelines for registering pesticides in the United States, Office of Pesticides Programs. FEDERAL REGISTER 43 (132):29718-29722.

C-3.2 *Test 1: Cellulose decomposition.* (a) *Objectives.* Cellulose is one of the most abundant organic materials in plants. Dead plant matter, consisting largely of cellulose, is degraded by a number of species of bacteria and fungi. This degradation is accomplished in a stepwise manner going from cellulose to cellobiose to glucose to organic acids and CO_2.

The degradation of cellulose is of particular interest to farmers. The fertility of farmland depends in part on the presence of organisms which degrade dead plant matter. The organisms which decompose the various forms of cellulose are some of the most important microorganisms contributing to humification processes in soils. The inhibition of, or interference with, cellulose degradation by toxic chemicals adversely impacts the recycling of carbon and soil fertility by retarding the breakdown of the vast amounts of cellulose that enter the soil. All chemical substances, except water-insoluble gases, should be considered for this test.

(b) *Rationale.* There are two basic methods available for evaluating cellulose degradation by microorganisms. One method uses variations of soil burial tests in which a cellulose substrate is buried in soil containing a mixed culture that includes cellulolytic microorganisms. The other type employs a liquid culture of cellulolytic microorganisms and measures evolved CO_2. The second is the type proposed here.

One advantage of the liquid culture method over soil burial is time. Typical soil burial tests last for 7 to 8 weeks while liquid culture requires only 7 days. In addition, test compounds in liquid culture are more apt to be in contact with the microorganisms than in soil burial tests because possible soil sorption of test substance is avoided. Pure culture studies in liquid medium also reduce the possibility of lowered toxicity due to biodegradation of the test material. Studies using pure cultures have the two advantages of simpler experimental procedures and greater reproducibility of data.

The major disadvantages of pure cultures are that they are a poor representation of the natural environment and that they fail to allow for synergistic and competing reactions. It could be argued, for example, that inhibition of *Trichoderma longibrachiatum*, specified in this test, should not be taken as evidence that the test compound will inhibit cellulose degradation since other organisms in the soil may be unaffected by the concentration of test material and may degrade cellulose and/or transform the test material. This argument has some validity and only additional testing with mixed cultures in natural soil samples would resolve that question. Tests of that sort, however, are too complex and are not adequately standardized to be justified by the data needs of a preliminary assessment.

(c) *Test Description.* In the proposed test, pure, ball-milled cellulose is added to a mineral salts growth medium as the sole carbon source. This mixture is then innoculated with a known cellulase-producing microorganism and added to an apparatus which allows for growth of the microorganisms and collection of evolved carbon dioxide (CO_2). The quantity of CO_2 produced in the presence of the test substance in comparison with CO_2 production in the absence of the test substance would indicate the effect on microbial decomposition of cellulose.

(d) *Methods*—(1) *Test details.* The cellulase-producing organism which can be used in this test is *Trichoderma longibrachiatum* (ATCC 26921), formerly *T. viride*. Pure stock cultures of the organism are maintained by biweekly subculture on a growth medium for cellulase-producing microbes (Eggins and Pugh 1961). The medium consists of $NaNO_3$, 0.5g; K_2HPO_4, 1.0g; $MgSO_4.7H_2O$, 0.5g; $FeSO_4.7H_2O$, 0.01g; cellulose (ball milled) 12.0g; agar; and distilled water, 1.0 liter, and is modified by the following addition: 0.1g of $CaCl_2$ and 0.5g of $(NH_4)_2SO_4$ per liter.

The apparatus for organism culture and CO_2 collection has been described by Bartha and Pramer (1975). The apparatus allows for semistatic aeration of growing cultures with the cultures receiving CO_2-free air throughout the test. One hundred ml of liquid growth medium (as above but without agar) is despensed aseptically into flasks along with the test compound at one or several concentrations. Testing at five or more concentrations, at least three of which inhibit cellulose decomposition by more than 10% and less than 90% of the control response, supports extrapolation of results to any expected environmental concentration.

Such results are not needed for environmental assessment if the data show that a test chemical is so slightly toxic at reasonably expected environmental concentrations that no detriment to the microbes or to the cellulose degradation process is likely.

For each run of this test, a stock inoculum is prepared by suspending *Trichoderma* spores from the stock culture in distilled water. Stock inoculum for each run should be prepared no more than one hour prior to inoculating flasks. One ml of *Trichoderma* spore inoculum is added to each flask and the flasks are incubated at 22±3°C in darkness. At days 1, 3, and 7, CO_2 evolved by the cultures and collected in the CO_2 absorbant (KOH) is determined titrimetrically. Bartha and Pramer (1965) describe the procedure for introduction and recovery of the KOH from the incubation flask. Appropriate controls consist of flasks containing (1) *Trichoderma* spore inoculum and liquid growth medium and (2) liquid growth medium only (to account for chemogenic CO_2 production). Three replicates of each treatment and each control should provide adequate replication.

(2) *Calculations and Data Which Should be Recorded.* The quantity of CO_2 measured (as mg CO_2) in the presence, and absence, of the test chemical on days 1, 3, and 7 are the data needed for assessment.

(e) *References.*

Bartha, R., and D. Pramer. 1965. Features of a flask and method for measuring the persistence and biological effects of pesticides in soil. *Soil Sci.* 100 (1): 6870.

Eggins, H. O. W., and Pugh, G. J. F. 1961. Isolation of cellulose-decomposing fungi from soil. *Nature*, Lond. 193:9495.

C-3.3 *Nitrogen Transformation.* (a) *Objectives.* Almost all microorganisms, higher plants, and animals require combined nitrogen. In addition, the nitrogen cycle is a major biogeochemical cycle. The main aspects of this cycle are the fixation of gaseous nitrogen, the ammonification of organically bound nitrogen, nitrification, and denitrification.

Ammonification is a key initial step in the reintroduction of nitrogen from protein wastes into the soil and is one of the more readily measured reactions of the nitrogen cycle. As soon as an organism dies and its organic waste returns to the soil, biological decomposition begins and fixed nitrogen is released. The breakdown of proteins and other nitrogen-containing organics in soil and the production of ammonia are the work of widespread and varied microflora. The amino groups are split off to form ammonia in a series of reactions collectively called ammonification. Urea, a waste product found in urine, is also decomposed by numerous microorganisms with the formation of ammonia. This reaction can serve as a convenient assay method for ammonification activity. There is a strong correlation between an organism's ability to degrade urea and its capacity to degrade protein.

The ammonification test presented below is potentially applicable to all chemical substances except water-insoluble gases. Information from such testing would be used to assess the likelihood that the test chemical interferes with the normal conversion of organically-bound nitrogen into ammonia.

(b) *Rationale.* Consideration of at least some aspects of the nitrogen cycle are essential for assessing the effects of substances on microorganisms. An easily measured feature of the nitrogen cycle is the oxidation of nitrite to nitrate by *Nitrobacter* bacteria (Winely and San Clemente, 1970). This focuses on a part of the nitrogen cycle less important than the critical step involving the conversion of organic nitrogen into ammonia.

The preferred method uses urea as a readily obtainable, reproducible nitrogenous organic compound. Some investigators have used pieces of liver or kidney tissue, vegetable meal, dried blood, and casein hydrolysate as nitrogen sources, but these substances are not standardizable. Percolation techniques may also be used for the same purposes in the study of soluble proteins, peptones, polypeptides, and amino acids in solution (Greenwood and Lees, 1956). Methodology using fertile soil and urea and following the evolution of ammonia nitrogen is relatively simple to conduct and will provide meaningful results. Urea is a suitable nitrogen source not only because it is readily available and relatively easy to handle, but in addition, the ability to degrade urea has been associated with general proteolytic capabilities.

Nonsymbiotic nitrogen fixation, nitrogen mineralization and ammonification usually show no response to applications of toxic chemicals such as herbicides (R. Rubinstein et al. 1975). Nitrification is one of the most sensitive conversions in the soil. Nitrification may be inhibited by concentrations of chemicals not inhibiting other impor-

tant biochemical reactions so there are reasons for choosing nitrification as the process which would give results most useful for assessment. One of the arguments against this, as noted earlier, is that ammonification is a more vital part of the nitrogen cycle than nitrification. In addition, the temporary inhibition of nitrate formation is often beneficial in that it slows down the loss of nitrogen from the root areas of plants by leaching and denitrification. Lastly, nitrification by *Nitrobacter* may be too sensitive to inhibition by chemicals in laboratory studies and might give results not representative of natural circumstances and environments. Although inhibition of nitrifying activity could lead to ammonium ion accumulation and serious problems such as root damage, ammonification is considered the more appropriate process to be examined as a first step in looking for effects on the nitrogen cycle.

(c) *Test Description.* The response measured in this test is the ammonification of urea nitrogen by a microbial assemblage in fresh soil or sediment. Although this test uses urea as the nitrogen-containing compound to be mineralized, it may be modified to allow estimation of the mineralization of other N-containing materials.

(d) *Methods*—(1) *Test Details.* Urea is added to sieved soil or sediment (1 mm fraction) along with the test chemical. Testing at five or more concentrations, at least three of which inhibit ammonification activity by more than 10% and less than 90% of the control response, supports extrapolation of results to any expected environmental concentration. Such data are not necessary for assessment if the test substance produces no toxic or inhibitory effects, as determined by this test, at or near reasonably expected environmental concentrations and if no detriment to the ammonification process is likely.

The preferred procedure for this test has been described by Curl and Rodiguez-Kabana (1972). Other procedures which are suitable have been described by Porter (1965), McGarity and Myers (1967), and Greaves et al. (1978). Appropriate controls are: (1) incubation vessels containing soil or sediment only, and (2) incubation vessels containing soil or sediment, and nitrogenous amendment only. Incubation should be at 22±3° C for 2 to 3 weeks. Three replicates of each treatment and control should provide adequate replication. Suitable methods for the analysis for ammonia nitrogen may be found in "Methods for Chemical Analysis of Water and Wastes" (1974).

(2) *Calculations and Data to be Recorded.* Ammonia production for each test unit at each sampling time and the cumulative ammonia production for each test unit over the complete duration of the test is needed for assessment. Ammonia production should be reported as milligrams of ammonia nitrogen (mg NH_3N) per 100 grams of oven dry soil.

(e) *References.*

Curl, E. A., and R. Rodringuez-Kabana. 1972. *Research Methods in Weed Science* R. E. Wilkinson (ed.) Southern Weed Science Society, pp. 178-197.

Environmental Protection Agency. 1975. *Methods for Chemical Analysis of Water and Wastes.* EPA-625/6-74-003.

Greaves, M. P., et al., 1978. Methods of analysis for determining the effects of herbicides on soil microorganisms and their activities. *Technical Report,* Agriculture Research Council, Weed Research Organization. No. 45, p. 55.

Greenwood, D. J. and Lees, H. 1956. Studies on the decomposition of amino acids in soil. I. A preliminary survey of techniques. *Plant Soil* 7:253.

McGarity, J. W., and M. G. Myers. 1967. A survey of urease activity in soils of Northern New South Wales. *Plant Soil* 27:217-238.

Porter, L. K. 1965. Enzymes. *In* C. A. Black (ed.), *Methods of Soil Analysis* (pp. 1536-1549). American Society of Agronomy, Madison.

Rubinstein, R., et al. 1975. *Test Methods for Assessing the Effects of Chemicals on Plants* (p. 3-6). Prepared for Office of Toxic Substances. U.S. Environmental Protection Agency. EPA 560/5-75-008.

Winely, C. L. and C. L. San Clemente. 1970. Effects of pesticides on nitrite oxidation by *Nitrobacter agilis. Appl. Microbiol.* 19:214-19.

C-3.4 *Test 3: Sulfur Transformation (Sulfate Reduction).* (a) *Objectives.* The sulfur cycle is one of the major biogeochemical cycles. Sulfur is found in soil, waters, and the atmosphere in its most reduced form as a result of volcanic action and the decomposition of organic matter. Free sulfur occurs in some soils, and the oxidized form, sulfate, occurs in all soils. Both sulfur and hydrogen sulfide (H_2S) are oxidized by combustion and by microorganisms to sulfates which are used by plants. Sulfur is essential to all living organisms as a part of sulfur-containing amino acids. It is released from organic compounds (plant and animal wastes) by anaerobic decomposition, as H_2S, in its most reduced state.

Sulfate-reducing bacteria are widely distributed in nature where anoxic conditions exist—as in sewage, sediments, muds, and in bovine rumina. Two groups of bacteria are able to reduce sulfate to H_2S (Frobisher et al. 1974). The best known of these are the *Desulfovibrio* organisms. These organisms have been thoroughly studied because they are responsible for serious odor and corrosion problems associated with sulfate reduction. However, these problems tend to obscure the necessary and beneficial role played by *Desulfovibrio* in the sulfur cycle.

Data on sulfur transformation (sulfate reduction) is potentially applicable to the assessment of all chemical substances except water insoluble gases (i.e., those with solubility in water of less than 1 mg/1 at 30°C). If it can be demonstrated that the minimum inhibitory concentration is greater than the highest concentration tested and also, that the highest concentration tested is significantly higher than reasonably expected environmental concentrations, it may be assumed that no detriment to the sulfate reduction process is likely.

(b) *Rationale. Desulfovibrio* was chosen as the test organism because it plays an important role in the sulfur cycle and because it functions under conditions of low oxidation-reduction potential (anaerobic conditions) and will provide some indication of potentially adverse effects under such conditions.

Standard methods for the determination of sulfate-reducer activity are described in Standard Methods (APHA, 1975) and by the American Society for Testing and Materials (1978). The Standard Methods procedure 2a.1 (p. 1001) was selected as being reproducible and relatively simple and as adequate for the screening test.

(c) *Test Description.* The test for inhibitory effects on sulfate reducer activity is a modified time-contact evaluation with the organism and the test compound in contact with each other for a selected period of time. Following the period of contact between test compound and *Desulfovibrio* suspension, the organisms are transferred into a sulfate-reducing medium.

(d) *Methods*—(1) *Test details.* The sulfate-reducing organism *Desulfovibrio desulfuricans* strain Hildenborough (NCIB 8303) should be used in this test. The organism can be obtained as freeze dried material from cultures which have been grown at 30°C (Saleh, *et al.,* 1964). Stock cultures of the organism should be maintained by weekly subculture in a growth medium for the heterotrophic growth of sulfate-reducers (Adams and Postgate, 1961). The medium consists of: K_2HPO_4, 0.5g; NH_4Cl, 1.0g; Na_2SO_4, 1.0g; $CaCl_2.6H_2O$, 0.1g; $MgSO_4.7H_2O$, 2.0g; sodium lactate (70 percent solution), 3.5g; yeast extract (spray dried), 1.0g; $FeSO_4.7H_2O$, 0.002g; sodium thioglycollate, 0.1g; ferrous ammonium sulfate 0.5g; water, to make 1.0 litre, final pH 7.5.

Fifteen ml of a 4- to 6-day *Desulfovibrio* culture should be placed in 1485 ml of fresh sulfate-reducer medium. This stock culture is inverted once to distribute the microbial inoculum. The stock culture should then be dispensed, in 99 ml aliquots, into eleven screw cap-type milk dilution bottles and the bottles numbered one through eleven. One ml aloquots from bottles 1

and 2 should then be added to two screw cap culture tubes (20 x 125 mm), the culture tubes filled to capacity with sulfate-reducer medium, sealed and numbered 1 and 2. As described below, chlorine solution or test chemical should then be added to bottles 3 through 11 to provide the indicated final concentrations:

Aliqout bottle No.	Addition	Final conc. of test material (mg/l)
1, 2	None	0
3	Chlorine	1
4	do	10
5	do	50
6	Test Chemical.	1
7	do	10
8	do	50
9	do	100
10	do	500
11	do	1000

A suitable chlorine stock solution should be prepared from hypochlorite solution, containing 30,000 to 50,000 mg/l chlorine equivalent (Standard Methods, 1976, p. 346).

Following addition of chlorine or test chemical, each bottle should be capped and the contents mixed. The bottles and tubes should then be maintained at 22±3°C in the dark. At the end of 3 and 24 hours, the contents of each bottle should be mixed by inverting, then 1 ml aliquots from each dilution bottle should be transferred into screw cap culture tubes filled with sulfate-reducer medium. The tubes should then be capped and numbered to correspond to the bottle numbers and labeled to indicate elapsed incubation time. The inoculated tubes should be incubated in the dark at 30°C for 21 days. The procedure for observing the presence of sulfate-reducing bacteria is found in Method 2a.1 of Standard Methods (1976, p. 1001). If growth of sulfate-reducing bacteria does not occur in the control tubes, the entire test should be repeated with a fresh source of inoculum. If sulfate-reducer growth occurs in the controls, but does not occur in any of the test chemical treatment tubes, the test should be repeated using concentrations of the test chemical of 1.0, 0.1, 0.01, and 0.001 mg/l.

(2) *Calculations and Data Which Should be Recorded.* A detailed description of the test procedures should be provided including the preparation and handling of the test compound and the contenst of each bottle and tube. In addition, culture tubes which display evidence of sulfate-reducing bacteria (blackening of the medium) should be noted along with the day on which that evidence was first observed. The minimum inhibitory concentration of test substance should be recorded as greater than the highest test chemical concentration at which growth is observed.

(e) *References.*

Adams, M. E., and Postgate, J. R. 1960. On sporulation in sulphate-reducing bacteria. *J. Gen. Microbiol. 24:291-24.*

American Public Health Association. 1975. *Standard Methods for the Examination of Water and Waste Water* (14th Edition).

American Society for Testing and Materials. 1978. *Annual Book of Standards.* Part 31. Sulfate-reducing bacterial in water and water-formed deposits. ASTM. Philadelphia, PA. pp. 955-959.

Forbisher, M., R. D. Hinsdill, K. T. Crabtree, and C. R. Goodheart. 1974. Pages 674-676 *Fundamentals of Microbiology,* 9th ed. W. B. Saunders Co., Philadelphia.

Saleh, A. M., et. al. 1964. The effect of inhibitors on sulphate-reducing bacteria: A compilation. *J. Appl. Bacteriol.* 27:281293.

C-4 *Plant Effects Tests.* C-4.1 *General.* All organisms require energy to perform vital functions and use radiant energy of sunlight as the ultimate source of energy. Green plants use this energy directly through the process of photosynthesis when suitable inorganic carbon and nutrients are present. The sun's energy is converted into chemical energy which is stored in plants in the form of sugars, starches and other organic chemicals to be used by the plants themselves or by other organisms as energy sources. Photosynthesis is the source of virtually all atmospheric oxygen. Plants also synthesize vitamins, amino acids, and other metabolically active compounds essential to many organisms. In this context, the maintenance of the biosphere depends upon the normal functioning of green plants.

Data from the tests in this section are expected to provide preliminary indications of the effects of chemical substances on the following groups of plants: Blue-green algae, diatoms, green algae, monocotyledons, and dicotyledons.

Blue-green algae are one of two groups of organisms capable of converting atmospheric nitrogen into forms which can be utilized by all living organisms. Diatoms and unicellular green algae are responsible for most of the world's photosynthesis and are the primary food energy base for most organisms inhabiting aquatic environments. They are, therefore, necessary for all aquatic life and for human food taken from fresh water and marine environments (e.g., fish).

Monocotyledons and dicotyledons are the two major groups of terrestrial flowering plants. The most highly evolved and widely distributed plants, they are the source of most human food and fiber, as well as shelter and important medicinals. These groups of plants are recognized as major converters of radiant energy to chemical energy in terrestrial environments.

General criteria for selecting specific organisms for preliminary assessment data are given above in the Discussion of Ecological Effects Tests (section C-1). In addition, plants were considered for their importance as a direct source of food for humans, or for animals consumed by humans. While no battery of test organisms meet all criteria fully, we have selected organisms which, on the basis of the available scientific literature and expert advice, come closest to fulfilling as many criteria as possible.

Other groups, possibily important to ecosystems, were not included. Among these are red algae, brown algae, dinoflagellates, mosses, ferns and gymnosperms. Representatives of these groups are not included in these testing recommendations either because suitable tests are not available, or because these groups of plants are considered secondary in importance to the maintenance of environmental quality, or because they fail to adequately meet one or more of the other criteria.

C-4.2 *Test 1: Algal Inhibition.* (a) *Objectives.* Testing for inhibition or stimulation of the growth of algae indicates the extent to which a test chemical can affect primary producers in lakes, streams, estuaries and oceans. It can also generally indicate phytotoxicity or plant growth stimulation.

Substances which drastically inhibit growth at or near concentrations expected in the environment may reduce aquatic productivity. However, even those substances which inhibit algal growth only partially, or which stimulate growth, at or near concentrations expected in the environment might shift relative algal populations so that undesirable species could increase. In the latter case, it may be important for assessment of certain chemicals to include tests of the relative sensitivity of the major groups of algae: green algae, blue-green algae, and diatoms. If diatoms or green algae grow less in the presence of the chemical than blue-green algae, for example, a bloom of the less desirable blue-green species could develop. Further testing beyond these guidelines could be needed to test that hypothesis.

Substances which have no effect on algal growth at concentrations within several orders of magnitude of the levels expected in the environment would not be expected to harm the environment through effects on algae. Further testing would probably add little additional value for the assessment process.

(b) *Rationale.* Algae were selected to represent aquatic primary productivity because they constitute the major mechanism for fixation of energy in most aquatic locations. Techniques for culturing and measuring them are simpler and less expensive than for larger

plants or for attached organisms (e.g., periphyton).

The parameters recommended to measure potential effects on algae are inhibition of dry weight increase and changes in cell size. There are other potential effects which are not recommended. Lethality, for example, is commonly measured for other organisms, but it is difficult to determine for microscopic organisms and for nonmotile organisms. Inhibition of photosynthesis and/or respiration could be measured, but the balance between photosynthesis and respiration is accumulated as growth. In addition, growth represents the product which is important in the food chain and is therefore more directly relevant to assessment.

An alternative to measurement of dry weight that can be used is measurement by electronic particle counter (Miller, et al., 1978). This method is acceptable for assessment if accompanied by a calibration curve and conversion of data into dry weight equivalents. Dry weight equivalence is needed for comparing all data in assessment.

Uncertainties in using these data in assessment center upon whether the selected species are adequate indicators of the potential for stimulation or toxicity to non-selected algal species, whether benefits of algae to the food chain can be accurately predicted from changes in dry weight and cell size, and whether there are significant interactive effects (such as competition) which are affected at lower concentrations of the chemical substance than any individual species. Inadequacies of species selection result from having a poor data base on toxicity to algae, so relative sensitivity is not well known. The lack of indicators is also due to having no representatives of some major groups such as red algae, brown algae, and dinoflagellates.

Food and particle size are two factors most likely to affect the consumption of phytoplankton in food chains, although taste, texture and nutritional quality may sometimes prove significant. These are relatively unknown areas for planktivorous organisms, and no simple methodologies exist for their evaluation. Competition among algae also limits extrapolation from laboratory tests to field conditions. These areas, therefore, should receive major emphasis in future test development.

(c) *Test Description.* The inhibition or stimulation of algae by chemical substances is determined by inoculating an appropriate growth medium amended with various concentrations of test chemical. When this test is performed, the organisms are separately incubated under conditions favorable for growth for a stanard period of time. Algal growth occuring in the presence of the chemical compared to growth occuring in its absence would indicate the degree of inhibition or stimulation. In addition to observations on growth, observations on the potential for nitrogen fixation for *Anabaena flos-aquae* would be useful for assessment.

(d) *Methods*—(1) *Test details. Anabaena flos-aquae, Skeletonema costatum, Navicula seminulum* var. *hustedtii,* and/or *Selenastrum capricornutum* are grown separately under conditions favorable to the growth of each. When this test is performed, *A. flos-aquae* and *S. capricornutum* should be grown in a suboptimum freshwater medium at 24°C for 7 days (EPA, 1971). Artificial seawater with Na_2SiO_3 should be used as the medium for *S. costatum* (EPA, 1974, p. 10). For *N. seminulum* var. *hustedtii,* the standard medium should have 20 mg of Si/1 added as $Na_2SiO_3.5H_2O$ (Payne and Hall, 1977). Other cultural conditions for *N. seminulum* follow those given above for *A. flos-aquae* and *S. capricornutum* (EPA, 1971). The experimental design and procedures should determine the effects, if any, due to changes in inorganic carbon when the test chemical causes pH shifts. The light intensities given in the references should be used. For toxicity testing, a medium not containing chelating agents is desirable but no EDTA-free medium exists that is as widely accepted as these two media. For *S. costatum,* 24°C is a suitable temperature. The test details of Sikka and Butler (1977) should be used. Hattori (1962) describes the medium and culture conditions for testing the potential for nitrogen fixation.

Growth should be measured as dry weight increase (or by a method calibrated with dry weight increase) and by an indication of cell size. If an automatic particle counter is used, adequate disruption of cell clumps and filaments is necessary for valid results; this is particularly important for the filamentous alga, *A. flos-aquae* (Shiroyama, et al, 1975).

If measurement is by any technique other than dry weight determination, a calibration curve is useful.

The effect on nitrogen fixation in *A. flos-aquae* as measured by reduction of acetylene (Hardy, et al., 1973) contributes to an understanding of potential impact on the nitrogen cycle.

Testing at five or more concentrations, at least three of which inhibit growth by more than 20% and less than 95% of normal growth, and with at least one no effect concentration, permits extrapolation of results to inhibitions at any expected environmental concentration. These concentrations should be spread over the range as evenly as possible. Data at lower concentrations permit conclusions about the possibility of stimulation. More data are not useful for assessment if a substance is non-stimulatory and nontoxic at reasonably expected environmental concentrations.

(2) *Calculations and Data Which Should be Recorded.* The dry weight gain of the test algae obtained in the untreated controls should be included, along with gain in the various test concentrations. The 95% confidence limits should be calculated for each growth response. For each response, any changes in cell size should be included. For *Anabena flos-aquae,* changes in acetylene reduction will serve as an indicator of nitrogen fixation.

(e) *References.*

Eutrophication and Lake Restoration Branch. 1974. *Marine Algal Assay Procedure: Bottle Test.* Environmental Protection Agency, Corvallis, OR. 43 pp.

Hardy, R.W.F., et al. 1973. Applications of the acetylene-ethylene assay for measurement of nitrogen fixation. *Soil Bio. Biochem.* 5:47-81.

Hattori, A. 1962. Light induced reduction of nitrite and hydroxylamine in a blue-green alga, *Anabaena cylindrica. Plant Cell Physiol.* 3:355-369.

Miller, W. E., et al. 1978. *The Selenastrum capricornutum Printz Algal Assay Bottle Test.* Environmental Protection Agency, Corvallis, OR. EPA-600/9-78-018, 126 pp.

National Eutrophication Research Program. 1971. *Algal Assay Procedure: Bottle Test.* Environmental Protection Agency, Corvallis, OR. 82 pp.

Payne, A. G., and R. H. Hall. 1977. A method for measuring algal toxicity and its application to the safety assessment of new chemicals. *Proceedings of the Second Symposium of Algal Toxicity.* Cleveland, OH.

Shiroyama, T., et al. Comparison of the algal growth responses of *Selenastrum capricornutum* Printz and *Anabaena flos-aquea* (Lyngb.) De Brebisson in waters collected from Shagawa Lake, Mn. *Proceedings: Biostimulation and Nutrient Assessment Workshop,* September 10-12, 1975, University of Utah, Logan, PPWG, 168-1, pp. 127-148.

Sikka, H. C., and G. L. Butler. 1977. *Effects of Selected Waste Water Chlorination Products and Captan on Marine Algae.* U.S. EPA 600/3-77-029.

C-4.3 *Test 2: Lemna Inhibition.* (a) *Objectives.* Testing for inhibition of *Lemna* (duckweed) growth can serve as an indicator of the extent to which a chemical substance can interfere with aquatic higher plants. Substances which significantly inhibit the growth of *Lemna* at or near concentrations expected in the environment may be presumed hazardous to this group of organisms. Chemicals which inhibit *Lemna* growth only partially at or near concentrations expected in the environment may shift relative populations of macrophytes and algal species. Therefore, it may be important to include a comparison of the relative sensitivity of *Lemna* and algae. If *Lemna* is considerably less sensitive to a given test chemical than algae, an

extensive growth of macrophytes is a possibility. If data indicate the possibility of severe effects on macrophytes or excessive dominance of macrophytes over algae, more information would be needed. For example, testing the relative sensitivity of beneficial plants (pondweeds, saltmarsh grass) compared to undesirable plants (water hyacinth, watermilfoil) would reduce assessment uncertainties.

Substances which have no effect on *Lemna* at concentrations within several orders of magnitude of the levels expected in the environment, and to which other aquatic organisms (e.g. fish, invertebrates) are probably relatively insensitive, are considered safe for aquatic exposure.

(b) *Rationale. Lemna* was selected to represent aquatic macrophytes because it is well known genetically and physiologically and is one of the few aquatic macrophytes used extensively in culture. It is easy to culture and tests can be performed at less expense than would be possible with larger plants.

Aquatic macrophytes possess many of the developmental/structural characteristics unique to higher plants. Roots are particularly important in this regard because they are frequently more sensitive than other plant parts, and their inclusion among the measurements made on *Lemna* serves as an important indicator of potential toxicity. Unfortunately, roots may also be especially sensitive to such environmental variables as nutrients and temperature. For that reason, and because foliage may also be sensitive, it is important to hold cultural conditions constant during testing. The fact that *Lemna* is not completely typical of higher plants introduces an uncertainty into its use as a test organism. Further research is needed to ascertain that *Lemna* is an adequate indicator, or an alternative aquatic macrophyte should be found.

Of the two general approaches to culturing *Lemna*, the most commonly used is static (batch) culture in which nutrients and test substance are present at the beginning of the experiment and decline as the plant takes them up. A less commonly used technique is a flow-through system in which nutrients and test chemical are continuously replenished during the test (Walbridge, 1977). The static system is considered acceptable, though the flow-through system may be preferable because it maintains constant concentrations of test chemical and nutrients throughout the test.

Whichever system is used, response can be measured several ways. Since roots are generally most sensitive, a measure of their growth often indicates maximum sensitivity of the species. However, roots are less useful in assessment than measures more directly related to productivity and standing crop of plants in the ecosystem. For these two purposes, dry weight and frond number are commonly used. For preliminary assessment, data from either of these latter measurements are suitable. For a more complete hazard evaluation both sets of data would be useful.

There are uncertainties in the counting of fronds which could be avoided by measuring frond area as an indicator of size. Area is suitable for most assessment purposes, and could be included in addition to number of fronds.

The major uncertainty in the use of *Lemna* data in assessment lies in extrapolation to a wide variety of aquatic plants. No single species can fully represent the diverse life forms and habitats of plants which grow in water.

(c) *Test Description.* To determine inhibition of *Lemna minor* or *Lemna gibba* (duckweed) by a chemical, fronds should be placed on an appropriate growth medium amended with several concentrations of chemical and incubated under conditions favorable for growth for a standard period of time. The increase in fronds and dry weight should be measured, and other indications of phytotoxicity occurring in the presence of the chemical compared to that occurring in untreated controls observed.

(d) *Methods*—(1) *Test Details.* Data suitable for assessment can be obtained by growing *Lemna minor* or *L. gibba* on nutrient medium under simulated natural daylight (3000 lux) at 24° for seven days. Growth should be measured as an increase in frond number and root length, with dry weight determined at the end of each experiment (Hillman, 1959, 1961) and observations on necrosis and other effects made. Testing at five or more concentrations of test chemical with at least three inhibiting growth by more than 10% and less than 90% of normal and with at least one no-effect concentration permits extrapolation of results to most expected environmental concentrations. These concentrations should be spread over the range of partial inhibition as evenly as possible. Such data are not useful for assessment if a chemical is so slightly toxic that, at reasonably expected environmental concentrations, no detriment is conceivable.

(2) *Calculations and Data Which Should be Recorded.* Growth of untreated controls, growth with various concentrations of the test chemical, inhibition (or stimulation) with the test chemical compared to the untreated controls, and the mean 50 percent inhibitory concentration should be recorded. The 95% confidence limits and observations of abnormal growth or development should also be included. For each quantified parameter, frond numbers, root length and dry weight are the data useful in assessment. Sublethal effects, such as necrosis, discoloration, or altered morphology, should be recorded whenever observed.

(e) *References.*

Hillman, W. S. 1959. Experimental control of flowering in *Lemna*, II. Some effects of medium composition, chelating agents and high temperatures on flowering of *L. perpusilla* 6746. *Amer. J. Bot.* 45: 489-495.

Hillman, W. S. 1961. The *Lemnaceae*, or duckweeds. A review of the descriptive and experimental literature. *Botan. Review* 27: 221-287.

Walbridge, C. T. 1977. A Flow Through Testing Procedure with Duckweed (*Lemna minor* L.) EPA-600/3-77-108, 20 pp.

C-4.4 *Test 3: Seed Germination and Early Growth.* (a) *Objectives.* Assessment of potential ecological effects of phytotoxic chemicals needs to include an evaluation of possible impacts on terrestrial plants. While all terrestrial plants are of interest in assessment, angiosperms (flowering plants) are of particular concern since they constitute the dominant vegetation in many parts of the United States and are also the source of all major food crops.

These tests are designed to reveal possible adverse effects of chemicals on critical early stages in the life cycles of angiosperms. Chemical inhibition of seed germination or early seedling growth at concentrations which approach expected environmental levels would indicate a potential hazard. To assess further any chemical which causes a significant reduction in germination or seedling growth in any of the test species, additional data should include exposure data and:

(1) Additional seed germination and early seedling growth tests using other species of the same genus, related genera, and unrelated genera to determine if the effect is species specific.

(2) Observations of effects of the chemical over the entire life cycle of the affected species and of additional annual species to show whether the effect is restricted to germination and early stages of seedling growth.

If abnormalities are noted in other growth parameters (e.g., chlorosis, necrosis, abnormal leaf or stem shape), testing directed toward any oberved abnormalities would improve assessment.

Lack of inhibitory effects of a chemical in these preliminary tests does not necessarily mean that the chemical is without potential for causing damage to terrestrial plants, since the tests cover over a few species and only a small portion of their life cycles. If other tests in these Guidelines demonstate that a chemical is

biologically active or subject to high environmental release, more testing of potential effects on reproduction, such as flowering or seed formation, may be needed.

(b) *Rationale.* Chemical inhibition of any of the major physiological processes of higher plants (e.g., photosynthesis, respiration, mineral nutrient uptake, translocation) may interfere with normal growth and development. This, in turn, may cause reproductive failure, disruption of food webs, or decreased crop production. In some cases, chemical inhibition of higher plant growth may decrease vegetational ground cover, causing loss of topsoil through erosion, which, in turn, could cause further decreases in plant growth.

Results of seed germination and early seedling growth tests contribute to assessment because these are critical and easily measured stages in the growth of flowering plants (angiosperms). We recommend the six selected species because they are all either human foods or feeds for domesticated food animals, and represent plant families of ecological and/or economic significance. While more rapid procedures measure specific physiological processes, such as respiration and photosynthesis, we refrain from recommending these because of uncertainties in extrapolating from physiological processed to ecological effects.

Ideally, test results would permit an evaluation of effects of chemicals over the entire life cycle of the test organism. Restricting the test to the early stages of development cannot reveal the possible effects of chemicals on, for example, flower induction and subsequent stages leading to successful sexual reproduction. These processes are essential for plants to perform essential ecological functions and, in many cases, to produce food. Tests for effects of chemicals on these critical life cycle stages are not yet available as standardized methods.

Because early growth is rapid and depends upon a high level of metabolic activity, such growth could be singularly vulnerable to chemical inhibition. Additionally, the cuticle and other structures which protect plants by impeding penetration of chemicals are less well developed in young seedlings than in more mature plants, thus rendering early stages of growth most vulnerable to general inhibition.

(c) *Test Description.* These tests measure effects of chemicals on seed germination and on early stages of growth in seedlings of flowering plants. Percent germination of seeds, shoot height, shoot and root dry weight, and visible abnormalities are measured. Effects of chemicals on seed germination are measured after direct exposure of nongerminated seeds. Effects on seedling growth are measured following exposure of seedlings after seed germination.

All chemicals should be tested by the routes of exposure considered by the submitter as likely to be significant in the environment. If a major route of exposure will be through the roots, then the test chemical should be added to the nutrient medium with which plants are irrigated. Foliar application may be by dusting, or spraying with an appropriate carrier if necessary. if a carrier is used, a control should be included consisting of carrier without test chemical. Chemicals which are gases at environmental temperatures, or which volatize readily at environmental temperatures, are tested for their effects on early seedling growth by fumigation procedures, outlined in Rubenstein et al. (1974).

(d) *Procedures*—(1) *Test Details.* The following are recommended as the preferred species:

MONOCOTYLEDONS

Oats—*Avena sativa* L. 'Clintford'
Ryegrass—*Lolium perenne* L. 'Manhattan'
Corn—*Zea mays* L. 'Butter and sugar'

DICOTYLEDONS

Cucumber—*Cucumus sativus* L. 'Marketeer'
Bean—*Phaseolus vulgaris* L. 'Pinto'
Tomato—*Lycopersicum esculentum* Mill. 'Rutgers'

Pending completion by EPA of the development and validation of other seed germination and seedling development test protocols, the procedures used will be those in Rubenstein et al. (1975), pages 3-35 through 3-46 with the following modifications:

(A) Vermiculite for seedling growth tests should be prewashed with nutrient solution to minimize adsorption of the test chemical.

(B) Fresh weights need not be recorded.

(C) Seeds that have not been treated with pesticides or other chemicals should be used.

(D) For seedling growth tests, seeds should be germinated on sheets of high purity filter paper.

(E) For seedling growth, ED_{50} should be estimated for 50 per cent growth inhibition rather than for lethality.

(F) Seedlings showing any signs of bacterial or fungal infection, or of infestation by insects, during the three week culture period before treatment should be removed.

(G) Where fumigation is required to evaluate the chemical, procedures in Rubenstein et al. (1975), Section 3.14, pages 3-121 through 3-124, and section 1.3.4 should be used.

(2) *Calculations and Data Which Should be Recorded.* Measurements on seed germination, seedling height, and shoot and root dry weight with 95% confidence limits are useful for assessment. All observations of foliar lesions, chlorosis, necrosis, or growth abnormalities should be recorded. Also the results of germination and growth in the presence of test chemical should be calculated as a percentage of untreated controls, including the 95% confidence limits. For fumigation tests, the presence of lesions serves as an indicator of the potential for toxicity. The rationale for selection of test concentrations should be included.

(e) *References.*

Rubenstein, R., et al. 1975. *Test Methods for Assessing the Effects of Chemicals on Plants.* EPA 560/5-75-008.

C-5 *Animal Effects Tests.* C-5.1 *General.* The potential of a chemical to produce adverse ecological effects can be indicated by the results of preliminary testing of "representative" animals. Preliminary tests and test organisms should be selected on the basis of taxonomic, ecological, toxicological, and chemical exposure criteria. Test schemes should reflect those ecological hazards that a specific chemical substance may cause. Test responses—death, reproductive and/or behavioral dysfunction, and impairment of growth and development—are important factors for hazard assessment. Such responses indicate that the need for subsequent testing for effects at levels of ecological organization above the population level, i.e., the community or ecosystem levels.

The tests recommended below represent the current state of methodology for preliminary assessment of ecological hazard. They will be subject to modification or replacement as test methods and assessment strategies are further developed. Additional tests, both general and specific, are available and their use is suggested if preliminary testing indicates a more detailed assessment is necessary.

C-5.2 *Test 1: Acute Toxicity to Aquatic Invertebrates.* (a) *Objectives.* Acute toxicity of a chemical substance to invertebrates is an important factor in preliminary assessment of impact on ecosystems. Invertebrates have broad ecological roles and show various sensitivities to chemicals. Therefore, recommended tests include a variety of invertebrates from various phyla, habitats and trophic levels.

The physical/chemical characteristics of a chemical substance provide important indications about the most appropriate species to use in testing. For example, species living in or consuming sediment are most appropriate for testing chemicals with high affinities for sediment. On the other hand, planktonic or epifaunal invertebrates are more appropriate for substances expected to be present in the water column.

An invertebrate acute toxicity test is potentially useful in evaluating effects of a chemical substance entering natu-

ral waters in either a dissolved or suspended form. Observations made during an acute invertebrate test also provide guidance for the approximate concentrations of test chemicals to be used in a chronic study. For example, a *Daphnia* acute test could be performed before a chronic *Daphnia* test in order to estimate appropriate test concentrations.

(b) *Rationale.* Of the different methods of measuring acute toxicity of chemical substances to aquatic invertebrates, the one recommended (EPA 1975) is standardized and has been extensively used. This test has provided data on a variety of animals and chemicals on which comparisons can be based during risk assessments. The American Society for Testing and Materials and other organizations are expected to publish updated acute methods in the near future. These may supplement or supersede the test given below.

(c) *Test Description.* An EC_{50} determination is carried out using young or immature aquatic invertebrates which are exposed to a chemical substance for 48 or 96 hours. Several concentrations of the chemical substance are used. Observations are made of the number of animals affected and/or the extent of the effect at prescribed intervals. Data are then analyzed to determine the concentration of the chemical substance that effects 50% of the test animal population during the exposure.

(d) *Methods*—(1) *Test Details.* Tests should be performed on a sensitive life stage of the test organisms according to EPA (1975). Useful background information for the conduct of the test may be found in Standard Methods (1975). A list of species that have been used in acute tests, and the preferred test temperature for each is given in Table 1. The appropriate duration of exposure for each organism is given in the main reference (EPA, 1975).

(2) *Calculations and Data Which Should be Reported.* Results should include 24-, 48-, and 96-hour EC_{50} or LC_{50} values and their 95% confidence limits, and the percent of organisms that died or showed the effect in the control treatment. Useful information would include the pH, concentration of the chemical substance and impurities (as practicable) and the oxygen concentration in the aquaria at 0-, 48-, and 96- hr. Loading (grams of organisms per liter), information on behavorial or physiological abnormalities and unusual occurences affecting test conditions should also be reported.

(e) *References.*

Environmental Protection Agency. 1975. *Methods for Acute Toxicity Tests with Fish, Macroinvertebrates and Amphibians.* The Committee on Methods for Toxicity Tests with Aquatic Organisms. Ecological Research Series. EPA-660/3-75-009.

Standard Methods for the Examination of Water and Wastewater. 1975. American Public Health Association. (14th ed.) APHA, New York. 762 pp.

TABLE 1.—*List of Species for Acute Tests*

Species	Test temperature (C)*
Marine and estuarine invertebrates:	
Copepods:	
Acartia tonsa	22
Acartia clausi	12
Shrimp: *Penaeus setiferus, P. duorarum, P. aztecus*	22
Grass shrimp: *Palaemonetes pugio, P. intermedius, P. vulgaris*	22, 22
Sand shrimp: *Crangon septemspinosa*	17
Shrimp: *Pandalus jordani, P. danae*	12
Bay shrimp: *Crangon nigricauda*	17
Mysid shrimp: *8Mysidopsis bahia*	22
Blue crab: *Callinectes sapidus*	22
Shore crab: *Hemigrapsus* sp., *Pachygrapsus* sp.	12
Green crab: *Carcinus maenas*	22
Fiddler crab: *Uca* sp	22
Oyster: *Crassostrea virginica, C. gigas.*	22
Polychaetes: *Capitella capitata*	22
Freshwater invertebrates:	
Daphnids: *Daphnia magna, D. pulex, D. pulicaria*	20
Amphipods: *Gammarus lacustris, G. fasciatus,* or G., *pseudolimnaeus*	17, 17
Crayfish: *Oronectes* sp., *Cambarus* sp., *Procambarus* sp., or *Pacifastacus leniusculus*	17, 22, 17
Stoneflies: *Pteronarcys* sp.	12
Mayflies: *Baetis* sp. or *Ephemerella* sp.	17
Mayflies: *Hexagenia limbata* or *H. bilinata*	22
Midges: *Chironomus* sp	22
Snails: *Physa integra, P. heterostropha, Amnicola limosa*	22
Planaria: *Dugesia tigrina*	22

* Freshwater amphipods, daphnids, and midge larvae should be cultured and tested at the test temperature. Other invertebrates should be held and tested within 5° C of the temperature of the water from which they were obtained. They should be tested at the recommended test temperature if it is within this range; otherwise they should be tested at the temperature from the series 7, 12, 17, 22, and 27° C that is closest to the recommended test temperature and is within the allowed range.

C-5.3 *Test 2: Acute Toxicity to Fish.*

(a) *Objectives.* Acute toxicity of a chemical substance to fish is an important factor in assessing its potential impact on aquatic ecosystems.

An acute toxicity test on fish is appropriate in preliminary assessment of potential effects from dissolved or suspended chemical substances that are expected to enter natural waters. In addition, acute test results can be used for determining test concentrations for chronic, subchronic and bioconcentration tests for fish.

(b) *Rationale.* EPA's currently preferred methods for acute testing of freshwater and marine fishes (EPA 1975) will be used for this test. The American Society for Testing and Materials and other organizations are expected to publish updated acute test methods in the near future and these may supplement or supersede EPA (1975).

EPA would prefer that manufacturers not conduct acute tests on the goldfish (*Carassius auratus*) although it is listed in EPA (1975), because the goldfish is less sensitive to certain classes of compounds than other species. In addition, fathead minnows (*Pimephales promelas*) should normally not be the only species tested, even though they are a good species for chronic exposure tests, because, like the goldfish, they are less sensitive to certain classes of compounds than other commonly tested species. At certain times of the year, however, other species of proper size and age may not be available, leaving fathead minnows, which are easily reared year-round in the laboratory, as the species of choice.

Rainbow trout (*Salmo gairdneri*) and bluegill sunfish (*Lepomis macrochirus*) are suggested as standard test species. These two fish, one a cold water species and the other a warm water species, have generally been the most sensitive to most previously tested chemical substances. The choice of species may depend upon the geographical area of expected chemical release and available testing facilities.

If salt water exposure is probable, testing a marine species is advised. Even though marine species generally are no more sensitive than fresh water species, toxic effects can be significantly modified by water chemistry.

(c) *Test Description.* An LC_{50} determination is carried out using young fish exposed to a chemical substance for 96 hours. Several concentrations of a chemical substance are used and the number of fish killed are observed at prescribed intervals. Data are analyzed to determine the approximate concentration of chemical substance that will, on the average, decrease the test fish population by 50% in 96 hours.

(d) *Methods*—(1) *Test details.* EPA (1975) gives adequate procedures and examples of acceptable test species. Of the species listed in this reference, only goldfish (*Carassius auratus*) is not recommended. For the sake of uniformity in data, the preferred test species is either rainbow trout (*Salmo gairdneri*) or bluegill sunfish (*Lepomis macrochirus*).

(2) *Calculations and Data Which Should be Recorded.*

Results should include 24-, 48-, and 96-hour LC_{50} values and their 95% confidence limits, the percent of organisms that died in the control treatment, and the loading (grams of organisms per liter) in each treatment. Other useful information would include pH, concentration of test chemical and impurities (as practicable), and oxygen concentration in the aquaria at 0-, 48-, and 96-hours. Observations of behavioral and physiological abnormalities and unusual occurrences af-

fecting test conditions should also be reported.

(e) *References.*

Environmental Protection Agency. 1975. *Methods for Acute Toxicity Tests with Fish, Macroinvertebrates and Amphibians.* The Committee on Methods for Toxicity Tests with Aquatic Organisms. Ecological Research Series EPA-660/3-75-009.

C-5.4 *Test 3: Quail Dietary Test.* (a) *Objectives.* The objective of a quail dietary test is to give preliminary indication of possible effects of a chemical substance on terrestrial birds. This test is designed to determine the concentration of a substance in food that will be lethal to 50 percent of a test population as well as to observe behavioral, neurological, and physiological effects. The test is appropriate for a chemical which might be found in or on terrestrial bird food.

(b) *Rationale.* The recommended method (EPA, 1975) is the most complete and generally applicable method for performing a quail dietary test. The bobwhite quail (*Colinus virginianus*) is an appropriate test species since it is native to the United States, a desirable sports species, easily and economically reared, widely available, and generally more sensitive to many hazardous chemicals than other common test species.

(c) *Test Description.* An avian five-day LC_{50} is performed by feeding birds food containing a known concentration of test chemical substance for five days. Surviving birds are fed uncontaminated food for another three days. The main purpose of the test is to estimate the concentration of substance that will kill one-half of the birds fed the substance for five days. During both feeding periods, birds are observed for possible sublethal toxic effects.

(d) *Methods*—(1) *Test Details.* The preferred test species is bobwhite quail (*C. virginianus*). A suggested procedure is presented in EPA (1975).

(2) *Calculations and Data Which Should be Recorded.* It is suggested that the calculated LC_{50}, the 95% confidence interval, and methods used be recorded. In cases where the LC_{50} exceeds 5000 ppm, neither calculated median response level nor 95% confidence limits are necessary. Sample size at this dose should be 10 or greater. If any birds die at the lowest dose tested, sequentially lower doses should be given to produce a dose-response series that includes at least one level in which no mortality occurs. The slope of the dose-response relationship should be estimated. However, tabulation of response data is sufficient when the method does not allow calculation of a slope. An estimated nondiscernible effect level would greatly help the assessment process. A description of the nature, time of occurrence, severity, and duration of any observed toxic effect is suggested, including death, behavioral or physiological abnormalities and gross pathological abnormalities. The total volume of material administered and concentrations of chemical substance consumed in the feed during the 5-day exposure period should be recorded.

(e) *References.*

Environmental Protection Agency 1975. Office of Pesticide Programs, FIFRA Registration Guidelines Subpart E, Hazard Evaluation: Wildlife and Aquatic Organisms. FEDERAL REGISTER 40 (123): 26915.

C-5.5 *Terrestrial Mammals.* (a) *Rationale for Omission of Tests.* Wild terrestrial mammals are omitted from the recommended preliminary tests for ecological effects, since EPA believes the acute health effects tests will provide a preliminary estimate of acute hazard to terrestrial mammals. A review of the published comparative toxicology data (Tucker and Crabtree, 1970; Fairchild, 1977; Office of Science and Technology, 1971) supports this assumption, showing that for most compounds, common laboratory species (rats, mice) are equally or more sensitive than mule deer, wild mice, or European ferrets.

Many other responses of wild terrestrial mammals to toxicants (e.g. reproduction) cannot be measured by tests using laboratory mammals. EPA may recommend additional testing for these responses in wild mammals at a future date.

(b) *References.*

Fairchild, E. T. 1977. *Agriculture Chemicals and Pesticides: A subfile of the NIOSH Registry of Toxic Effects of Chemical Substances.* U.S. Department of Health, Education, and Welfare.

Office of Science and Technology. 1971. *Ecological Effects of Pesticides on Non-Target Species.* Executive Office of the President.

Tucker, R. K. and D. Crabtree. 1970. *Handbook of Toxicity of Pesticides to Wildlife.* Bureau of Sport Fisheries and Wildlife. Denver Wildlife Research Center Res. Publ. No. 84.

C-5.6 *Test 5: Daphnia Life Cycle.* (a) *Objectives.* Aquatic invertebrates are the most common food chain links between phytoplankton and desirable species of fish and shellfish. The extent to which chemical substances affect reproduction and growth of aquatic invertebrates is important since healthy stocks of fish and shellfish are dependent on adequate sources of food. This test is applicable to new chemicals that are soluble or suspendable in water, and are predicted to enter natural freshwater systems.

(b) *Rationale.* Few tests have been developed and validated for invertebrates which cover the entire life cycle. A life cycle test is desired for assessment because it would give a better estimate of total hazard than, for example, an acute toxicity test. One of the most widely performed and economical life cycle test uses *Daphnia*, a freshwater zooplankton. *Daphnia* have a planktonic existence, short life cycle, and can be easily cultured. They have been widely used in toxicological testing, and are sensitive to toxicants. Although no invertebrate life cycle tests have been completely standardized, the *Daphnia* life cycle test has been used extensively by many researchers. Some problems exist for determining the best methods for toxicological studies and for culture. However, until better test systems are developed, *Daphnia* life cycle tests will provide the best data for evaluating effects of chemicals on reproduction and longevity of freshwater zooplankton. In addition, when a population of *Daphnia* are healthy and growing, individuals reproduce parthenogenically. This may present some problems in drawing conclusions about organisms which do not reproduce in this manner.

(c) *Test Description.* Reproduction and life-cycle tests on *Daphnia* begin with newborn daphnids, which are exposed to a chemical substance in culture for approximately three or four weeks. Reproductive impact of the chemical substance is evaluated by comparing the number of young produced by the organisms exposed to a chemical substance with the number produced by controls. Chronic lethal effects are evaluated by observing survival of the daphnids initially exposed throughout their life cycle.

(d) *Methods*—(1) *Test details.* Testing conditions can vary, but a satisfactory test should insure that the control *Daphnia* are healthy. Generally, more than 80% of a healthy control *Daphnia* population will survive 28 days and produce more than 100 young each during that period. To be useful, a test should include concentrations of test chemical that show no effect on reproduction as well as levels with a statistically significant effect upon reproduction. These concentrations should be within tenfold of each other.

No experimental design can be recommended, at this time, but the test should meet the standard for longevity and reproduction stated above. The literature shows no clear consensus for a particular food type, for *Daphnia pulex* or *Daphnia magna*, or for flow-through exposure rather than renewal. Published protocols available for *Daphnia* life cycle testing (Standard Methods, 1976; Beisinger, 1975; Winner, 1976) are not standardized or validated with respect to number of animals used, duration of test, water hardness and quality, photoperiod,

food, performance of control animals, temperature, statistical analysis and presentation of data, number of animals per test chamber, volume of test chambers, or when samples should be taken for determining chemical concentration. Most of these issues are being addressed by two scientific groups. The American Society for Testing and Materials (Subcommittee on Safety to Man and the Environment, Committee on Pesticides) and the Interagency Regulatory Liaison Group are preparing standard methods. Methods being developed by these groups are improved over those currently available. Most recent drafts or published protocols from these groups offer the most valuable guidelines for a *Daphnia* life cycle test.

(2) *Calculations and Data Which Should be Recorded.* Useful information would include the initial loading (grams of organisms per liter), percentage survival and daily production of young for each treatment and control, general observations of other effects or symptoms, and unusual occurrences affecting test conditions. For flow-through tests, a description of the toxicant delivery system and flow rate as average volume of test solution passing through each test chamber in 24 hours would be helpful.

(e) *References.*

Standard Methods for the Examination of Water and Wastewater. 1976. 14th ed. American Public Health Association. New York, p. 762.

Biesinger, K. E. 1975. Tentative procedure for *Daphnia magna* chronic tests in a standing and flowing system. FEDERAL REGISTER 40(123):26902-26903.

Winner, R. W. 1976. *Toxicity of Copper to Daphnids in Reconstituted and Natural Waters.* U.S. Environmental Protection Agency, EPA-600/3-76-051.

C-5.7. *Test 6: Mysidopsis bahia Life Cycle.* (a) *Objectives.* Reproduction and growth of invertebrates are important factors when evaluating adverse effects of chemical substances that will enter marine or estuarine environments. For example, Mysid shrimp (*Mysidopsis bahia*) represent a link between plankton on which they feed and fish which feed on them. The objective of this test is to give a preliminary indication of potential effects of a chemical substance on an important link in marine food chains.

(b) *Rationale. Mysidopsis bahia* is an excellent species for life cycle test for marine invertebrates due to its sensitivity to known toxic chemicals, ease of culturing, short life cycle, and importance in near-shore marine food webs. The combination of a well designed test methodology and the desirable qualities of *M. bahia* are unique at this time. No other life cycle test on marine invertebrates offers the same advantages.

(c) *Test Description.* Young *M. bahia*, less than 24 hours old, are exposed to various concentrations of a chemical substance. Survival and production of young are monitored daily for 28 days. The impact on the shrimp is determined by comparing reproduction and mortality of animals exposed to a chemical substance with those of controls.

(d) *Methods*—(1) *Test Details.* Nimmo, et al (1976) and Nimmo, et al (1978) give details for culturing and performing a life cycle test for *M. bahia.*

(2) *Calculations and Data which Should be Recorded.* The loading, percentage survival, and production of young in each treatment should be recorded, along with a summary of general observation of other effects or symptoms, and unusual occurrences affecting test conditions. For flow-through tests, a description of the chemical delivery system and flow rate as an average volume passing through each test chamber in 24 hours would be useful.

(e) *References.*

Nimmo, D. R., et al. 1976. *Aquatic Toxicity and Hazard Evaluation.* F. L. Mayer and J. L. Hamelink, eds. ASTM 635. p. 109-126.

Nimmo, D. R., et al. 1978. *Bioassay Procedures for the Ocean Disposal Permit Program.* EPA-600/9-78-010. pp. 59-60, and 64-68.

C-5.8. *Test 7: Fish Embryo Juvenile Test.* (a) *Objectives.* The objective of this test is to give preliminary indication of potential effects of a chemical on fish. Chemical substances can have significant chronic effects on individual fish at concentrations 2 to 500 times lower than LC_{50} values. When long term exposure is probable, data on chronic effects contribute to assessment. Any chemical substance, whether dissolved or suspended, predicted to continously enter natural waters is a prime candidate for chronic testing. If the chemical will primarily enter a freshwater system, freshwater species are most appropriate. Similarly, if an exposure is mainly marine or estuarine, test species from those habitats are the most appropriate.

(b) *Rationale.* A fish embryo-juvenile test usually provides data indicative of a chronic study. The test exposes early life stages of the fish, which are usually the most sensitive part of the life cycle of a fish. Differences in sensitivities between a chronic and embryo-juvenile test are generally small or negligible, while differences in cost are great. The embryo-juvenile test is usually an excellent, cost effective substitute for a chronic fish study.

(c) *Test Description.* In an embryo-juvenile test, fish eggs and fry hatched from these eggs are exposed to a chemical at several concentrations for a few weeks. Effects on hatchability of eggs, and growth and survival of fry are determined by comparing responses at each concentration with the control.

(d) *Methods*—(1) *Test Details.* Acceptable methods may be found in Allison and Hermanutz (1977), Eaton et al. (1978), Hansen et al. (1978), and Sauter et al. (1976). Some of these references are for the life cycle or partial life cycle tests. Duration of these tests may be modified to include only the embryo-juvenile portion of the life-cycle (e.g., for sheepshead minnows, 28 days).

(2) *Calculations and Data Which Should be Recorded.* Percent hatch, percent survival, and growth as a percentage of control fish growth along with 95% confidence limits should be recorded for each treatment and control. Other useful information includes general observations of any behavioral or physical abnormalities, the loading and unusual occurrences affecting test conditions. For flow-through systems, a description of the test chemical delivery system and flow rate as average volume of test solution passing through each test chamber in 24 hours should be recorded.

(e) *References.*

Allison, D. T. and R. O. Hemanutz. 1977. *Toxicity of Diazinon to Brook Trout and Fathead Minnows.* U.S. Environmental Protection Agency, EPA Series 600/3-77-060.

Eaton, J. G., J. M. McKim and G. W. Holcombe. 1978. Metal toxicity to embryos and larvae of seven freshwater fish species. I. Cadmium. *Bull. Environ. Contam. Toxicol.* 19:95-103.

Hansen, D. J., et al. 1978. Life cycle toxicity test using sheepshead minnows (*Cyprinodon variegatus*). pp. 109-117. In *Bioassay Procedures for the Ocean Disposal Permit Program.* U.S. Environmental Protection Agency, EPA-600/9-78-010.

Sauter, S., et al. 1976. *Effects of Exposure to Heavy Metals on Selected Freshwater Fish.* EPA Ecological Research Series EPA-600/3-76-105.

C-5.9 *Test 8: Fish Bioconcentration.* (a) *Objectives.* Bioconcentration, the uptake of a compound from water into living tissue, affects the movement, distribution and toxicity of chemical substances in the environment. A substances that bioconcentrates may affect life far removed from the initial points of environmental release and may alter ecological processes at concentrations much lower than predicted from acute and subacute results. Bioconcentration is the first step in the process of food chain biomagnification; therefore, substances that bioconcentrate should also be evaluated for their effects on organisms other than fish.

Results of bioconcentration studies are useful in assessing risk to the environment especially when the substance is highly lipid soluble (e.g., octanol/water partition coefficient is

greater than 1000), poorly soluble in water (e.g., water solubility less than 0.9×10^{-3} molar at 20°C), and does not undergo rapid chemical or biological transformation. At this time, a persistence standard, i.e., the concentration below which a chemical poses only a minimal hazard to the environment, is not available. Such a standard would need to reflect the local variability in the chemical and biotic characteristics of aquatic environments.

(b) *Rationale.* Since a standardized bioconcentration test is not currently available, the most frequently used method for measuring bioconcentration is recommended. This procedure is based on a steady state approach. At this time, there is insufficient data available to conclude that any other approach (e.g. kinetic approach) is superior.

Since adsorption of hydrophobic chemicals is a physical process that should not vary significantly between organisms, the choice of test organism, i.e., fish, is based on sampling convenience, ease of culture and handling.

(c) *Test Description.* Fish are exposed to the chemical substance in water for 28 days or until their tissue concentration reaches steady state. After steady state or 28 days, fish are placed in uncontaminated water for 7 days. During the exposure (1–28 days or steady-state) and depuration (1–7 days) periods, fish are sacrificed periodically and the concentration of chemical substance in their tissues is measured. The bioconcentration factor, the relative uptake rate, and the depuration rate constants are estimated from these data.

(d) *Methods*—(1) *Test Details.* The most commonly tested species are fathead minnow, *Pimephales promelas*, and bluegill sunfish, *Lepomis macrochirus*. Examples of other acceptable test species and handling, holding, and acclimation procedures are given in EPA (1975).

The exposure should be conducted in 60 liters or more of water in a glass aquarium. The chemical should be delivered with a conventional Mount-Brungs diluter (Mount and Brungs 1967), modified to give only one concentration of chemical, or a metering pump with diluent water pump. Both delivery systems discharge directly into the treated aquarium. Diluent water should be delivered at a rate sufficient to maintain the oxygen concentration greater than 60% of saturation. The final concentration of the test chemical should be $\frac{1}{10}$ to $\frac{1}{100}$ of the 96 hour LC_{50}, or the highest concentration not having a toxic effect during the test. No observable toxic effects should be evident in test animals at any time during the test. Water temperature should be 22±1°C, and photoperiod should be $\frac{12}{12}$ hours.

The test substance should be added to the dilution water without use of any solvents or carriers other than water, if possible. If carriers or solvents other than water are necessary, they should be kept to a minimum. Hydrochloric acid may help prepare aqueous stock solutions, but it can affect the pH of the test solutions appreciably. Dimethylformamide, ethanol, methanol, and triethylene glycol are recommended for use in preparing stock solutions of water insoluble chemicals. The solubility of the test chemical in the stock solution should be determined. If a carrier is used, the experimental design should contain appropriate controls to determine any carrier effects on the results.

One day prior to testing, 80 acclimated and sexually immature fish of uniform size should be placed in a control tank and the diluent system for the treated aquarium started. Fish should be large enough for ease of sample preparation, but should not mature sexually during the test because mature females often accumulate more test chemical than males. After verification of the desired concentration of test chemical in the treated tank, 65 of the fish should be transfered to the test tank and 15 fish left in the control tank. Five control fish are analyzed on day one and the last day of exposure and at the end of the test. The fish should be fed throughout the test; however, feeding on sampling days should follow sampling of the fish.

The concentration of the chemical in water should be determined daily by analytical methods that yield greater than 90% recovery of the test chemical. To find the degree of bioconcentration of the test chemical, five fish should be removed after 1, 2, 3, 4, 7, 14, 21, and 28 days of exposure and the test chemical concentration and sex (if obvious) of each whole fish determined. Exposure can be terminated early if the concentration of test chemical in fish reaches steady state. After steady state or 28 days, the remaining fish should be placed in an aquarium containing water free of test chemical. This begins the depuration phase. Five fish should be removed 1, 2, 4 and 7 days later and the test chemical concentration and sex (if obvious) for each fish determined. These sampling days and fish numbers are minimal; additional and more frequent sampling is desirable. Analytical methods should recover greater than 90% of the chemical from tissue, as demonstrated by recovery studies. Flow-through waste water should be treated with particulate filters and activated charcoal or other suitable means to remove the test chemical, impurities or other degradation products before discharging the water.

The mean concentration of chemical in water should be recorded each day that fish are collected, and the bioconcentration factor calculated by dividing the concentration in tissue by the average measured concentration in water up to and including the day sampled. Bioconcentration factors vs. time should be plotted to determine if a steady-state was reached, and if so, the steady state value is recorded as the bioconcentration factor. If steady-state is not reached, the data should be analyzed using a curve-fitting technique to estimate the steady-state bioconcentration factor.

(2) *Calculations and Data Which Should be Recorded.* The bioconcentration factor, the uptake rate constant, and depuration rate constant should be calculated for the test chemical and significant impurities, depending on the quality of the data. Other useful information includes the mean (±SE) concentration of the test chemical and significant impurities in both tissue and water, for each sample day, the concentration of any solvents used in preparing test solutions, behavioral and physiological abnormalities observed and unusual occurrences affecting test conditions.

(e) *References.*

Environmental Protection Agency. 1975. *Methods for Acute Toxicity Tests with Fish, Macroinvertebrates, and Amphibians.* The Committee on Methods for Toxicity Tests with Aquatic Organisms. Ecological Research Series EPA-660/3-75-009.

Mount, D. I., and W. A. Brungs. 1967. A simplified dosing apparatus for fish toxicological studies. *Water Res.* 1:2129.

[FR Doc. 79-6561 Filed 3-15-79; 8:45 am]

federal register

FRIDAY, MARCH 16, 1979

PART V



DEPARTMENT OF LABOR

Employment Standards Administration

■

MINIMUM WAGES FOR FEDERAL AND FEDERALLY ASSISTED CONSTRUCTION

General Wage Determination Decisions

[4510-27-M]

DEPARTMENT OF LABOR

Employment Standards Administration, Wage and Hour Division

MINIMUM WAGES FOR FEDERAL AND FEDERALLY ASSISTED CONSTRUCTION

General Wage Determination Decisions

General wage determination decisions of the Secretary of Labor specify, in accordance with applicable law and on the basis of information available to the Department of Labor from its study of local wage conditions and from other sources, the basic hourly wage rates and fringe benefit payments which are determined to be prevailing for the described classes of laborers and mechanics employed in construction activity of the character and in the localities specified therein.

The determinations in these decisions of such prevailing rates and fringe benefits have been made by authority of the Secretary of Labor pursuant to the provisions of the Davis-Bacon Act of March 3, 1931, as amended (46 Stat. 1494, as amended, 40 U.S.C. 276a) and of other Federal statutes referred to in 29 CFR 1.1 (including the statutes listed at 36 FR 306 following Secretary of Labor's order No. 24-70) containing provisions for the payment of wages which are dependent upon determination by the Secretary of Labor under the Davis-Bacon Act; and pursuant to the provisions of Part 1 of Subtitle A of Title 29 of Code of Federal Regulations, Procedure for Predetermination of Wage Rates (37 FR 21138) and of Secretary of Labor's Orders 12-71 and 15-71 (36 FR 8755, 8756). The prevailing rates and fringe benefits determined in these decisions shall, in accordance with the provisions of the foregoing statutes, constitute the minimum wages payable on Federal and federally assisted construction projects to laborers and mechanics of the specified classes engaged on contract work of the character and in the localities described therein.

Good cause is hereby found for not utilizing notice and public procedure thereon prior to the issuance of these determinations as prescribed in 5 U.S.C. 553 and not providing for delay in effective date as prescribed in that section, because the necessity to issue construction industry wage determination frequently and in large volume causes procedures to be impractical and contrary to the public interest.

General Wage Determination Decisions are effective from their date of publication in the FEDERAL REGISTER without limitation as to time and are to be used in accordance with the provisions of 29 CFR Parts 1 and 5. Accordingly, the applicable decision together with any modifications issued subsequent to its publication date shall be made a part of every contract for performance of the described work within the geographic area indicated as required by an applicable Federal prevailing wage law and 29 CFR, Part 5. The wage rates contained therein shall be the minimum paid under such contract by contractors and subcontractors on the work.

MODIFICATIONS AND SUPERSEDEAS DECISIONS TO GENERAL WAGE DETERMINATION DECISIONS

Modifications and supersedeas decisions to general wage determination decisions are based upon information obtained concerning changes in prevailing hourly wage rates and fringe benefit payments since the decisions were issued.

The determinations of prevailing rates and fringe benefits made in the modifications and supersedeas decisions have been made by authority of the Secretary of Labor pursuant to the provisions of the Davis-Bacon Act of March 3, 1931, as amended (46 Stat. 1494, as amended, 40 U.S.C. 276a) and of other Federal statutes referred to in 29 CFR 1.1 (including the statutes listed at 36 FR 306 following Secretary of Labor's order No. 224-70) containing provisions for the payment of wages which are dependent upon determination by the Secretary of Labor under the Davis-Bacon Act; and pursuant to the provisions of part 1 of subtitle A of title 29 of Code of Federal Regulations, Procedure for Predetermination of Wage Rates (37 FR 21138) and of Secretary of Labor's orders 13-71 and 15-71 (36 FR 8755, 8756). The prevailing rates and fringe benefits determined in foregoing general wage determination decisions, as hereby modified, and/or superseded shall, in accordance with the provisions of the foregoing statutes, constitute the minimum wages payable on Federal and federally assisted construction projects to laborers and mechanics of the specified classes engaged in contract work of the character and in the localities described therein.

Modifications and supersedeas decisions are effective from their date of publication in the FEDERAL REGISTER without limitation as to time and are to be used in accordance with the provisions of 29 CFR Parts 1 and 5.

Any person, organization, or governmental agency having an interest in the wages determined as prevailing is encouraged to submit wage rate information for consideration by the Department. Further information and self-explanatory forms for the purpose of submitting this data may be obtained by writing to the U.S. Department of Labor, Employment Standards Administration, Office of Government Contract Wage Standards, Division of Wage Determinations, Washington, D.C. 20210. The cause for not utilizing the rulemaking procedures prescribed in 5 U.S.C. 553 has been set forth in the original General Wage Determination Decision.

NEW GENERAL WAGE DETERMINATION DECISIONS

South Carolina.—SC78-1048.

MODIFICATIONS TO GENERAL WAGE DETERMINATION DECISIONS

The numbers of the decisions being modified and their dates of publication in the FEDERAL REGISTER are listed with each State.

Alaska:	
AK79-5105	Feb. 9, 1979.
Arkansas:	
AR79-4025	Feb. 2, 1979.
California:	
CA78-5107	July 7, 1978.
CA78-5123	Aug. 18, 1978.
Florida:	
FL76-1021	Jan. 30, 1976.
FL78-1065	Aug. 11, 1978.
FL78-1070	Aug. 25, 1978.
Illinois:	
IL78-2117	Nov. 13, 1978.
IL78-2122	Oct. 20, 1978.
IL78-2128	Oct. 27, 1978.
Iowa:	
IA78-4109; IA78-4112	Nov. 24, 1978.
Montana:	
MT79-5101	Feb. 9, 1979.
Nevada:	
NV78-5124	Sept. 15, 1978.
North Dakota:	
ND78-5113	July 21, 1978.
Pennsylvania:	
PA78-3014	Mar. 24, 1978.
PA78-3016	Apr. 14, 1978.
PA78-3037	Apr. 21, 1978.
PA78-3043	May 12, 1978.
South Carolina:	
SC78-1040	Apr. 14, 1978.
SC78-1085	Sept. 29, 1978.
Texas:	
TX78-4086	Aug. 25, 1978.
TX78-4090; TX78-4091; TX78-4092	Sept. 15, 1978.
TX78-4114	Oct. 20, 1978.
TX78-4115	Dec. 1, 1978.
TX78-4003; TX79-4004; TX79-4005; TX79-4008; TX78-4009; TX79-4010; TX79-4011	Jan. 5, 1979.
West Virginia:	
WV78-3018	June 9, 1978.
Wisconsin:	
WI78-2108; WI78-2110; WI78-2116	Oct. 20, 1978.

SUPERSEDEAS DECISIONS TO GENERAL WAGE DETERMINATION DECISIONS

The numbers of the decisions being superseded and their dates of publication in the FEDERAL REGISTER are listed with each State. Supersedeas Decision numbers are in parentheses following the numbers of the decisions being superseded.

Alabama:	
AL78-1095 (AL79-1046)	Dec. 1, 1978.
Arizona:	
AZ78-5115 (AZ79-5110)	July 28, 1978.
Guam:	
GU78-5127 (GU79-5111)	Sept. 15, 1978.
Massachusetts:	
MA78-2082 (MA79-2008)	Sept. 22, 1978.
North Carolina:	
NC76-1095 (NC79-1027)	Sept. 3, 1976.
Pennsylvania:	
PA77-3126 (PA79-3005)	Sept. 9, 1977.
PA77-3129 (PA79-3004)	Sept. 16, 1977.
South Carolina:	
SC75-1038 (SC79-1047)	Mar. 21, 1975.
South Dakota:	
SD78-5001 (SD79-5113)	Jan. 20, 1978.
Texas:	
TX78-4038 (TX79-4032); TX78-4039 (TX79-4049)	Apr. 14, 1978.
TX78-4080 (TX79-4033)	Aug. 11, 1978.
TX78-4081 (TX79-4031)	Aug. 18, 1978.
TX76-4085 (TX79-4038)	Aug. 25, 1978.
TX78-4094 (TX79-4053); TX78-4095 (TX79-4039)	Sept. 22, 1978.
TX79-4007 (TX79-4048); TX79-4006 (TX79-4050)	Jan. 5, 1979.
Wyoming:	
WY78-5014 (WY79-5108); WY78-5015 (WY79-5109)	Mar. 10, 1979.

CANCELLATION OF GENERAL WAGE DETERMINATION DECISIONS

None.

Signed at Washington, D.C. this 9th day of March 1979.

DOROTHY P. COME,
Assistant Administrator, Wage and Hour Divison.

NEW DECISION

STATE: South Carolina COUNTY: Spartanburg
DECISION NUMBER: SC79-1048 DATE: Date of Publication
DESCRIPTION OF WORK: Building Construction Projects (does not include single family homes and garden type apartments up to and including 4 stories).

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
BRICKLAYERS	$6.00				
CARPENTERS	5.20				
CEMENT MASONS	4.62				
ELECTRICIANS	6.69				
GLAZIERS	5.73				
IRONWORKERS, Structural & Ornamental	8.60				
LABORERS:					
Laborers, unskilled	3.00				
Pipelayers	3.50				
PAINTERS, Brush	4.00				
PLUMBERS & Pipefitters	6.00				
ROOFERS	4.25				
SHEET METAL WORKERS	4.75				
SPRINKLER FITTERS	8.25	.75	1.05		.08
TILE SETTERS	5.40				
TRUCK DRIVERS	3.50				
WELDERS - Rate for craft.					
POWER EQUIPMENT OPERATORS:					
Backhoes	4.10				
Concrete pumps	5.08				
Cranes, derricks, draglines	6.35				
Front end loaders	5.00				
Motor graders	4.00				
Rollers	3.20				
Scrapers - Pans	4.25				
Tractors	3.80				

MODIFICATIONS P. 1

DECISION NO. AK79-5105 - Mod. #1
(44 FR 8476 - February 9, 1979)
Statewide, Alaska

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Change:					
Carpenters:					
Area 1:					
Piledrivermen	$16.12	.90	2.25		.10
Areas 2 and 3:					
Piledrivermen	16.37	.90	2.25		.10
Sprinkler Fitters	17.52	.75	1.05		.08

DECISION NO. AR79-4025 - Mod. #1
(44 FR 6864 - February 2, 1979)
Statewide, Arkansas

CHANGE:					
Bulldozer operator, rough	$4.25				
Finishing machine operator	4.30				

MODIFICATIONS P. 2

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
DECISION NO. CA78-5107 - Mod. #4 (43 FR 29444 - July 7, 1978) Alameda, Alpine, Amador, Butte, Calaveras, Colusa, Contra Costa, Del Norte, Eldorado, Fresno, Glenn, Humboldt, Kings, Lake, Lassen, Madera, Marin, Mariposa, Mendocino, Merced, Modoc, Monterey, Napa, Nevada, Placer, Plumas, Sacramento, San Benito, San Francisco, San Joaquin, San Sierra, Siskiyou, Sutter, Tahama Trinity, Tulare, Tuolumne, Yolo, and Yuba Counties, California					
Change:					
ELECTRICIANS:					
Alameda County					
Electricians	$15.16	1.30	3%+1.65		.069
Cable Splicers	17.06	1.30	3%+1.65		.069
DECISION NO. CA78-5123 - Mod. #5 (43 FR 36839 -August 18, 1978) Imperial, Kern, Los Angeles, Orange, Riverside, San Bernardino, San Luis Obispo, Santa Barbara and Ventura Counties, California					
Change:					
PAINTERS:					
Imperial, Orange, Riverside, Los Angeles (Pomona Area), San Bernardino (excluding Western portion)					
Brush; Paint Burners; Spray	$12.37	1.23	1.38	.75	.07
Paperhanger; Spray (swing stage)	12.87	1.23	1.38	.75	.07
Brush (swing stage); Spray (swing stage)	12.62	1.23	1.38	.75	.07
Steeplejack	14.02	1.23	1.38	.75	.07
Iron, Steel and Bridge (ground work and spray ground work)	13.12	1.23	1.38	.75	.07
Iron, Steel and Bridge (swing stage and spray swing stage)	13.37	1.23	1.38	.75	.07

MODIFICATIONS P. 3

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
DECISION #FL76-1021 - Mod. #4 (41 FR 4749 - January 30, 1976) Bay, Escambia, Gulf, Okaloosa, Santa Rosa, and Walton Counties, Florida					
Change: Mod. #2 as published on February 16, 1979 in 44 FR 10215 to read: Mod. #3					
DECISION No. FL78-1065 - Mod. #3 (43 FR 35809 - August 11, 1978) Brevard and Volusia (excluding Cape Canaveral, Kennedy Space Flight Center, Patrick Air Force Base, and Melabar Radar Site), Lake, Orange, Osceola, Polk, and Seminole Counties, Florida					
Change:					
Carpenters	$6.79				
Cement Masons	6.44				
DECISION #FL78-1070 - Mod. #3 (43 FR 38277 - August 25, 1978) Pinellas County, Florida					
CHANGE:					
Sprinkler Fitters	$10.61	.75	1.05		.10

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
DECISION #IL78-2117 - MOD #3 (43 FR 52638 - November 13, 1978) Madison & St. Clair Counties, Illinois					
OMIT:					
LABORERS:					
Freebury & Vicinity					
Labors	$10.55	.50	.80		.035
Dynamite	12.05	.50	.80		.035
Hod Carrier	11.05	.50	.80		.035
ADD:					
LABORERS:					
New Athens & Vicinity					
Laborers	10.55	.50	.80		.035
Dynamite Men	12.05	.50	.80		.035
Hod Carriers	11.05	.50	.80		.035
Decision #IL78-2122 - Mod. #4 (43 FR 49186 - October 20, 1978) Peoria and Tazewell Counties, Illinois					
Change:					
Plumbers and Steamfitters:					
Peoria County & N. Of Hwy. #98 in Tazewell Co.	12.71	.51	1.05		.15
DECISION #IL78-2128 - MOD. #4 (43 FR 50323 - October 27, 1978) Clark, Clay, Coles, Crawford, Cumberland, Douglas, Edgar, Edwards, Effingham, Fayette, Jasper, Lawrence, Richland, Wabash and Wayne Counties, Illinois					
CHANGE:					
ASBESTOS WORKERS:					
Remainder of Counties	$11.70	.45	1.00		.03

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Decision #IA78-4109-Mod. #2 (43 FR 55174-November 24,1978) Building Scott County, Iowa					
CHANGE:					
Electricians	$12.49	.55	7.5%		.03
Cable Splicers	13.49	.55	7.5%		.03
Decision #IA78-4112-Mod. #2 (43 FR 55178- November 24,1978) Building Woodbury County, Iowa					
CHANGE:					
Painters: Brush	9.83	.77	.50		
DECISION #MT79-5101 - Mod. #1 (44 FR 8508 - February 9, 1979) Statewide, Montana					
Change:					
CEMENT MASONS:					
Cement Masons	$9.43	.85	.25		
Grinder, Bush Hammer and Clipping Fan preparing finished surface Epoxy	9.58	.85	.25		
ELECTRICIANS:					
Broadwater, Lewis & Clark and Meagher Counties	12.15	.60	3%+.50		5%
Flathead, Lake, Lincoln, Mineral, Missoula, Ravalli and Sanders Counties:					
Electricians	12.25	.60	3%+.50		5%
Cable Splicers	12.85	.60	3%+.50		5%
TRUCK DRIVERS:					
For all classifications change only the Pensions Fund to $.70 per hour					

DECISION #NV78-5124 - Mod. #6
(43 FR 41351 - September 15, 1978)
Statewide (does not include the Nevada Test Site and Tonopah Test Range, and highway construction in Douglas County), Nevada

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vocation	Education and/or Appr. Tr.
Change:					
Bricklayers; Stonemasons:					
Clark, Esmeralda, Lincoln, Nye County (south of Hwy. #6)	$12.97	.90	.60		.06
Remaining Counties and Nye County (north of Hwy. #6)	12.60	.95	.60		.01
Elevator Constructors:					
Nevada east of 118° longitude and south of 39° north latitude:					
Elevator Constructors	14.53	.895	.69	3% + a	.03
Elevator Constructors' Helpers	10.17	.895	.69	3% + a	.03
Elevator Constructors' Helpers (Prob.)	7.265				
Nevada west of 118° longitude:					
Elevator Constructors	16.37	.895	.69	3% + a	.03
Elevator Constructors' Helpers	11.46	.895	.69	3% + a	.03
Elevator Constructors' Helpers (Prob.)	8.185				
Marble Masons:					
Clark, Esmeralda, Lincoln, Nye County (south half)	12.97	.90	.60		.06
Remaining Counties and Nye County (north half)	11.85	.95	.60		.01
Painters:					
Remaining Counties including Lake Tahoe Area:					
Brush and Roller	13.43	.70	.75		.02
Spray; Taper; Paperhangers	13.95	.70	.75		.02
Spray - swing stage up to 40 ft.; Spray - steel	14.20	.70	.75		.02

DECISION #NV78-5124 (Cont'd):

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vocation	Education and/or Appr. Tr.
Change (Cont'd):					
Painters (Cont'd):					
Remaining Counties including Lake Tahoe Area (Cont'd):					
Brush - swing stage up to 40 ft.; Brush - steel; Sandblaster	$13.70	.70	.75		.02
Roofers:					
Remaining Counties and Nye County (north half)	12.85	.85	1.00		.05
Terrazzo Workers; Tile Setters:					
Remaining Counties and Nye County (north half)	11.85	.95	.60		.01
Clark, Esmeralda, Lincoln, Nye County (south half)	12.97	.90	.60		.06

DECISION NO. ND78-5113 - Mod #3
(43 FR 31563 - July 21, 1978)
Burleigh, Cass, Grand Forks, Morton, Richland, Steele, Walsh, and Ward Counties, North Dakota

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
CHANGE:					
LINE CONSTRUCTION:					
Group 1	$11.40	.45	3%		1/2%
Group 2	11.37	.45	3%		1/2%
Group 3	9.12	.45	3%		1/2%
Group 4	7.60	.45	3%		1/2%
Group 5	6.98	.45	3%		1/2%

GROUP 1: Journeyman Cable Splicer; Journeyman Lineman.

GROUP 2: Tractor dozer operator, D-4 and larger; all rigs erecting steel tower and "H" fixtures, also tension pulling machines.

GROUP 3: Groundman - Operating special equipment. Hole digging machines; Aerial baskets on energized circuits; Tractors, D-4 and larger, Transmission line pole hauling; All fifth wheel trucks and other setting and assembly equipment excluding steel tower and "H" fixtures erection.

GROUP 4: Groundman - Truck or tractor driver with winch; Operators of trucks up to and including 2½ tons; Tractor including D-2 and smaller, including wheel tractors and crawler tractors.

GROUP 5: Groundman - Truck or tractor driver without winch; Operators of trucks up to and including 2½ tons D-2 and smaller, including wheel tractors and crawler tractors.

DECISION #PA78-3014 - Mod. #9
(43 FR 12603 - March 24, 1978)
Armstrong, Allegheny, Beaver, Butler, Fayette, Indiana, Washington & Westmoreland Counties, Pennsylvania

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Change:					
Electricians Zone 2	$12.08	6%	3%	1.00	1½%
Bricklayers: Zone 4	10.98	.75	.87		.02
DECISION #PA78-3016 - Mod. #6 (43 FR 16106 - April 14, 1978) Lehigh County, Pennsylvania					
Change:					
Cement Masons	$10.67	1.00	.41		
Electricians	11.05	.70	3%+.80		.02
Plasterers	10.52	1.00	.41		.01
Modification #6 in 44 FR - 8473, dated 2/19/79; to read Modification #5					
DECISION #PA78-3037 - Mod #3 (43 FR 17239 - April 21, 1978) Blair County, Pennsylvania					
Change:					
Carpenters	$10.40	6%	8%	9%	1½%
Soft Floor Layers	10.40	6%	8%	9%	1½%
DECISION #PA78-3043 - Mod. #5 (43 FR 20707 - May 12. 1978) Elk, Forest, Mckean, and Warren Counties, Pennsylvania					
Change:					
Asbestos Workers Zone 2 - Forest County	$12.89	.55	1.00		.02

MODIFICATIONS P. 10

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
DECISION #SC78-1040 - Mod. #3 (43 FR 16110 - April 14, 1978) Abbeville, Cherokee, Laurens, Newberry and Union Counties, South Carolina					
Change: Decision No. referred to under omission of Cherokee & Union Counties in Mod. #2 as published February 23, 1979 in 44 FR 10937 to read: SC79-1038					
DECISION #SC78-1085 - Mod. #2 (43 FR 45164 - September 29, 1978) Statewide, South Carolina					
Omit: Electricians	$6.87				

MODIFICATIONS P. 11

DECISION #TX78-4086 - Mod. #3 (43 FR 38285 - August 25, 1978) - Tom Green Co., Texas
DECISION #TX78-4090 - Mod. #5 (43 FR 31364 - September 15, 1978) - Bowie Co., Texas
DECISION #TX78-4091 - Mod. #5 (43 FR 41365 - September 15, 1978) - Gregg Co., Texas
DECISION #TX78-4092 - Mod. #2 (43 FR 41365 - September 15, 1978) - Smith Co., Texas
DECISION #TX78-4114 - Mod. #6 (43 FR 49208 - October 20, 1978) - Lubbock Co., Texas
DECISION #TX79-4003 - Mod. #2 (44 FR 1671 - January 5, 1979) - Brazos Co., Texas
DECISION #TX79-4005 - Mod. #1 (44 FR 1675 - January 5, 1979) - Bee, Kleberg & Nueces Cos., Texas
DECISION #TX79-4008 - Mod. #2 (44 FR 1680 - January 5, 1979) - Taylor Co., Texas
DECISION #TX79-4009 - Mod. #1 (44 FR 1681 - January 5, 1979) - Cameron, Hidalgo, Starr & Willacy Cos., Texas
DECISION #TX79-4010 - Mod. #3 (44 FR 1681 - January 5, 1979) - Wichita Co., Texas

Change Description of Work to Read As Follows:
Building Construction Projects (does not include single family homes & garden type apartments up to & including 4 stories). (Use current heavy & highway general wage determination for Paving & Utilities Incidental to Building Construction).

DECISION #TX79-4004 - Mod. #1 (44 FR 1673 - January 5, 1979) - El Paso Co., Texas

Change Description of Work to Read As Follows:
Building Construction Projects (does not include single family homes & garden type apartments up to & including 4 stories). (Use current highway general wage determination for Paving Incidental to Building Construction).

DECISION #TX79-4011 - Mod. #2 (44 FR 1683 - January 5, 1979) - Galveston & Harris Cos., Texas

Change Description of Work To Read As Follows:
Building Construction Projects (does not include single family homes & garden type apartments up to & including 4 stories). (Use current highway general wage determination for Paving & Utilities Incidental to Building Construction for Galveston (excluding Galveston Island) & Harris Cos.).

DECISION #TX78-4115 - Mod. #4 (43 FR 56408 - December 1, 1978) - Collin, Dallas, Denton, Ellis, Grayson, Hood, Hunt, Johnson, Kaufman, Palo Pinto, Rockwall, Tarrant & Wise Cos., Texas

Change Description of Work to Read As Follows:
Building Construction Projects (does not include single family homes & garden type apartments up to & including 4 stories). (Use current heavy & highway general wage determination for Paving Incidental to Building Construction in Tarrant Co. and for Paving & Utilities Incidental to Building Construction in remaining Cos.).

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
DECISION #TX78-4090-Mod. #5(CONT'D)					
Change:					
Elevator constructors:					
Mechanics	$10.09	.895	.69	4%+a+b	.035
Helpers	70%JR	.895	.69	4%+a+b	.035
Helpers (Probationary)	50%JR				
DECISION #TX78-4091-Mod. #5(CONT'D)					
Change:					
Electricians: Electricians	10.20	.60	3%		1/4%
Cable splicers	10.55	.60	3%		1/4%
DECISION #TX78-4092-Mod. #2(CONT'D)					
Change:					
Electricians: Electricians	10.00	.60	3%		1/4%
Cable splicers	10.40	.60	3%		1/45
DECISION #TX78-4114-Mod. #6(CONT'D)					
Change:					
Bricklayers & stonemasons	10.02		.30		.03
Sheet metal workers	10.89	.50	.55		.11
DECISION #TX79-4003-Mod. #2(CONT'D)					
Change:					
Elevator constructors:					
Mechanics	10.74	.895	.69	4%+a+b	.035
Helpers	70%JR	.895	.69	4%+a+b	.035
Helpers (Probationary	50%JR				
DECISION #TX79-4005-Mod. #1(CONT'D)					
Change:					
Electricians: Electricians	11.30	.60	3%		3/4%
Cable splicers	11.425	.60	3%		3/4%
Line construction:					
Linemen	11.32	.60	3%		1/2%
Cable splicers	11.445	.60	3%		1/2%
Groundmen (1st year)	5.66	.60	3%		1/2%
Groundmen	6.23	.60	3%		1/2%

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
DECISION #TX79-4008-Mod. #2(CONT'D)					
Change:					
Electricians: Electricians	$10.15	.60	3%		1/4%
Cable splicers	10.40	.60	3%		1/4%
Line construction:					
Lineman	10.15	.60	3%		1/4%
Cable splicers	10.40	.60	3%		1/4%
Groundman (over 1 year of experience)	7.61	.60	3%		1/4%
Groundman (under 1 year of experience)	6.09	.60	3%		1/4%
Equipment operator	8.32	.60	3%		1/4%
Flat bed truck driver	6.29	.60	3%		1/4%
DECISION #TX79-4009-Mod. #1(CONT'D)					
Change:					
Plumbers & pipefitters	8.70	.55	.25		.05
DECISION #TX79-4010-Mod. #3(CONT'D)					
Change:					
Cement masons	9.53				
Elevator constructors:					
Mechanics	10.09	.895	.69	4%+a+b	.035
Helpers	70%JR	.895	.69	4%+a+b	.035
Helpers (Probationary)	50%JR				
DECISION #TX79-4004-Mod. #1(CONT'D)					
Change:					
Elevator constructors:					
Mechanics	8.68	.895	.69	4%+a+b	.035
Helpers	70%JR	.895	.69	4%+a+b	.035
Helpers (Probationary)	50%JR				

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
DECISION #TX79-4011-Mod. #2(CONT'D)					
Change:					
Elevator constructors:					
Mechanics	$10.74	.895	.69	4%+a+b	.035
Helpers	70%JR	.895	.69	4%+a+b	.035
Helpers (Probationary)	50%JR				
DECISION #TX78-4115-Mod. #4(CONT'D)					
Change:					
Elevator constructors:					
Mechanics	10.09	.895	.69	4%+a+b	.035
Helpers	70%JR	.895	.69	4%+a+b	.035
Helpers (Probationary)	50%JR				
Ironworkers:					
Zone 2	9.525	.55	1.00		.10

DECISION #WV78-3018 - Mod. #5
(43 FR 25278 - June 9, 1978)
State of West Virginia excluding the
Counties of Berkeley, Jefferson & Morgan

Change:	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Cement Masons & Plasterers:					
Area 11	11.53	.55	.50	a	.03
Electricians:					
Brooke (Buffalo Twp. only), Marshall, Ohio, & Wetzel Counties:					
Wiremen	11.70	.50	3%+.35	1.00	.04
Cable Splicers	11.95	.50	3%+.35	1.00	.04
Jackson, Pleasants, Ritchie, Tyler, Wirt & Wood Counties:					
Wiremen	11.10	.50	3%+1.25	1.25	.04
Cable Splicers	11.35	.50	3%+1.25	1.25	.04
Boone, Braxton, Calhoun, Clay, Fayette (Falls & Kanawha Twps), Gilmer, Kanawha, Putnam, Raleigh (Clear Fork & Marsh Fork Twps.), Roane & Webster Counties:					
Wiremen	13.00	.50	3%+.25		.04
Cable Splicers	14.30	.50	3%+.25		.04
Glaziers:					
Area 1	10.93				
Lathers:					
Area 2	12.25		.20		.01
Line Construction:					
Boone, Braxton, Cabell, Calhoun, Clay, Gilmer, Kanawha, Lincoln, Logan, Mason, Mingo, Putnam, Roane, Wayne, & Webster Counties:					
Linemen	12.73	.60	3%+ .52	.92	½%
Cable Splicers	14.00	.60	3%+.52	.92	½%
Groundmen	8.27	.60	3%+.52	.92	½%
Mechanized Equipment Operator	10.18	.60	3%+.52	.92	½%
Brooke (Bufalo Twp. Only), Marshall, Ohio, & Wetzel Counties:					
Linemen & Equipment Operators	10.80	.50	3%+.35	1.00	.04
Cable Splicers	11.05	.50	3%+.35	1.00	.04
Groundmen	8.64	.50	3%+.35	1.00	.04
Jackson, Pleasants, Ritchie, Tyler, Wirt, & Wood Counties:					
Linemen & Equipment Operators	11.00	.60	3%+1.25	1.27	½%
Cable Splicers	12.10	.60	3%+1.25	1.27	½%
Groundmen	8.80	.60	3%+1.25	1.27	½%

DECISION #WV78-3018 - Mod. #5

Change: (Cont'd)	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Plumbers & Steamfitters: Boone, (remainder of County), Braxton (remainder of County), Clay, Fayette, Greenbrier, Jackson (remainder of County), Kanawha, Pocohontas, Putnam, Roane (remainder of County), Summers, & Webster (remainder of County) Counties:	11.50	.65	.80		.05
Plumbers & Pipefitters:					
Area 1	10.66	.55	.95	10%	.04
Area 2	10.91	.55	.95	10%	.04
Area 3	11.16	.55	.95	10%	.04
Area 4	11.41	.55	.95	10%	.04

DECISION #WI78-2108 - MOD #2
(43 FR 49215 - October 20, 1978)
Statewide, Wisconsin

ADD:
TRUCK DRIVERS:
Sheboygan County Only

Tandem Truck	$ 8.24	a	b
Semi & Tri Axle	8.30	a	b

FOOTNOTE:
a. $79.47 per month Health and Welfare fringe benefit
b. $ 9.00 per week Pension fringe benefit

DECISION NO. WI78-2110 - MOD #3
(43 FR 49222 - October 20, 1978)
Ashland, Bayfield and Douglas Counties, Wisconsin

WISC. 18 - LAB

CHANGE:

LABORERS: (BAYFIELD & DOUGLAS COUNTIES)	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
GENERAL LABOR: Handling of material for carpenters, craftsmen, cleaning forms, rough, grading, digging shallow trenching, tool checkers, general labor around building & construction work	$ 9.15	.45	.40		
CONCRETE WORK: Concrete, bituminous concrete aggregates for walls, footings foundations, floors, any other const. Mixing, vibrating, gunniting, etc. Operating motorized wheelbarrows, buggies or machines of similar character, the hooking on, signaling, dumpling & unhooking of bucket when concrete or aggregates are conveyed by crane, derrick or similar method. Placing of concrete or aggregates, Assembly, uncoupling cleaning, etc. of equipment used in mixing or conveying concrete, aggregates or mortar, all vibrating, grinding, spreading, flowing, puddling, leveling and strike-off of concrete or aggregates by floating, rodding or screening, Loading, unloading, etc. etc., of prestressed or precast concrete slabs, wall, etc. Mixing, handling, conveying, placing & spreading of grout, cutting of concrete or aggregate	9.15	.45	.40		

DECISION NO. WI78-2110 - MOD #3 (Cont'd)

LABORERS:
CONCRETE WORK: (Cont'd)

WISC. 18 - LAB

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Jackhammer, concrete busters, air spades, sheeting drivers, air hammers, jumping jack tamper	$ 9.40	.45	.40		
Vibrators, mason tenders, tile & terrazzo helpers demolition & wrecking laborers, Lanscaping	9.15	.45	.40		
Steel burners & steel form setters, mixing by hand for two or more bricklayers, hod carriers & plaster laborers	9.40	.45	.40		
Mixing by hand for one bricklayer, operator of power machinery used in cleaning brick roofing helper & Kettlemen, jack men on slip forms, underpinning, lagging, bracing, propping, shoring and all basement work etc.	9.15	.45	.40		
Miners, shafts, tunnels, underground sewers, drilling & blasting & compressed air work under ground or in compression chamber	9.50	.45	.40		
SEWER WORK:					
Pipelayers, cement manhole builder	9.40	.45	.40		
Bottom man and bracers, caulker & joint man, swanper on a pipe gang, buffing machine man	9.30	.45	.40		
Kettlemen, top man	9.15	.45	.40		
DYNAMITE MAN	9.60	.45	.40		
Handling creosoted lumber, piling square timber & like material where covered with creosote applying bit, or creosote on wood, steel or cement	9.40	.45	.40		
Work on towers or scaffolds 25 ft. or more above ground	9.40	.45	.40		

DECISION NO. WI78-2110 - MOD #3 (Cont'd)

LABORERS:
CONCRETE WORK:

WISC. 18 - LAB

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
BITUMINOUS WORKER:					
Dumper, ironer, smoother, shoveler, loader, utility man raker, luteman	$ 9.15	.45	.40		
STEEL WORK:					
Handling of all rods, mesh & material for use in reinforcing concrete const. hoisting rods, mesh & other materials except when a derrick or outrigger operated by other than hand is used	9.15	.45	.40		

DECISION #WI78-2116 - MOD #2
(43 FR 49228 - October 20, 1978)
Calumet, Fond Du Lac, Manitowoc, Outagamie, and Sheboygan Counties, Wisconsin

ADD:
TRUCK DRIVERS:
Sheboygan County Only:

Tandem Truck	$ 8.24	a	b
Semi & Tri Axle	8.30	a	b

FOOTNOTE:
a. $79.47 per month Health and Welfare fringe benefit
b. $ 9.00 per week Pension fringe benefit

SUPERSEDEAS DECISION

STATE: Alabama
COUNTIES: *See below
DECISION NO.: AL79-1046
DATE: Date of Publication
Supersedes Decision No.: AL78-1095 dated December 1, 1978, in 43-FR-56361
DESCRIPTION OF WORK: Building construction projects (does not include single family homes and garden type apartments up to and including 4 stories)

*Counties: Lawrence, Limestone, Morgan

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Asbestos workers	11.61	.45	.80		.05
Bricklayers:					
Bricklayers, Marble masons, Stonemasons, Pointers, Cleaners, Caulkers	10.50				
Carpenters:					
Carpenters, & Soft floor layers	8.60	.45	.30		.03
Millwrights	9.24	.45	.30		.03
Piledrivermen	9.00	.45	.30		.03
Cement masons	9.35				
Electricians:					
Electricians, linemen	10.60	.50	3%+.45		1%
Cable splicers	10.85	.50	3%+.45		1%
Groundmen	8.55	.50	3%+.45		1%
Elevator Constructors	9.74	.545	.35	a+b	.02
Ironworkers:					
Ornamental, reinforcing, structural	9.805	.70	.70		.08
Laborers (Lawrence County):					
Laborers, mason tenders, plasterers' tenders	5.90	.30	.45		
Air tool operators (jackhammer, vibrator, mortar mixers, pipelayers	6.10	.30	.45		
Laborers (Limestone & Morgan Counties):					
Laborers, mason tenders	5.55	.35	.50		
Air tool operator (jackhammer, vibrator), mortar mixer	5.80	.35	.50		
Plasterers & Troweling machine operator	9.60				
Plumbers, pipefitters, steamfitters:					
Lawrence Co. (Eastern portion of Co., north from intersection of State Rt. 33 Rt. 20 to Wheeler Lake including Moulton & Wren, excluding Bankhead National Park), Limestone Co. & Morgan Co	10.80	.55	.55		.15

AL79-1046 - (Cont'd)

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Plumbers, steamfitters:					
Lawrence Co., (Remaining portion)	10.70	.50	.60		.08
Roofers	8.90		.20		.10
Sheet metal workers	10.80	.79	1.07		.11
Terrazzo workers & tile setters	9.85				

PAID HOLIDAYS:
A-New Year's Day, B-Memorial Day, C-Independence Day, D-Labor Day, E-Thanksgiving Day, F-Christmas Day

FOOTNOTES:
a. 6 paid holidays: A through F.

b. Employer contributes 8% of regular hourly rate to Vacation Pay Credit for employee who has worked in the business more than 5 years. Employer contributes 6% of regular hourly rate to Vacation Pay Credit for employee who has worked in the business less than 5 years.

AL79-1046 (Cont'd)

POWER EQUIPMENT OPERATORS	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
GROUP A	10.58	.45	.45		
GROUP B	9.24	.45	.45		
GROUP C	8.52	.45	.45		

GROUP A - Backhoe, bulldozer, crane, crane car, central mixing plant, concrete pump, derrick, dragline, dredge, drill, elevating grader, finishing machine (concrete), forklift, front end loader, gradall, grout pump, helicopter pilot, hoist, locomotive engineer, mechanic, motor patrol, mucking machine, piledriver, post hole digger, scraper (pull type & self prop.) shovel, sweeper, tractor (spec. equip.), trenching machine, well point & winch truck operators

GROUP B - Bituminous dist., central air comp., concrete mixer (port.) fireman floating equip., front end loader, rubber tire, ½ cu. yd. & under, locomotive brakeman, locomotive flagman, locomotive switchman, oiler-driver (35 ton crane & over outboard motor boat (when used for towing), paving machine, portable hoist "Buck hoist type", post hole digger mounted on farm type tractor & walk behind type trenching machine operators

GROUP C - Air compressor (port.) conveyor, fireman stationary equip., oiler, outboard motor boat & pump operators

Oiler driver - additional $.10 per hour

All cranes, derricks & gantry operators operating such equipment with an overall height of 150', including jibs; all scraper operators - (in tandem) additional $.25 per hour.

SUPERSEDEAS DECISION

STATE: Arizona COUNTY: Maricopa
DECISION NUMBER: AZ79-5110 DATE: Date of Publication
Supersedes Decision No. AZ78-5115 dated July 28, 1978, in 43 FR 33018
DESCRIPTION OF WORK: Residential Projects (consisting of single family homes and garden type apartments up to and including 4 stories)

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
ASBESTOS WORKERS:					
Zone 1: Area lying within 15 miles radius from the City Hall in Phoenix	$ 12.84	.82	$ 1.30		.03
Zone 2: Area lying beyond the limits of Zone 1 and within 30 miles radius from the City Hall in Phoenix	13.44	.82	1.30		.03
Zone 3: Area lying beyond the limits of Zone 2 and within 40 miles radius from the City Hall in Phoenix	13.64	.82	1.30		.03
Zone 4: Area lying beyond the limits of Zone 3 and within 50 miles radius from the City Hall in Phoenix	14.09	.82	1.30		.03
Zone 5: Area lying beyond the limits of Zone 4 within the union's jurisdiction	16.09	.82	1.30		.03
BOILERMAKERS	14.36	1.075	1.00	1.00	.03
BRICKLAYERS: Stonemasons:					
Zone A: 0-35 road miles from City Hall in Phoenix	11.77	.65	.90		.09
Zone B: 35-50 road miles from City Hall in Phoenix	12.71	.65	.90		.09
Zone C: 50-75 road miles from City Hall in Phoenix	13.30	.65	.90		.09
Zone D: 75-100 road miles from City Hall in Phoenix	13.89	.65	.90		.09
Zone E: 100-200 road miles from City Hall in Phoenix	14.36	.65	.90		.09
Zone F: 200 road miles and over from City Hall in Phoenix	15.30	.65	.90		.09
CARPENTERS:					
Carpenters; Drywall Applicator	9.785	.845	.955		.05
Piledrivermen; Floorlayers (finish)	10.07	.845	.955		.05
Millwrights	10.20	.845	.955		.05

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
CEMENT MASONS:					
Northern portion	$ 10.21	.95	$ 1.30		.05
Southern portion	10.22	.85	.85		.05
DRYWALL:					
From Courthouse in Phoenix, Mesa, including Williams AFB and Luke AFB:					
Zone A: 0-40 miles	10.21	.59	.50		.07
Zone B: 41-60 miles	11.21	.59	.50		.07
Zone C: 61 miles and over	12.46	.59	.50		.07
Texture Spraymen:					
Zone A: 0-40 miles	9.81	.59	.50		.07
Zone B: 41-60 miles	10.81	.59	.50		.07
Zone C: 61 miles and over	12.06	.59	.50		.07
ELECTRICIANS:					
Zone A Description below	13.55	.96	3%+.88		3/4%

Zone A Description

Beginning at the northeast corner of the Port McDowell Indian Reservation; a line extending southward following the Reservation boundary line to intersect with a line extending along Ellsworth Road; south on Ellsworth Road to McKellips Road; a line extending east on McKellips Road to a point 1 mile east of the intersection of State Highway 88 and U. S. 60 and 70 near Apache Junction; southward to Baseline Road; west on Baseline Road to the Maricopa County Line; a line extending south on the Maricopa County Line to a point 5 miles south of Hunt Highway; then extending straight west to a point 5 miles west of Interstate 10; then northwest on a line parallel with Interstate 10 to intersect with Pecos Road; west on Pecos Road to intersect with a line extending south on Rooks Road; north on Rooks Road a line extending straight north to intersect with a line 2 miles north of Deer Valley Road; straight east to intersect with a line extending north on 24th Street; straight north to intersect with the Carefree Highway; east on the Carefree Highway to Cave Creek; northeast following along Cave Creek to a point 11 miles north of Deer Valley Road; east to intersect with a line extending along Pima Road; south on Pima Road to a point 2 miles north of Deer Valley Road; straight east to the northwest corner of Port McDowell Indian Reservation; along the northern boundary of the Reservation to the northeast corner.

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
ELECTRICIANS: (Cont'd)					
Zone B: That area outside of Zone A and formed by measuring 16 road miles from Pecos Road on the south; by measuring 18 road miles from the outer boundaries of the following: Powers Road on the east, from Hunt Highway on the south to one mile south of Pinnacle Peak Road on the north, and 1 mile south on Pinnacle Peak Road and from Cotton Lane on the west:					
Electricians	$ 15.55	.96	3%+.88		3/4%
Zone C: That area outside of zone B and extending to the outside limits of the union's jurisdiction:					
Electricians	16.55	.96	3%+.88		3/4%
ELEVATOR CONSTRUCTORS	13.85	.895	.69	3%+a	.03
ELEVATOR CONSTRUCTORS' HELPERS	9.695	.895	.69	3%+a	.03
ELEVATOR CONSTRUCTORS' HELPERS (PROB.)	6.925				
GLAZIERS	11.34	.85	.30		.01
IRONWORKERS	12.30	1.34	2.47		.11
MARBLE WORKERS	10.99	.65	.70		.19
PAINTERS:					
Zone A: 0-40 miles from Court House in Phoenix, Mesa and including Luke and Williams Air Force Bases:					
Brush; Roller; Taper; Sandblaster (Nozzleman); Sandblaster (Pot Tender)	10.19	.60	.40		.08
Spray; Paperhangers	10.44	.60	.40		.08
Creosote Applier	10.52	.60	.40		.08
Swing Stage:					
Brush; Sandblaster	10.59	.60	.40		.08
Spray	10.84	.60	.40		.08

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
PAINTERS: (Cont'd)					
Zone B: 41-60 miles from Court House in Phoenix:					
Brush; Roller; Taper; Sandblaster (Nozzleman); Sandblaster (Pot Tender)	$ 11.19	.60	.40		.08
Spray; Paperhangers	11.44	.60	.40		.08
Creosote Applier	11.52	.60	.40		.08
Swing Stage:					
Brush, sandblaster	11.59	.60	.40		.08
Spray	11.84	.60	.40		.08
Zone C: 61 miles and over from Court House in Phoenix:					
Brush; Roller; Taper; Sandblaster (Nozzleman); Sandblaster (Pot Tender)	12.44	.60	.40		.08
Spray; Paperhangers	12.69	.60	.40		.08
Creosote Applier	12.77	.60	.40		.08
Swing Stage:					
Brush, sandblaster	12.84	.60	.40		.08
Spray	13.09	.60	.40		.08
PLASTERERS:					
Northern 3/4 of County:					
Zone A: 0-35 miles from Phoenix	9.045	.60	.85		.035
Zone B: 35-60 miles from Phoenix	9.795	.60	.85		.035
Zone C: 60 miles and over from Phoenix	10.67	.60	.85		.035
Southern 1/4 of County:					
Zone A: 0-30 miles from Tucson	8.57	.35	.60		
Zone B: 30-40 miles from Tucson	9.07	.35	.60		
Zone C: 40-50 miles from Tucson	9.32	.35	.60		
Zone D: 50 miles and over from Tucson	10.07	.35	.60		
PLASTERERS' TENDERS	9.16	.85	.85		.10

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
PLUMBERS; Steamfitters:					
FREE ZONE 0-15 miles					
The "Free Zone" (Zone I) shall be 15 road miles from the stated base points in Flagstaff, Yuma, Tucson and Douglas. The "Free Zone" from Phoenix shall be 15 mile radius from the stated base point. In addition, all areas within the City limits of Phoenix, Chandler, Scottsdale, Tempe, Glendale, Mesa, Kingman, Havasu City, Prescott, Winslow and Holbrook will be included as Free Zones. Any work contracted for outside of these zones will be determined from the Phoenix and Tucson basing points:					
Zone 1: 0-15 miles	13.24	.75	$ 1.35		.13
Zone 2: 15-30 miles	13.64	.75	1.35		.13
Zone 3: 30-40 miles	14.09	.75	1.35		.13
Zone 4: 40 miles and over	15.59	.75	1.35		.13
ROOFERS	10.16	.845	.20		.02
SHEET METAL WORKERS:					
Zone 1: 0-25 miles excluding Luke & Williams Air Force Bases	11.70	.90	1.30		.10
Zone 2: 25-50 miles including Luke & Williams Air Force Bases	12.35	.90	1.30		.10
Zone 3: 50 miles and over	14.20	.90	1.30		.10
SOFT FLOOR LAYERS:					
Zone A: 0-40 miles from Court House in Phoenix and including Luke and Williams Air Force Bases	9.21	.59	.12		.12
Zone B: 41-60 miles from Court House in Phoenix	10.21	.59	.12		.12
Zone C: 61 miles and over	10.71	.59	.12		.12
SPRINKLER FITTERS	12.74	.75	1.05		.08
TERRAZZO WORKERS; Tile Setters	10.79	.65	.90		.16

FOOTNOTE

a. Employer contributes 4% of basic hourly rate for 5 years' service and 2% of basic hourly rate for 6 months' to 5 years' service as Vacation Pay Credit. Six Paid Holidays: A through F.

PAID HOLIDAYS:

A-New Year's Day; B-Memorial Day; C-Independence Day; D-Labor Day; E-Thanksgiving Day; F-Christmas Day.

LABORERS	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Group 1:	$ 8.36	.92	.98		.10
Group 2:	8.49	.92	.98		.10
Group 3:	8.63	.92	.98		.10
Group 4:	8.74	.92	.98		.10
Group 5:	8.91	.92	.98		.10
Group 6:	9.285	.92	.98		.10
Group 7:	9.915	.92	.98		.10
POWER EQUIPMENT OPERATORS (Except Piledriving and Steel Erection)					
Group 1:	8.93	1.05	1.00		.08
Group 2:	9.30	1.05	1.00		.08
Group 3:	9.76	1.05	1.00		.08
Group 4:	10.29	1.05	1.00		.08
Group 5:	10.82	1.05	1.00		.08
Group 5A:	11.13	1.05	1.00		.08
Group 6:	11.46	1.05	1.00		.08
Group 7:	12.06	1.05	1.00		.08
TRUCK DRIVERS					
Group 1:	8.52	.92	.98		.08
Group 2:	8.65	.92	.98		.08
Group 3:	8.87	.92	.98		.08
Group 4:	9.22	.92	.98		.08
Group 5:	9.38	.92	.98		.08
Group 5A:	9.56	.92	.98		.08
Group 6:	9.70	.92	.98		.08
Group 7:	10.11	.92	.98		.08
Group 8:	10.625	.92	.98		.08
Group 8A:	11.28	.92	.98		.08
Group 8B:	10.97	.92	.98		.08
Group 8C:	9.08	.92	.98		.08

LABORERS

Group 1: All Helpers not herein separately classified; Cesspool Diggers and Installer; Chat Box Man; Checker, tool dispatcher; Concrete Dump Manbelt, pipe and/or hoseman; Dumpman and/or spotter; Fence Builder, Guard Rail Builder, highway; Form Strippers; Labor, general or construction; Landscape Gardener and Nurseryman; Packing rod steel and pans; Rip Rap Stoneman; Astro Turf Layer; Cleanup, Bull Gang; Trackman-railroad

Group 2: Cement Finisher Tender; Concrete Curer (impervious membrane); Cutting Torch Operator; Fine Grader (highway, engineering and sewer work only); Kettleman - Tarman; Power type concrete buggy

Group 3: Bander; Chucktender (except tunnel); Creosote Tieman; Guinea Chaser; Powderman Helper; Rip-rap Stone Paver; Sandblaster (pot tender); Spiker and Wrenchers

Group 4: Cement Dumpers (skip-type mixer or handling bulk cement); Chain Saw Machines (on clearing and grubbing); Concrete Vibrating Machines; Cribber and Shorer (except tunnel); Floor Sanders, concrete; Hydraulic Jacks and similar mechanical tools not separately classified herein; Operators and Tenders of pneumatic and electric tools; Pipe Caulker and/or Backup Man (pipeline); Pipe Wrapper; Pneumatic Gopher; Rigger/Signalman (pipeline)

Group 5: Air and water wash-out Nozzleman; Asphalt Rakers and Ironers; Driller; Grade Setter (pipeline); Hand guided Trencher and similar operated equipment; Jackhammer and/or Pavement Breakers; Pipelayers (including but not limited to non-metallic, transite and plastic pipe, water pipe, sewer pipe, drain pipe, underground tile and conduit); Rock Slinger; Scaler (using bos'n chairs or safety belt); Tampers (mechanical, all types); Precast Manhole Erector

Group 6: Concrete Cutting Torch; Concrete Saw (hand guided); Driller (Core, Diamond, Wagon or Air Track); Drill Doctor and/or air tool Repairman; Gunman and Mixerman (gunite); Sandblaster (Nozzleman)

Group 7: Concrete Road Form Setter; Gunite Nozzleman or Roadman; Drillers, Joy Mustang, PR 143, 200 Gardner-Denver, Hydrasonic; Powderman; Scaler (drillers); Welders and/or Pipelayers installing process piping; Form Setter and/or Builder

POWER EQUIPMENT OPERATORS
(Except Piledriving and Steel Erection)

Group 1: Air Compressor Operator; Field Equipment Serviceman Helper; Heavy Duty Repair Helper; Heavy Duty Welder Helper; Oiler; Pump Operator

Group 2: Conveyor Operator; Generator Operator - portable; Power Grizzly Operator; Self-propelled Chip Spreading Machine - Conveyor Operator; Watch Fireman; Welding Machine Operator - gasoline and diesel power

Group 3: Concrete Mixer Operator - skip type; Dinkey Operator (under 20 tons wt.); Driver-moto Paver, Slurry Seal Machine and similar type equipment; Motor Crane Driver; Power Sweeper Operator - self-propelled; Ross Carrier or Fork Lift Operator; Skip Loader Operator - all types with rated capacity 1½ cu. yds. or less; Wheel type Tractor Operator (Ford, Ferguson or similar type) with attachments such as Fresno, Push Blade, Post Hole Auger, Mower, etc., excluding compacting equipment

Group 4: A-Frame Boom Truck or Winch Truck Operator; Asphalt Plant Firemen; Elevator Hoist Operator (including Tuskey Hoist or similar type); Grade Checker (excluding Civil Engineer); Multiple Power Concrete Saw Operator; Pavement Breaker, Mechanical Compactor Operator, power propelled; Roller Operator - all types - except as otherwise classified; Screed Operator; Self-propelled Chip Spreading Machine Operator (including Slurry Seal Machine Operator); Stationary Pipewrapping and Cleaning Machine Operator; Tugger Operator

Group 5: Aggregate Plant Operator (including crushing, screening and sand plants, etc.); Asphalt Plant Mixer Operator; Beltcrete Machine; Boring Machine Operator; Concrete Mechanical Tamping, Spreading or Finishing Machine (including Clary, Johnson or similar types); Concrete Pump Operator; Concrete Batch Plant Operator, all types and sizes; Conductor, Brakeman or Handler; Drilling Machine, including water wells; Elevating Grader Operator - all types and sizes (except as otherwise classified); Field Equipment Serviceman; Highline Cableway Signalman; Kolman Belt Loader Operator or similar, with belt width 48" or over; Locomotive Engineer (including Dinkey - 20 tons wt. and over); Motopaver and similar type equipment operator; Operating Engineer Rigger; Pneumatic-tired Scraper Operator (Turnapull, Euclid, Cat, D-W, Hancock and similar equipment) up to and including 12 cu. yds.; Power Jumbo Form Setter Operator; Pressure Grout Machine Operator (as used in heavy engineering construction); Road Oil Mixing Machine Operator; Roller Operator - on all types asphalt pavement; Self-propelled Compactor, with blade; Skip Loader Operator - all types with rated capacity over 1½ but less than 4 cu. yds.; Slip Form Operator (power driven lifting device for concrete forms); Soil Cement Road Mixing Machine Operator - single pass type; Stationary Central Generating Plant Operator - rated 300 K.W. or more; Surface Heater and Planer Operator; Traveling Pipewrapping Machine Operator

POWER EQUIPMENT OPERATORS (Cont'd)
(Except Piledriving and Steel Erection)

Group 5A: Heavy Duty Mechanic and/or Welder; Pneumatic Tired Scraper, all sizes and types over 12 cu. yds. up to and including 45 cu. yds. MRC (Turnapull, Euclid, Cat, D-W, Hancock and similar equipment); Tractor Operator (Pusher, Bulldozer, Scraper) up to 400 net horsepower rating; Trenching Machine Operator

Group 6: Auto-Grade Machine (CMI and similar equipment); Boring Machine Operator (including Mole, Badger and similar type); Concrete Mixer Operator - paving type, ar. Mobile Mixer; Concrete Pump Operator with boom attachment (truck mounted); Crane Operator - Crawler and Pneumatic type, under 100 ton capacity MRC; Crawler type Tractor Operator - with boom attachment; Derrick Operator; Forklift Operator for hoisting personnel; Grade-all Operator; Helicopter Hoist; Highline Cableway Operator (less than 20 tons rated capacity); Mass Excavator Operator (150 Bucyrus Erie and similar types); Mechanical Hoist Operator (two or more drums); Motor Grade Operator - any type power blade; Motor Grade Operator with elevating grader attachment; Mucking Machine Operator; Overhead Crane Operator; Piledriver Engineer (portable, stationary or skid rig); Pneumatic-tired Scraper Operator - all sizes and types (Turnapull, Euclid, Cat, D-W, Hancock and similar equipment over 45 cu. yds., MRC); Power driven Ditch Lining or Ditch Trimming Machine Operator; Skip Loader Operator - all types with rated capacity 4 cu. yds., but less than 8 cu. yds.; Slip Form Paving Machine Operator (including Gunnert, Zimmerman and similar types); Specialized Power Digger Operator - attached on wheel-type tractor; Tower Crane (or similar type) Operator; Tractor Operator (Pusher, Bulldozer, Scraper (400 net horsepower and over); Tugger Operator (two or more); Universal Equipment Operators - Shovel, Backhoe, Dragline, Clamshell, etc. up to 8 cu. yds.

Group 7: Crane Operator - pneumatic or crawler (100 ton hoisting capacity and over MRC rating); Helicopter Pilot - FAA qualified when used in construction work; Highline Cableway Operator, over 20 ton rated capacity and using traveling head and tail tower; Remote control earth moving equipment operator; Skip Loader Operator - all types with rated capacity of 8 cu. yds. or more; Universal Equipment - Shovel, Backhoe, Dragline, Clamshell, etc., 8 cu. yds. and over

TRUCK DRIVERS

Group 1: Teamsters; Pickups; Station Wagons; Manhaul Driver

Group 2: Dump or Flatrack (2 or 3 axle); Water Truck (under 2,500 gallons); Buggymobile (1 cu. yd. or less); Tireman; Bus Drivers, Ambulance Driver, Self-propelled Street Sweeper; Warehouseman

Group 3: Dump or Flatrack (4 axle); Dumptor or Dumpster (less than 7 cu. yds.); Water Truck (2,500 gallons but less than 4,000 gallons)

Group 4: Dumptor or Dumpster (7 cu. yds. but less than 16 cu. yds.); Dump or Flatrack (5 axle); Water Truck (4,000 gallons and over); Slurry type equipment or Leverman; Flaherty Spreader or similar type equipment or Leverman; Transit Mix (8 cu. yds. or less)

Group 5: Dump or Flatrack (6 axle); Transit Mix (over 8 cu. yds. but less than 10.5 cu. yds.); Rock Truck (i.e. Dart, Euclid and other similar type End Dumps, single unit less than 16 cu. yds.)

Group 5A: Oil Tanker or Spreader and/or Bootman, Retortman or Leverman

Group 6: Transit Mix (over 10.5 cu.yds. but less than 14 cu. yds.); Ross Carrier; Fork Lift or Lift Truck; Hydro Lift, Swedish Crane Iowa 300 and similar types; Concrete Pump (when integral part of transit mix truck); Dump or Flat Rack (7 axle)

Group 7: Dump or Flatrack (8 axles)

Group 8: Off-highway equipment Driver including but not limited to: 2 or 4 wheel power unit, i.e., Cat, DW Series, Euclid, International and similar type equipment, transporting material when top loaded or by external means including pulling Water Tanks, Fuel Tanks or other applications under Teamster Classifications; Rock Trucks (Dart, Euclid, or other similar End Dumps types) 16 cu. yds. and over; Eject-alls; Dumptor or Dumpster (16 cu. yds. and over); Dump or Flatrack(9 axles)

Group 8A: Heavy Duty Mechanic/Welder; Body and Fender Man

Group 8B: Field Equipment Serviceman or Fuel Truck Driver

Group 8C: Heavy Duty Mechanic/Welder Helper

SUPERSEDEAS DECISION

STATE: Guam
DECISION NUMBER: GU79-5111 DATE: Date of Publication
Supersedes Decision No. GU78-5127 dated September 15, 1978 in 43 FR 41437
DESCRIPTION OF WORK: Building, Residential, Heavy, and Highway Construction Projects.

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Air hammer operator including airbreaker, air gun, and air tool operators	6.00				
Asbestos and insulation workers	6.75				
Asphalt heater tenders	5.50				
Asphalt mixing machine tenders	5.50				
Asphalt rakers, blacktop rakers	5.50				
Asphalt plant dryer operator	6.00				
Asphalt plant operator	6.00				
Asphalt paving machine operator	7.00				
Blade grader operator	7.00				
Bricklayers	6.75				
Bulldozer operator	7.00				
Carpenters including hardwood floor layers, framing carpenters	6.75				
Cement Masons	6.75				
Concrete paving machine operator	7.00				
Crane operator	7.00				
Concrete mixer operator including batch and mix plant operator, and mixing machine operator	6.00				
Derrick, dragline, hoist operator	7.00				
Dredge pipe installer	6.00				
Dredge dipper tenders including bucket operator	6.00				
Dredge operators including dredge pumpers	6.75				
Drywall applicator including nailer, sheetrocker	6.00				
Earth boring machine operators	7.00				
Elevating grader operator	7.00				
Finegraders including slopers	5.50				
Floor sanding machine operator including floor scraper, and floor finishers	5.50				
Fence erector including ironworker wirefence erector, wirefence builder	6.00				
Forklift operator	6.00				

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Form tamper operator, tamping machine operator including road form tamping machine	6.00				
Form grader operators	7.00				
Foundation drill operators	7.00				
Glazier	6.00				
Heater planer operators	7.00				
Horizontal earth boring machine operator	7.00				
Laborers, hod carriers	5.00				
Lathers including metal and rockboard lathers	6.00				
Line maintainers including high tension line maintainers	6.75				
Mason Tender	5.50				
Metal road form setter, metal road form fitter	6.00				
Millwrights, machine erectors	6.00				
Motor grader operator	7.00				
Mucking machine operator	7.00				
Oilers	5.50				
Painters including structural steel and finish painters	6.00				
Pile driver operator	7.00				
Pile driving jetters	6.00				
Pipelayers	6.75				
Pipelaying fitters, spacers	6.00				
Plasterers	6.00				
Portable pump operator	6.00				
Plumbers, pipefitters, steamfitters, and sprinkler installer	6.75				
Power shovel operators	7.00				
Reinforcing ironworker including reinforcing bar setters	6.00				
Reinforcing steel erectors, reinforcing rod tiers	6.00				
Roofers, aluminum, shingle, and composition roofers	6.75				
Road mixer operators	7.00				
Road roller operator	7.00				
Rock drill operator	7.00				

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Sheet metal workers	6.75				
Scraper operator	7.00				
Sheet pile hammer operator	7.00				
Shield runner	7.00				
Subgrader operator	7.00				
Sweeper operator	7.00				
Tapers, drywall finisher, wall board and plaster board finisher, tapers and bedders, floaters	6.00				
Truck mechanic	6.00				
Truck drivers including concrete mixing trucks, dump trucks	6.00				
Terrazzo workers	6.75				
Tile setters	6.75				
Tower excavator operator	7.00				
Trenching machine operator	7.00				
Utility tractor operator	7.00				
Water well drillers	7.00				
Well drill operators, cabletool, rotary drill	7.00				

SUPERSEDEAS DECISION

STATE: Massachusetts COUNTY: Essex
DECISION NO.: MA79-2008 DATE: Date of Publication
Supersedes Decision No. MA78-2082, dated September 22, 1978 in 43 FR 43169
DESCRIPTION OF WORK: Building, Residential, Heavy, Highway and Marine Construction, Projects.

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
ASBESTOS WORKERS	$12.11	1.10	1.00		.01
BOILERMAKERS	11.80	1.05	10%		.02
BRICKLAYERS & STONEMASONS:					
Andover, Boxford, Danvers, Lawrence, Lynn, Lynnfield, Marblehead, Methuen, Middleton, Nahant, N. Andover, Peabody, Salem, Saugus, Swampscott & Topsfield	10.85	.70	1.25		.09
Veneer Plasterers	8.85	.70	1.25		.09
Remainder of County	11.20	1.00	.60		.09
Veneer Plasterers	9.30	1.00	.60		.06
CARPENTERS & SOFT FLOOR LAYERS:					
Amesbury, Boxford, Georgetown, Groveland, Haverhill, Newbury, Newburyport, Rowley, Salisbury, W. Newbury, Lynn, Lynnfield Nahant, Saugus and Swampscott, Andover, Lawrence, Methuen, N. Andover, & W. Andover	11.05	.90	1.00		.07
Remainder of County	10.10	1.00	1.00		
CEMENT MASONS & PLASTERERS:					
Amesbury, Boxford, Georgetown, Groveland, Haverhill, Lawrence, Merrimac, Methuen, N. Andover, Salisbury & West Salisbury	10.34	.70	.75		
Danvers, Lynn, Lynnfield, Marble Head, Middleton, Nahant, Peabody, Salem, Saugus, Swampscott and Topsfield	9.30	.50	.85		.05
Remainder of County	9.45	.60	.60		.05
ELECTRICIANS:					
Andover, Lawrence, Methuen and North Andover, Salisbury & W. Newbury	11.22	.75	3%+.40		.02
Lynn, Lynnfield, Nahant, Saugus and Swampscott	12.23	.75	3%+1.55		.07
Amesbury, Boxford, Georgetown, Groveland, Haverhillm Merrimac Newbury, Newburyport, Rowley	11.22	.75	3%+.40		.02
Remainder of County:					
Electrical contracts over $30,000	10.80	.92	3%+.26		.02

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	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
ELECTRICIANS:					
Electrical contract $30,000 and less	$10.10	.92	3%+.26		.02
ELEVATOR CONSTRUCTORS	12.02	.895	.69	a+b	.03
ELEVATOR CONSTRUCTORS' HELPERS	70%JR	.895	.69	a+b	.03
ELEVATOR CONSTRUCTORS' HELPERS (PROB.)	50%JR				
GLAZIERS	11.15	.77	.69		.03
IRONWORKERS	10.84	1.10	1.80		.06
LABORERS (BUILDING):					
Laborers, carpenters tenders, wrecking laborers	8.50	.60	.80		.10
Jackhammer ops; pavement breakers; asphalt rakers; carbide core drilling machines; chain saw ops; pipelayers, barco type jumping tampers, laser beam ops, concrete ops, mason tenders, mortar mixers, ride-on motorized buggy ops, dence beam rail erectros and plasterers tenders	8.75	.60	.80		.10
Air track, block pavers, rammers curb setter	9.00	.60	.80		.10
Blaster, powdermen	9.25	.60	.80		.10
Open air caisson, cylindrical work and boring crew:					
Laborers, top man	8.50	.60	.80		.10
Helper	8.62	.60	.80		.10
Bottom man	9.25	.60	.80		.10
Driller	9.37	.60	.80		.10
LATHERS	9.25	.45	.55		.05
LEADBURNERS	9.25	.35			
LINE CONSTRUCTION:					
Linemen	12.00	.70	3%+.50		3/8 of 1%
Equipment Operators	11.28	.70	3%+.50		3/8 of 1%
Driver Groundman	9.03	.70	3%+.50		3/8 of 1%
Groundman	7.68	.70	3%+.50		3/8 of 1%
MARBLE, TILE SETTERS & TERRAZZO WORKERS	10.30	.85	1.10		

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	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
MARBLE SETTERS' HELPERS	$ 9.33	.85	.50		
MILLWRIGHTS	11.30	.90	1.00		.10
PAINTERS:					
Essex, Gloucester, Manchester, & Rockport:					
Brush	6.20	.30			
Spray	6.65	.30			
Roller	6.50	.30			
Remainder of County:					
New Construction:					
Brush and Tapers	10.96	.82	1.20		.04
Sandblasters and spray	11.96	.82	1.20		.04
Steel (new & repaint-steel)	13.08	.82	1.20		.04
Repaint: Brush	9.26	.82	1.20		.04
Spray and Sanblasting	10.26	.82	1.20		.04
PILEDRIVERMEN	10.90	.85	1.00		
PLUMBERS & STEAMFITTERS:					
Andover, Georgetown, Groveland, Lawrence, Methuen, N. Andover	11.15	.87	1.00		.05
Lynn, Lynnfield, Nahant, Saugus and Swampscott:					
Plumbers	12.45	1.02	1.28		.05
Steamfitters	12.61	.94	1.45		.08
Remainder of County	10.95	1.65	.62		.05

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	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
ROOFERS					
Haverhill and Lawrence	$ 7.65	.70	1.55		.05
Remainder of County	10.20	.70	1.55		.05
Re-roofing & repair	9.65	.70	1.55		.05
Pitch work	11.20	.70	1.55		.05
SHEET METAL WORKERS	11.63	1.16	1.45		.08
SPRINKLER FITTERS	12.08	.65	.95		.08
TERRAZZO WORKERS' HELPERS	9.95		.25		.05

PAID HOLIDAYS:
A-New Year's Day; B-Memorial Day; C-Independence Day; D-Labor Day; E-Thanksgiving day; F-Christmas Day

FOOTNOTES:
a. Employer contributes 4% basic hourly rate for 5 years or more of service or 2% basic hourly rate for 6 months to 5 years of service as vacation pay credit.

b. Holidays: A through F

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	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
LABORERS:					
CLASS I	$ 8.50	.60	.80		.10
CLASS II	8.75	.60	.80		.10
CLASS III	9.00	.60	.80		.10
CLASS IV	9.25	.60	.80		.10

CLASSIFICATIONS

CLASS I
Carpenter tenders, cement finisher tenders, laborers, wrecking laborers

CLASS II
Asphalt rakers, fence and guard rail erectors, laser beam op., mason tender, pipelayer, pneumatic drill op., pneuamtic tool op., wagon drill op.

CLASS III
Air track op., block pavers, rammers, curb setter

CLASS IV
Blasters, powdermen

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BUILDING CONSTRUCTION:

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
POWER EQUIPMENT OPERATORS:					
CLASS I	11.75	1.10	1.00	a	.03
CLASS II	11.63	1.10	1.00	a	.03
CLASS III	9.81	1.10	1.00	a	.03
CLASS IV	10.71	1.10	1.00	a	.03
CLASS V	8.68	1.10	1.00	a	.03
CLASS VI	9.21	1.10	1.00	a	.03

CLASSIFICATIONS

CLASS I Cranes, shovels, truck cranes, cherry pickers, draglines, trench hoes, backhoes, three drum machines, derricks, pile drivers, elevator towers, hoists, gradalls, shovel dozers, front end loaders, fork lifts, augers, boring machines, rotary drills,post hole hammers, post hole diggers, pumpcrete machines, asphalt plant (on site), concrete batching and/or mixing plant (on site), crusher plant (on site), paving concrete mixers, timber jacks, Boom over 150, including jib additional $.35 per hour; Boom over 185' including jib - additional $.70 per hour; Boom 210' including jib - additional $1.00 per hour; Boom over 250' including jib - additional $1.50 per hour Boom over 295' including jib - additional $2.00 per hour
CLASS II Sonic or vibratory hammers, graders, tandem scrapers, concrete pumps, bulldozers, tractors, york rakes, mulching machines, portable steam boiler, portable steam generators, rollers, spreaders, tampers (self propelled or tractor drawn), asphalt pavers, mechanics maintenance, paying screed machines, stationary steam boilers, paving concrete finishing machines, cal trucks, ballast regulators, switch tampers, rail anchor machinery, tire trucks (when operated by the employer on the job site)
CLASS III Pumps (1-3 grouped), compressors, welding machines (1-3 grouped), generators, concrete vibrators, lighting plants, heaters (power driven 1-5), well-point systems (operating and installing), syphones-pullsometers, concrete mixers, values controlling permanent plant air or steam, conveyors, Jackson type tampers, single diaphragn pump, lighting plants
CLASS IV Assistant engineers (firemen)
CLASS V Oilers (other than truck cranes and gradalls)
CLASS VI Oilers on truck cranes and gradalls

PAID HOLIDAYS:
A-New Year's Day; B-Memorial Day; C-Independence Day; D-Labor Day; E-Thanksgiving Day; F-Christmas Day

FOOTNOTE:

a. Holidays: A through F, Washington's Birthday, Columbus Day, Veterans Day and Patriots Day.

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HEAVY & HIGHWAY CONSTRUCTION:

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
POWER EQUIPMENT OPERATORS					
GROUP 1	11.75	1.10	1.00	a	.03
Hourly premium for boom lengths including jib					
Over 150 feet + $ .45					
Over 185 feet + .80					
Over 210 feet + 1.15					
Over 250 feet + 1.75					
Over 295 feet + 2.50					
GROUP 2	11.63	1.10	1.00	a	.03
GROUP 3	9.81	1.10	1.00	a	.03
GROUP 4	10.71	1.10	1.00	a	.03
GROUP 5	8.68	1.10	1.00	a	.03
GROUP 6	9.21	1.10	1.00	a	.03

CLASSIFICATIONS

GROUP 1 Power shovels, cranes, truck cranes, derricks, pile drivers, trenching machines, mechanical hoist pavement breakers, cement concrete pavers, draglines, hoisting engines,three drum machines, pumpcrete machines, uke loaders, shovel dozers, front end loaders, mucking machines, shaft hoists, steam engines, backhoe, gradalls, cable ways, fork lifts, cherry pickers, boring machines, rotary drills, post hole hammers, port hole diggers, asphalt plant on job site, concrete batching and/or mixing plant on job site, crusher plant on job site, paving concrete mixers, timber jacks

GROUP 2 Sonic or vibratory hammers, graders, scrapers, tandem scrapers, bulldozer, tractors, mechanic maintenance, York rakes, mulching machines paving screed machines, stationary steam boilers, paving concrete finishing machine, grout pumps, portable steam boilers, portable steam generators, rollers, spreaders. asphalt pavers, locomotives or machines used in place thereof, tampers, self propelled or tractor drawn, cal tracks, ballast regulators, rail anchor machines, switch tampers

GROUP 3 Pump (1-3 grouped), compressors, welding machine (1-3 grouped), generators lighting plants, heaters (power driven) (1-5), syphons-pulsometers, concrete mixers, valves controlling permanent plant air steam, conveyors, wellpoint system (operating and installing)

DECISION NO. MA79-2008

CLASSIFICATIONS CONT'D

GROUP 4 Assistant engineers (firemen)

GROUP 5 Oilers (other than truck cranes & gradalls)

GROUP 6 Oilers (on truck cranes & gradalls)

FOOTNOTES:

a. Holidays - New Years' Day, Memorial Day, Independence Day, Labor Day, Thanksgiving Day, Christmas Day, Washington's Birthday, Columbus Day, Veterans Day and Patriots Day

DECISION NO. MA79-2008

MARINE CONSTRUCTION	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
POWER EQUIPMENT OPERATORS					
GROUP I	11.75	1.10	1.00	a	.03
GROUP II	12.85	1.10	1.00	a	.03
GROUP III	11.70	1.10	1.00	a	.03
GROUP IV	11.63	1.10	1.00	a	.03
GROUP V	9.81	1.10	1.00	a	.03
GROUP VI	10.71	1.10	1.00	a	.03
GROUP VII	8.68	1.10	1.00	a	.03
GROUP VIII	9.21	1.10	1.00	a	.03

CLASSIFICATIONS

GROUP I - Shovels, cranes, truck cranes, cherry pickers, derricks, pile drivers two or more drum machines, lighters, derricks boats, trenching, mechanics hoists pavement breakers, cement concrete pavers, draglines, hoisting engines, pumpcrete machines, elevating graders, shovel dozers, front end loaders, backhoes, gradalls, cable ways, boring machines, rotary drills, post hole hammers, post hole diggers, fork lifts, timber jacks, asphalt plant (on site), concrete batching &/or mixing plant (on site), crusher plant, (on site, paving concrete mixers; Booms over 150' including jib - additional $.45 per hour - Booms over 185' including jib - additional $.80 per hour; Booms over 210' including jib - additional $1.15 per hour; Booms over 250' including jib - additional $1.75 per hour; Booms over 295' including jib additional $2.50 per hour

GROUP II - Master Mechanic

GROUP III - Swinger Engines

GROUP IV - Portable steam boilers, portable steam generators, sonic or vibratory hammers, graders, scrapers, tandem scrapers, concrete pumps, bulldozers, tractors york rakes, mulching machines, rollers, spreaders, tamper self-propelled or tractor drawn, asphalt pavers, concrete mixers with side loaders, mechanics - maintenance, cal tracks, ballast, regulator, switch tampers, rail anchor machines, tire trucks

GROUP V - Pumps, compressors, welding machines, heaters (power driven), valves controlling permanent plan air or steam, well point systems, augers - powered by independence engines & attached to pile drivers, hydraulic saws, generators, lighting plants, syphons-pulsometers, concrete mixers, conveyors

DECISION NO. MA79-2008

CLASSIFICATIONS

GROUP VI - Assistant engineers (firemen)

GROUP VII - Oilers (other than truck cranes and gradalls)

GROUP VIII - Oilers on truck cranes and gradalls

PAID HOLIDAYS:

A-New Year's Day; B-Memorial Day; C-Independence Day; E-Thanksgiving Day; F-Christmas Day

FOOTNOTE:

A. Holidays: A through F; Washington's Birthday; Patriots' Day; Columbus Day & Veterans' Day

DECISION NO. MA79-2008

BUILDING, HEAVY AND HIGHWAY CONSTRUCTION	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
TRUCK DRIVERS					
CLASS I	$ 8.515	.75	.80	a+b	
CLASS II	8.665	.75	.80	a+b	
CLASS III	8.715	.75	.80	a+b	
CLASS IV	8.815	.75	.80	a+b	
CLASS V	8.915	.75	.80	a+b	
CLASS VI	9.165	.75	.80	a+b	
CLASS VII	9.415	.75	.80	a+b	

CLASS I - Station wagons, Panel trucks and pickup truck

CLASS II - Two axle equipment; Helpers on low bed when assigned at the discretion of the employer, warehousemen, Forklift operators

CLASS III - Three axle equipment and Tiremen

CLASS IV - Four and five axle equipment

CLASS V - Specialized earth moving equipment under 35 tons other than convential type trucks, Low bed, Vachual, Mechanics, Paving restoration equipment, Mechanics

CLASS VI - Specialized earth moving equipment over 35 tons

CLASS VII - Trailers for earth moving equipment (double hookup)

FOOTNOTES:

a. One half day's pay each month in which an employee has worked 15 days provided he has been employed for 4 months.

b. Holidays: A through F, Washington's Birthday, Columbus Day, Veteran's Day and Patriots' Day provided an employee works two days of the calendar week in which the holiday falls.

SUPERSEDEAS DECISION

STATE: North Carolina COUNTY: See below*
DECISION NUMBER: NC79-1027 DATE: Date of Publication
Supersedes Decision No. NC76-1095 dated September 3, 1976 in 41 FR 37507.
DESCRIPTION OF WORK: Residential Projects consisting of single family homes and garden type apartments up to and including 4 stories.

*Alamance, Guilford, Randolph, and Rockingham	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
AIR CONDITIONING MECHANIC	$5.43				
BRICKLAYERS	6.00				
CARPENTERS	4.99				
CARPET LAYERS	4.25				
CEMENT MASONS	5.12				
DRYWALL HANGERS	6.25				
ELECTRICIANS	5.81				
INSULATION INSTALLERS	4.89				
LABORERS:					
Laborers, unskilled	3.45				
Mason tenders	3.55				
Mortar mixers	3.55				
PAINTERS, Brush	5.40				
PLUMBERS	6.50				
ROOFERS	5.50				
SHEET METAL WORKERS	4.96				
SOFT FLOOR LAYERS	4.65				
TILE SETTERS	4.85				
TRUCK DRIVERS	3.72				
WELDERS - Rate for craft.					
POWER EQUIPMENT OPERATORS:					
Backhoe	5.01				
Bulldozer	4.59				
Fork lift operator	3.50				
Front end loader	4.60				
Grader	5.45				
Paver	4.13				
Roller	3.50				
Tractor	4.69				

SUPERSEDEAS DECISION

STATE: PENNSYLVANIA COUNTY: Northumberland
DECISION NO.: PA79-3004 DATE: Date of Publication
Supersedes Decision No. PA77-3129 dated September 16, 1977, in 42 FR 46903
DESCRIPTION OF WORK: Building Erection and Foundation Excavation Projects, (does not include single family homes and garden type apartments up to and including 4 stories.

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Asbestos Workers	11.325	.65	.60		.01
Boilermakers	13.775	1.075	1.00		.02
Bricklayers & Stonemasons	10.00	.55	.65		
Carpenters	10.30	.50	.55		.05
Cement Masons	10.50				.01
Electricians:					
Delaware, Lewis & Trubut	9.73	.50	3%+.60	.75	.02
Remainder of County	11.45	.50	3%+.20		.05
Glaziers:					
Edgewell, Ralph, Knulpmont, Coal, Marion Heights Twps:	9.19	.40	.40		.01
Remainder of County	9.79	.40	.50		.01
Ironworkers	12.105	1.14	1.36		.03
Laborers:					
North of Susquehanna River	7.45	.40	.45		
South of Susquehanna River	8.00	.30	.35		
Lathers	10.11	.40	.35		.01
Line Construction:					
Linemen, dynamite man, heavy equipment operators	11.61	.50	3%		3/8 of 1%
Winch truck operators	8.16	.50	3%		3/8 of 1%
Groundman	7.80	.50	3%		3/8 of 1%
Marble & Tile Setters	10.25		.75		
Millwrights	11.45	.50	.55		.05
Painters:					
Brush	9.55	.75	.40		.10
Tapers	9.81	.75	.40		.10
Hazardous	10.81	.75	.40		.10
Piledrivermen	11.12	2.33	1.35	a	.12
Roofers:					
Coal, East Cameron, Jackson, Jordan, Little Mahony, Lower Augusta, Upper Mahony, Point Rockfeller, Shamokin, Upper Mahony, Washington, West Cameron, Zerbe Composition	10.41	.80	.55		
Remainder of County Composition	10.15	.90	.85		
Plumbers	11.30	.70	.80		.12
Steamfitters	11.30	.70	.80		.12
Sprinkler Fitters	12.31	.75	1.05		.08
Sheet Metal Workers	11.09	.65	.71		.02
Soft Floor Layers	9.20	.50	.55		.05
Welders: Receive rate for craft					

DECISION NO.: PA79-3004 Page 2

FOOTNOTES:

a. Paid Holidays: Washington's Birthday; Good Friday; Memorial Day; Labor Day; Presidential Election Day; Veterans' Day and Thanksgiving Day.

DECISION NO. PA79-3004

POWER EQUIPMENT OPERATORS	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	App. Tr.
GROUP 1	$12.44	7%	10.3%	a	1.8%
GROUP 2	12.15	7%	10.3%	a	1.8%
GROUP 3	11.28	7%	10.3%	a	1.8%
GROUP 4	10.51	7%	10.3%	a	1.8%
GROUP 5	10.04	7%	10.3%	a	1.8%
GROUP 6	9.13	7%	10.3%	a	1.8%
GROUP 7	12.69	7%	10.3%	a	1.8%
GROUP 7-A	12.94	7%	10.3%	a	1.8%
GROUP 7-B	13.18	7%	10.3%	a	1.8%

GROUP 1: Machines doing hook work, any machine handling machinery, cable spinning machines, helicopters, machines similar to the above

GROUP 2: All types of cranes, all types of backhoes, cableways, draglines, keystones, all types of shovels, derricks, trench shovels, trenching machines, hoist with two towers, pavers 21E and over, all types overhead cranes, building hoists (double drum) gradalls, mucking machines in tunnel, all front end loaders 3-½ c.y. and over, tandem scrapers, pippin type backhoes, boat Captains, batch plant operators (concrete) drills, self-contained rotary drills, fork lifts, 20 ft. lift and over machine to the above

GROUP 3: Conveyors, building hoists (single drum) scrapers and tournapulls, spreaders, high or low pressure boilers, concrete pumps, well drillers, bulldozers and tractors, asphalt plant engineers, roller (high grade finishing), ditch witch type trencher, all loaders under 3-½ cu. yds., mechanic-welders, motor patrols, drill helper-self contained rotary drills, core drill operator, forklift trucks under 20 ft. lift, machines similar to the above

GROUP 4: Welding machines, well points, compressors, pumps, heaters, farm tractors, form line graders, fine grade machines, road finishing machines, concrete breaking machines, rollers, seaman pulverizing mixer, power broom, seeding spreader, tireman (for power equipment), machines similar to above

GROUP 5: Fireman, grease truck

GROUP 6: Oilers and deck hands (personnel boats), core drill helper

GROUP 7: All machines with booms (including jib, masts, leads, etc.): 100 ft. and over

GROUP 7-A: 150 ft. and over

GROUP 7-B: 200 ft. and over

FOOTNOTE:
a. Paid Holidays: New Year's Day, Memorial Day, Independence Day, Labor Day, Thanksgiving Day, and Christmas Day, provided the employee works the day before and after the holiday.

SUPERSEDEAS DECISION

STATE: Pennsylvania COUNTY: Lycoming
DECISION NO.: PA79-3005 DATE: Date of Publication
Supersedes Decision No. PA77-3126, dated September 9, 1977, in 42 FR 45622.
DESCRIPTION OF WORK: Building Projects (does not include single family homes and garden type apartments up to and including 4 stories).

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Asbestos Workers	11.325	.65	.60		.01
Boilermakers	13.775	1.075	1.00		.02
Bricklayers & Stonemasons	9.90	.70	.65		.015
Carpenters	10.30	.50	.55		.05
Cement Masons	9.45				
ELectricians	9.73	.50	3%+.60	.75	.02
Elevator Constructors	10.895	.745	.56	b+c	.025
Elevator Constructors' Helpers	70%ofJR	.745	.56	b+c	.025
Elevator Constructors' Helpers (Prob.)	50%ofJR				
Ironworkers	12.105	1.14	1.36		.03
Laborers:					
Unskilled laborers, scaffold builders, wrecking, window cleaners & demolition	7.45	.40	.45		
Masons tenders, operators of jackhammers, paving breakers, vibrators & other pneumatic & mechanical tools coming under the jurisdiction of laborers, wagondrill operators, excavating for caisson, under pinning & pier holes (below 12"), non-mentallic pipe layers, plasterer tenders, mortar men (mixed by hand), handling & using cutting or burning torches in the wrecking of building	7.60	.40	.45		
Lathers	10.93		.20		.01
Lead Burners	10.75	.40	.25	a	.01
Line Construction:					
Linemen & cable splicers	11.61	.50	3%		3/8%
Winch truck drivers	8.16	.50	3%		3/8%
Groundmen	7.80	.50	3%		3/8%
Millwrights	11.45	.50	.55		.05
Painters:					
Brush	9.55	.75	.40		.10
Tapers	9.81	.75	.40		.10
Hazardous	10.81	.75	.40		.10
Plasterers	10.20				
Piledrivermen	11.12	2.33	1.35	d	.12
Plumbers	10.95	.74	.60	.50	.05

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Roofers & Kettlemen	10.15	.90	.85		
Sheet Metal Workers	11.09	.65	.71		.02
Soft Floor Layers	9.20	.50	.55		.03
Sprinkler Fitters	12.31	.75	1.05		.08
Steamfitters	10.95	.74	.60	.50	.05
WELDER rate for craft					

PAID HOLIDAYS: (Where Applicable)

A-New Year's Day; B-Memorial Day; C-Independence Day; D-Labor Day; E-Thanksgiving Day and F-Christmas Day

FOOTNOTES:

a. Holidays: A through F, Washington's Birthday, Good Friday and Christmas Eve, provided the employee has worked 45 full days for the employer.

b. Employer contributes 8% basic hourly rate for 5 years or more of service or 6% basic hourly rate for 6 months to 5 years of service as vacation pay credit.

c. Paid Holidays: A through F, plus the Friday after Thanksgiving Day.

d. Holidays: Washington's Birthday, Good Friday, Memorial Day, Labor Day, Presidential Election Day; Veterans' Day and Thanksgiving Day.

POWER EQUIPMENT OPERATORS	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	App. Tr
GROUP 1	$12.44	7%	10.3%	a	1.8%
GROUP 2	12.15	7%	10.3%	a	1.8%
GROUP 3	11.28	7%	10.3%	a	1.8%
GROUP 4	10.51	7%	10.3%	a	1.8%
GROUP 5	10.04	7%	10.3%	a	1.8%
GROUP 6	9.13	7%	10.3%	a	1.8%
GROUP 7	12.69	7%	10.3%	a	1.8%
GROUP 7-A	12.94	7%	10.3%	a	1.8%
GROUP 7-B	13.18	7%	10.3%	a	1.8%

GROUP 1: Machines doing hook work, any machine handling machinery, cable spinning machines, helicopters, machines similar to the above

GROUP 2: All types of cranes, all types of backhoes, cableways, draglines, keystones, all types of shovels, derricks, trench shovels, trenching machines, hoist with two towers, pavers 21E and over, all types overhead cranes, building hoists (double drum) gradalls, mucking machines in tunnel, all front end loaders 3-½ c.y. and over, tandem scrapers, pippin type backhoes, boat Captains, batch plant operators (concrete) drills, self-contained rotary drills, fork lifts, 20 ft. lift and over machine to the above

GROUP 3: Conveyors, building hoists (single drum) scrapers and tournapulls, spreaders, high or low pressure boilers, concrete pumps, well drillers, bulldozers and tractors, asphalt plant engineers, roller (high grade finishing), ditch witch type trencher, all loaders under 3-½ cu. yds., mechanic-welders, motor patrols, drill helper-self contained rotary drills, core drill operator, forklift trucks under 20 ft. lift, machines similar to the above

GROUP 4: Welding machines, well points, compressors, pumps, heaters, farm tractors, form line graders, fine grade machines, road finishing machines, concrete breaking machines, rollers, seaman pulverizing mixer, power broom, seeding spreader, tireman (for power equipment), machines similar to above

GROUP 5: Fireman, grease truck

GROUP 6: Oilers and deck hands (personnel boats), core drill helper

GROUP 7: All machines with booms (including jib, masts, leads, etc.): 100 ft. and over

GROUP 7-A: 150 ft. and over

GROUP 7-B: 200 ft. and over

FOOTNOTE:

a. Paid Holidays: New Year's Day, Memorial Day, Independence Day, Labor Day, Thanksgiving Day, and Christmas Day, provided the employee works the day before and after the holiday.

SUPERSEDEAS DECISION

STATE: South Carolina COUNTY: Greenville
DECISION NUMBER: SC79-1047 DATE: Date of Publication
Supersedes Decision No. SC75-1038 dated March 21, 1975 in 40 FR 12951.
DESCRIPTION OF WORK: Building Construction Projects (does not include single family homes and garden type apartments up to and including 4 stories).

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
AIR CONDITIONING MECHANICS	$5.50				
BRICKLAYERS	6.10				
CARPENTERS	5.15				
CEMENT MASONS	4.85				
ELECTRICIANS	4.61				
GLAZIERS	5.60				
IRONWORKERS, STRUCTURAL & ORNAMENTAL	9.48	.60	.50		.02
LABORERS:					
Laborers, unskilled	3.00				
Mason tenders	3.25				
Pipelayers	3.50				
Plasterers' tenders	4.00				
LATHERS	7.40				
PAINTERS, Brush	5.75				
PLASTERERS	6.58				
PLUMBERS & PIPEFITTERS	5.25				
ROOFERS	3.75				
SHEET METAL WORKERS	4.00				
SPRINKLER FITTERS	8.25	.75	1.05		.08
SOFT FLOOR LAYERS	5.00				
TILE SETTERS	5.75				
TRUCK DRIVERS	3.50				
WELDERS - Ratetfor craft.					
POWER EQUIPMENT OPERATORS:					
Backhoe	4.50				
Bulldozers	4.00				
Roller	3.48				
Scrapers - Pans	4.00				

SUPERSEDEAS DECISION

STATE: South Dakota COUNTIES: Statewide
DECISION NUMBER: SD79-5113 DATE: Date of Publication
Supersedes Decision No. SD78-5001 dated January 20, 1978, in 43 FR 3028
DESCRIPTION OF WORK: Heavy and Highway Construction Projects.

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Concrete Finisher	$6.58				
Form Builder	6.58				
Form Setter	6.58				
LABORERS:					
Air Tool Operator	4.78				
Common Laborer	4.78				
Landscape Worker	4.78				
Form Builder Helpers (bridge and culvert)	5.48				
Manhole Builder	6.24				
Piledriver (leadsman)	6.06				
Pipelayer (other than culvert)	6.06				
Powderman (blaster)	7.16				
Painter	6.06				
POWER EQUIPMENT OPERATORS:					
Asphalt Distributor	6.50				
Asphalt Paving Machine	6.62				
Asphalt Paving Machine Helper	4.88				
Asphalt Plant Helper	5.48				
Asphalt Plant, Stationary and traveling	6.62				
Auger Operator (truck type)	5.48				
Automatic Fine Grader Operator	6.78				
Broom, Self-propelled	5.48				
Bulldozer, 80hp or less	5.96				
Bulldozer, over 80 hp	6.62				
Bullfloat Machine	6.34				
Concrete Batch Plant	6.62				
Concrete Mixer	5.70				
Concrete Paver	7.16				
Concrete Paving Cure Machine	5.80				
Concrete Paving Form Grader	6.78				
Concrete Paving Finishing Machine	6.78				
Concrete Paving Joint Machine	6.50				
Concrete Paving Joint Sealer	5.80				
Concrete Paving Saw	6.34				
Concrete Paving Spreader	6.78				
Concrete Paving Subgrader	6.62				
Conveyor	4.88				

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vocation	Education and/or Appr. Tr.
POWER EQUIPMENT OPERATORS (cont'd)					
Cranes, Derricks, Draglines, Piledrivers, Backhoes, and Shovels, 1¼ cu. yds. or less	$6.62				
Cranes, Derricks, Draglines, Piledrivers, Backhoes, and Shovels over 1¼ cu. yds.	7.16				
Crusher, including those with integral screening plant	6.62				
Curb Machine	5.80				
Fireman (boiler and retort)	5.52				
Front End Loader, 1¼ cu. yds. or less	5.70				
Front End Loader, 1¼ cu. yds. to 3¼ cu. yds.	6.34				
Front End Loader, over 3¼ cu. yd	6.62				
Mechanic, heavy duty	7.06				
Mechanic Helper	5.70				
Mechanic, maintenance	6.34				
Motor Grader, finish	7.16				
Motor Grader, rough	6.50				
Oiler and Greaser	6.34				
Roller, self-propelled (hot mix)	5.80				
Roller, self-propelled (other)	5.22				
Roller, Sheepsfoot or 50 ton pneumatic	5.80				
Scrapers	7.42				
Spreader (materials)	6.34				
Stationary Plant	5.80				
Tractor, Crawler or Pneumatic	5.80				
Tractor, farm type with attachments (including loader)	4.88				
Tractor - pusher	6.88				
Traveling Plant (stabilization)	6.62				
Traveling Plant, helper	4.88				
Trenching Machine	6.34				
Wagon Drill including airtrac, trac-drill, etc.	6.34				
TRUCK DRIVERS:					
Euclid or Dumptor	5.44				
Truck Cranes	5.32				
Truck, single axle	4.78				
Truck, tandem or semi-trailer	5.22				
WELDERS:					
Welder, certified	6.78				
Welder, general	6.34				

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vocation	Education and/or Appr. Tr.
LINE CONSTRUCTION:					
Group 1	$11.40	.45	3%		1/2%
Group 2	11.37	.45	3%		1/2%
Group 3	9.12	.45	3%		1/2%
Group 4	7.60	.45	3%		1/2%
Group 5	6.98	.45	3%		1/2%

GROUP 1: Journeyman Cable Splicer; Journeyman Lineman.

GROUP 2: Tractor dozer operator, D-4 and larger; all rigs erecting steel tower and "H" fixtures, also tension pulling machines.

GROUP 3: Groundman - Operating special equipment. Hole digging machines; Aerial baskets on energized circuits; Tractors, D-4 and larger, Transmission line pole hauling; All fifth wheel trucks and other setting and assembly equipment excluding steel tower and "H" fixtures erection.

GROUP 4: Groundman - Truck or tractor driver with winch; Operators of trucks up to and including 2½ tons; Tractor including D-2 and smaller, including wheel tractors and crawler tractors.

GROUP 5: Groundman - Truck or tractor driver without winch; Operators of trucks up to and including 2½ tons D-2 and smaller, including wheel tractors and crawler tractors.

SUPERSEDEAS DECISION

STATE: Texas
DECISION NO.: TX79-4031
COUNTY: Bexar
DATE: Date of Publication
Supersedes Decision No. TX78-4081, dated August 18, 1978, in 43 FR 36851.
DESCRIPTION OF WORK: Building Construction Projects (does not include single family homes and garden type apartments up to 4 including 4 stories). (Use current heavy & highway general wage determination for Paving & Utilities Incidental to Building Construction).

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
ASBESTOS WORKERS	$11.05	.60	.60		.08
BOILERMAKERS	11.05	.80	1.00		.02
BRICKLAYERS & STONEMASONS	10.02	.45	.30	.25	.05
CARPENTERS:					
Carpenters	9.24	.48	.50	.40	.05
Millwrights	9.54	.48	.50	.40	.05
CEMENT MASONS	9.45	.45		.65	.02
ELECTRICIANS:					
Electricians	10.94	.60	5%		1%
Cable splicers	11.19	.60	5%		1%
ELEVATOR CONSTRUCTORS:					
Mechanics	10.34	.895	.69	4%+a+b	.035
Helpers	70%JR	.895	.69	4%+a+b	.035
Helpers (Prob.)	50%JR				
GLAZIERS	6.80				
IRONWORKERS	8.75	.55	1.15	.50	.07
LABORERS:					
GROUP 1 - General laborers	5.66	.38	.40		.05
GROUP 2 - All power tools & equipment operators; cutting torch man; power buggy op.; wagon drill op.; well driller; drilling rig tender; cement finisher tender; handling creosoted materials; scale man on batch plants; asphalt raker; concrete & clay & all non-metallic pipe laying; plasterer tender; brick tender; lather tender	5.91	.38	.40		.05
GROUP 3 - Mortar mixer man; grout machines; pumpcrete machines; gunnite mixing machines; running sand dryer & loading; operating sand blaster; bell hole man; blaster, powderman; gunnite nozzleman	6.01	.38	.40		.05
LINE CONSTRUCTION:					
Lineman	11.32	.60	3%		1/2%
Cable splicer	11.57	.60	3%		1/2%
Groundman (1st year)	5.66	.60	3%		1/2%
Groundman	6.23	.60	3%		1/2%

DECISION NO. TX79-4031

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
MARBLE SETTERS	$ 9.29	.45	.30	.25	
MARBLE SETTERS' FINISHERS	6.37				
PAINTERS:					
Brush; Paperhanger; Taper & floater	8.85		.20		.05
Spray; Structural steel	9.10		.20		.05
Spray on structural steel; Sandblasting	9.35		.20		.05
PLUMBERS & PIPEFITTERS	11.48	.55	.55		.10
ROOFERS:					
Roofers; Deckman	6.95	.25			
Kettlemen	6.18	.25			
Waterproofers	6.54	.25			
SHEET METAL WORKERS	10.89	3%+.45	.77		.07
SOFT FLOOR LAYERS	6.35				
SPRINKLER FITTERS	11.60	.75	1.05		.08
TERRAZZO WORKERS	9.29	.45	.30	.25	
TERRAZZO WORKERS' FINISHERS:					
Terrazzo finishers	6.37				
Floor machine operators	6.57				
Base machine operators	6.77				
TILE SETTERS	9.29	.45	.30	.25	
TILE SETTERS' FINISHERS	6.37				
TRUCK DRIVERS	3.64				
WELDERS - receive rate prescribed for craft performing operation to which welding is incidental.					

FOOTNOTES FOR ELEVATOR CONSTRUCTORS:
a - 1st 6 mos. - none; 6 mos. to 5 yrs. - 2%; over 5 yrs. - 4% of basic hourly rate
b - Paid Holidays A thru G

PAID HOLIDAYS FOR ELEVATOR CONSTRUCTORS:
A-New Years' Day; B-Memorial Day; C-Independence Day; D-Labor Day; E-Thanksgiving Day; F-the Friday after Thanksgiving Day; G-Christmas Day

DECISION NO. TX79-4031

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
POWER EQUIPMENT OPERATORS					
GROUP 1	$ 9.27	.45	.75		
GROUP 2	8.28	.45	.75		
GROUP 3	6.98	.45	.75		
GROUP 4	6.71	.45	.75		

CLASSIFICATION DEFINITIONS

GROUP 1 - All foundation drilling rigs; All rollers (5 tons or over); Backfiller; Backhoe; Blade graders (self-propelled); Bull clam; Bulldozers; Cableway; Clamshell operator; Crane (power operated, all types); Derricks (power operated, all types); Draglines; DW-10 caterpillar and similar tractors; Elevating graders (self-propelled); Euclid; Fork lift used on construction; Gasoline or diesel-driven welding machines (7 to 12); Gradall; Heavy duty mechanic; High lifts; Hoist (two drums or more); Locomotives; Mixer (14 cu. ft. or over); Mixmobile; Paving mixers (all sizes); Piledrivers; Pumpcrete machine operator; Rock crusher operator on job; Scoopmobile; Scrapers; Shovel (power operated); Turnapulls; Trenching machines (all sizes); Winch truck; All other equipment of similar nature, coming within the heavy equipment class, when power operated

GROUP 2 - Air compressor (any time there are three or more attachments operating on a 125 cu. ft. air compressor or less, a light equipment operator shall be employed. Any compressor over 125 cu. ft. shall have a light equipment operator); Blade graders (towed); Building elevator used on construction; Flex planes; Form graders; Hoist (single drum); Mixer (less than 14 cu. ft.); Pneumatic roller; Pulsometers; Pump (2½ or larger shall require a light equipment operator); Three to six welding machines or any three pieces or equipment of equal or similar nature, coming within the light equipment class when power operated; Roller (under 5 tons); Truck crane drivers

GROUP 3 - Fireman

GROUP 4 - Oiler

SUPERSEDEAS DECISION

STATE: Texas COUNTY: Harrison

DECISION NO.: TX79-4032 DATE: Date of Publication

Supersedes Decision No. TX78-4038, dated April 14, 1978, in 43 FR 16129.

DESCRIPTION OF WORK: Building Construction Projects (does not include single family homes & garden type apartments up to & including 4 stories). (Use current heavy & highway general wage determination for Paving & Utilities Incidental to Building Construction).

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
ASBESTOS WORKERS	$10.83	.50	.76		.03
BOILERMAKERS	11.05	.80	1.00		.02
BRICKLAYERS & STONEMASONS	10.75		.25		
CARPENTERS	6.59				
CEMENT MASONS	8.00				
ELECTRICIANS:					
Electricians	10.20	.60	3%		1/4%
Cable splicers	10.55	.60	3%		1/4%
GLAZIERS	5.15				
IRONWORKERS	6.88				
LABORERS:					
Laborers	3.21				
Mason tenders	4.15				
Plasterers' tenders	4.75				
LATHERS	8.95	.40	.20		
PAINTERS:					
GROUP 1 - Journeymen painters, paperhangers, hand rollers & tools used for cleaning	5.155				
GROUP 2 - Window jack or window sill; Sand tape & floating	5.275				
GROUP 3 - Swing stage; Spray & sandblasting; Sign painting; Steel swing stage, boatswain's chair, brush	5.65				
GROUP 4 - Steam cleaning, buffing, burners & torches	6.90				
GROUP 5 - Steel brush	5.40				
GROUP 6 - Steel swing stage, boatswain's chair, spray & sandblasting	7.65				
PLASTERERS	8.075				
PLUMBERS & PIPEFITTERS	7.60				
ROOFERS	8.10				
SHEET METAL WORKERS	10.425	.50	.66		.105
SPRINKLER FITTERS	11.60	.75	1.05		.08
WELDERS - receive rate prescribed for craft performing operation to which welding is incidental.					

DECISION NO. TX79-4032

POWER EQUIPMENT OPERATORS	Basic Hourly Rates	Fringe Benefits Payments: H & W	Pensions	Vacation	Education and/or Appr. Tr.
GROUP 1	$ 8.065	.40	1.00		.10
GROUP 2	9.40	.40	1.00		.10
GROUP 3	9.80	.40	1.00		.10

POWER EQUIPMENT OPERATORS CLASSIFICATION DEFINITIONS

GROUP 1 - Oiler-Fireman

GROUP 2 - Air compressor (1); Pump (1); Pulsometer; Conveyor; Throttle valves; Wagon drill; Elevators building; Form graders; Hoist, single drum; Mixers, less than 14 cu. ft.; Screening plants; Welding machine gas & diesel (2 or more); Crushing plants; Fork lifts (short, under 25 feet); Concrete pumps (all types); Bobcat type equipment

GROUP 3 - Ford tractor or like with any attachments (except backhoe); Drilling machines (all types); Scoopmobile; Hoist, two drums or more; Forklifts (over 25 feet); Winch trucks; Six wheel truck, when used continuously for 5 days; Mixermobile; Locomotives; Mixer, 14 cu. ft. or over; Blade graders, self-propelled; Cableways; Cranes - power operated to 100 feet; Fordson type backhoe; Derrick, power operated (all types); Gradall; Hy-Ho; Hop-To; Paving Mixer (all types); Pile drivers; Mobile concrete mixers over 14 cu. ft.; Bulldozers, loaders, tractovators; Scrapers and pulls; Welders; Trenching machines; Roller, ten tons or over; Air compressors, three; Air compressors & 1 pump; Pump, three or more; Air compressor & air tugger; Boilers, two or more fired by one man; Heavy duty mechanic

SUPERSEDEAS DECISION

STATE: Texas
DECISION NO.: TX79-4033
COUNTIES: Jefferson & Orange
DATE: Date of Publication
Supersedes Decision No. TX78-4080, dated August 11, 1978, in 43 FR 35886.
DESCRIPTION OF WORK: Building (including Residential) Construction Projects.

	Basic Hourly Rates	Fringe Benefits Payments: H & W	Pensions	Vacation	Education and/or Appr. Tr.
ASBESTOS WORKERS:					
Jefferson County	$11.75	.90	.90		.05
Orange County	11.47	.525	.90		.04
BOILERMAKERS	11.05	.80	1.00		.02
BRICKLAYERS & STONEMASONS	12.46	.63	.60		.04
CARPENTERS:					
Carpenters:					
Commercial	10.965	.55	.30		.05
Residential construction of not more than two units & condominium townhouses of not more than 6 units, excluding all apartments construction & multiple buildings for rental purposes	10.51	.55	.30		
Millwrights	11.405	.55	.30		.02
Piledrivermen	11.26	.55	.30		
CEMENT MASONS	11.02				
ELECTRICIANS	13.35	.50	3%+.285		.06
ELEVATOR CONSTRUCTORS:					
Mechanics	10.74	.895	.69	4%+a+b	.035
Helpers	70%JR	.895	.69	4%+a+b	.035
Helpers (Probationary)	50%JR				
GLAZIERS:					
Northern ½ of Jefferson Co.	10.875				
Southern ½ of Jefferson Co. & all of Orange Co.:					
Commercial	10.25				
Residential	10.10				
IRONWORKERS	10.55	.55	1.15		.10
LABORERS:					
GROUP 1 - Common laborer; asphalt ironer & raker; sand blaster, exclusive of preparation for painters; dumper, spotter & wagon drill; powder-man-blaster; well driller	6.68	.38	.53		.02
GROUP 2 - Carpenter tender	6.83	.38	.53		.02
GROUP 3 - Cement masons tender; air tool op. (jackhammer-vibrator)	6.88	.38	.53		.02
GROUP 4 - Plaster & lather tender; pipelayers, non-metallic pipe, including handling & laying pumperete pipe	6.98	.38	.53		.02
GROUP 5 - Mortar mixers, hod carriers & mason tender	7.03	.38	.53		.02
GROUP 6 - Machine man & nozzleman for gunniting 1½" and over	7.155	.38	.53		.02
LATHERS	11.385	.55			.01
LINE CONSTRUCTION:					
Linemen	13.635	.50	3%		1/2%
Groundmen	9.95	.50	3%		1/2%
PAINTERS:					
Southern ½ of Jefferson Co. & all of Orange Co.:					
GROUP 1 - Brush, wood & wall, paperhanger:					
Commercial	10.25				
Residential	10.10				
GROUP 2 - Brush, steel:					
Commercial	10.30				
Residential	10.15				

DECISION NO. TX79-4033

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
GROUP 3 - Spray:					
Commercial	$10.75				
Residential	10.62				
GROUP 4 - Sandblaster, power cleaning; All time spent rigging:					
Commercial	10.575				
Residential	10.36				
GROUP 5 - Brush, hot paint or creosote:					
Commercial	11.00				
Residential	10.36				
GROUP 6 - Spray, hot paint or creosote:					
Commercial	11.50				
Residential	10.89				
Twenty-five cents (25¢) per hour premium on all work from stage, chair, window jack or ledge in all classifications					
Northern ½ of Jefferson Co.:					
GROUP 1 - Brush:					
Commercial	10.975				
Residential	10.725				
GROUP 2 - Paper & vinyl hanger:					
Commercial	11.225				
Residential	10.975				
GROUP 3 - Brush, steel:					
Commercial	11.15				
GROUP 4 - Spray:					
Commercial	11.40				
Residential	11.15				
Twenty-five cents (25¢) per hour above the prevailing wage rate when working on window jacks or ledge, swing stage, bosun chair, cat walks, spider & skates in all classifications					
PIPEFITTERS	11.31	.65	.75		.08
PLASTERERS	11.30	.87	.30		.02
PLUMBERS	12.37	.34			.03
ROOFERS	9.61	.42	.35	.25	.06
SHEET METAL WORKERS:					
Commercial	11.30	.45	.55		.11
Work on a single family dwelling or multiple family housing unit less than 3 stories in height where each individual family apartment is indivudually conditioned by a separate & independent unit or system	6.98	3%+.40	.27		.10
SPRINKLER FITTERS	11.60	.75	1.05		.08
TILE SETTERS	10.95	.63	.60		.04
TRUCK DRIVERS:					
GROUP 1 - Under 1½ tons & wash, grease, tireman, fuel pump operators when used on construction	8.66	.53			
GROUP 2 - 1½ tons thru 2½ tons, dump truck less than 7 yds.	9.09	.53			
GROUP 3 - Over 2½ tons, farm tractors (when used to transport personnel or material), fork lifts (when used in warehouses, storage yards & when used to transport material), floats, hydraulic tail gate lifts	9.28	.53			
GROUP 4 - Euclids (not self-loading)	9.38	.53			
GROUP 5 - Warehousemen-material checker ; town driver	9.42	.53			

DECISION NO. TX79-4033

WELDERS - receive rate prescribed for craft performing operation to which welding is incidental.

FOOTNOTES FOR ELEVATOR CONSTRUCTORS:
a - 1st 6 mos. - none; 6 mos. to 5 yrs. - 2%; over 5 yrs. - 4% of basic hourly rate
b - Paid Holidays A thru G

PAID HOLIDAYS FOR ELEVATOR CONSTRUCTORS
A-New Years' Day; B-Memorial Day; C-Independence Day; D-Labor Day; E-Thanksgiving Day; F-the Friday after Thanksgiving Day; G-Christmas Day

POWER EQUIPMENT OPERATORS	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
GROUP 1	$11.835		.25		
GROUP 2	9.92		.25		
GROUP 3	9.20		.25		
GROUP 4	8.99		.25		

GROUP 1 - Heavy Duty Mechanic; Blade Grade, self-propelled; Bull Clam; Back Filler; Derrick - power operated, all types; Draglines; Push Cat; Bulldozer and all types of Cat Tractors; Cableway; Backhoe; Shovel; Crane-power operated, all types; Elevating Grader, self-propelled; Hoist - motor driven, two drums or more; Mix mobile; Winch Truck; Locomotive Crane; Mixer, 14 cu. ft. or more; Paving Mixer, all sizes; Piledrivers; Scraper - heavy type, over 3 cu. yds.; Trench Machine, all sizes; Gradall; High-Lift; Foundation Boring Machines; Gasoline or diesel driven welding machines - 7 to 12 machines; Pumpcrete Machine; Drill Operator - Water Well; DW-10 Euclid; Tournapulls; Asphalt Plants; Crushing Machines & Batch Plants; Scoopmobiles; Fingerlift Operator; Elevator when used to haul men or material on construction work; Well Point System & operation of similar dewatering devices
GROUP 2 - Air Compressor; Blade Grade - Towed; Flex Plane; Form Grader; Mixer, less than 14 cu. ft.; Pump, Pulsometer; Truck Crane Driver; Gasoline or diesel driven welding machines, 3 to 6 machines; Hoist - Single Drum; Scraper, 3 cu. yds. or less; Conveyors - power operated
GROUP 3 - Fireman
GROUP 4 - Oiler

SUPERSEDEAS DECISION

STATE: Texas COUNTY: Travis
DECISION NO.: TX79-4038 DATE: Date of Publication
Supersedes Decision No. TX78-4085, dated August 25, 1978, in 43 FR 38283.
DESCRIPTION OF WORK: Building Construction Projects (does not include single family homes & garden type apartments up to & including 4 stories). (Use current heavy & highway general wage determination for Paving & Utilities Incidental to Building Construction).

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
ASBESTOS WORKERS	$11.05	.60	.60		.08
BOILERMAKERS	11.05	.80	1.00		.02
BRICKLAYERS & STONEMASONS	10.42	.50	.40		.05
CARPENTERS:					
Carpenters	10.41	.48	.40		.04
Millwrights	10.66	.48	.40		.04
CEMENT MASONS	9.34	.60	.55		
ELECTRICIANS & CABLE SPLICERS	11.50		8%		.8%
ELEVATOR CONSTRUCTORS:					
Mechanics	10.24	.895	.69	4%+a+b	.035
Helpers	70%JR	.895	.69	4%+a+b	.035
Helpers (Probationary)	50%JR				
GLAZIERS	8.56		.20		.01
IRONWORKERS	10.05	.55	1.00		.12
LABORERS:					
GROUP 1 - General laborer and pier hole men	6.105	.275	.40		.02
GROUP 2 - Mason tender; Pipelayer (concrete & clay); Cement finisher tender; Scaffold builder; Gunnite & cement work mixer & power tool operator	6.255	.275	.40		.02
GROUP 3 - Plaster tender; Hod carrier; Mortar mixers; Lather tender; Water or damp proofers	6.43	.275	.40		.02
GROUP 4 - Gunnite over 1½" thick; Nozzlemen; Machine operator; Powderman & blaster	6.505	.275	.40		.02
LATHERS	10.925				.01
LINE CONSTRUCTION:					
Linemen	11.56	.60	3%		1/2%
Groundmen	6.36	.60	3%		1/2%
Groundmen (1st year)	5.78	.60	3%		1/2%
MARBLE, TILE & TERRAZZO WORKERS	8.46	.45			.04
MARBLE, TILE & TERRAZZO FINISHERS:					
Marble, tile & terrazzo finisher	6.37				
Terrazzo floor machine ops.	6.57				
Terrazzo base machine ops.	6.77				

DECISION NO. TX79-4038

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
PAINTERS:					
GROUP 1 - Brush; Taping & floating of sheetrock	$ 7.95				
GROUP 2 - Paperhangers; Chipper, burner, torch; Skeleton steelwork erected	8.20				
GROUP 3 - Spray; Steam cleaning, sand blast & other powered equipment	8.45				
Swinging stage, bosun chair, window jack or scaffold (above 2nd floor) - 25¢ per hour above all base rates					
PLASTERERS	9.99	.60	.55		.01
PLUMBERS & PIPEFITTERS	11.05	.45	.40		.05
ROOFERS:					
Roofers	5.23				.01
Kettlemen	5.08				.01
SHEET METAL WORKERS	10.89	3%+.45	.77		.07
SOFT FLOOR LAYERS	10.53	.50	.45		.14
SPRINKLER FITTERS	11.60	.75	1.05		.08
WELDERS - receive rate prescribed for craft performing operation to which welding is incidental.					

FOOTNOTES FOR ELEVATOR CONSTRUCTORS:
a - 1st 6 months - none; 6 months to 5 years - 2%; over 5 years - 4% of basic hourly rate
b - Paid Holidays A thru G

PAID HOLIDAYS FOR ELEVATOR CONSTRUCTORS
A-New Years' Day; B-Memorial Day; C-Independence Day; D-Labor Day; E-Thanksgiving Day; F-the Friday after Thanksgiving Day; G-Christmas Day

DECISION NO. TX79-4038

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
POWER EQUIPMENT OPERATORS					
GROUP 1	$10.44		.40		
GROUP 2	9.37		.40		
GROUP 3	8.15		.40		
GROUP 4	8.04		.40		

POWER EQUIPMENT OPERATORS CLASSIFICATION DEFINITIONS

GROUP 1 - Heavy Duty Mechanic; Blade Grader - Self-propelled; Bull Clam; Back Filler; Derricks, power operated (all types); Dragline; Push Cat Operator; Euclid Operator; Bull Dozer and all types of Cat Tractors; Cable-Way; Back Hoe; Crane, Power Operated (all types); Elevating Grader, self-propelled; Hoist, Motor Driven, two drums or more; Mix Mobile; High-Lifts & loaders, over 1/3 cu. yd. capacity; Winch Truck; Locomotive; Mixer, 14 cu. ft. or over; Paving Mixer (all sizes); Scraper; Trenching Machine (all sizes); Gradall; Foundation Boring Machine; Scoopmobile; Shovel, Power Operated; Pump Crete Machine; Clam Shell Operator; Rock Crusher, Operated on Job; Welding Machine, 6 to 12, Two 125 cu. ft. Compressors; Well Points, including installations

GROUP 2 - Blade Grader, Towed; Flex Plane; Form Grader; Mixer, less than 14 cu. ft.; Pulsometer; Truck Crane Driver & Oiler, Combination man; Gasoline or Diesel Driven Welding Machine, 3 to 6; Hoist, Single Drum; Pump, 2½ in. or larger; Pneumatic Roller; High-Lifts & Loader, 1/3 cu. yd. or less; Forklift, 1500 lbs. capacity or less; Air Compressors, anytime there are two or more attachments operating on a 125 cu. ft. compressor, a light equipment operator shall be employed. One 125 cu. ft. air compressor and one welding machine requires no operator. One 125 cu. ft. compressor and two welding machines or any 2 air compressors equivalent to a 125 cu. ft. air compressor requires a light equipment operator

GROUP 3 - Firemen

GROUP 4 - Oiler

SUPERSEDEAS DECISION

STATE: Texas COUNTIES: Ector & Midland
DECISION NO.: TX79-4039 DATE: Date of Publication
Supersedes Decision No. TX78-4095, dated September 22, 1978, in 43 FR 43241.
DESCRIPTION OF WORK: Building Construction Projects (does not include single family homes & garden type apartments up to & including 4 stories). (Use current heavy & highway general wage determination for Paving & Utilities Incidental to Building Construction).

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
ASBESTOS WORKERS	$10.50	.80	.95		.07
BOILERMAKERS	11.05	.80	1.00		.02
BRICKLAYERS & STONEMASONS:					
Ector County	8.00				
Midland County	9.60				
CARPENTERS	9.70				.05
CEMENT MASONS	6.00				
ELECTRICIANS:					
ZONE 1 - shall include that area covered by the city limits of Midland & Odessa & extend out 20 miles therefrom	10.65	.60	3%		1/10%
ZONE 2 - shall include that area extending from the outer limits of Zone 1 out to & including 50 miles from the city limits of Midland & Odessa	10.95	.60	3%		1/10%
ZONE 3 - shall include that area extending from the outer limits of Zone 2 & shall extend to the outside limits of the Union Jurisdiction	11.15	.60	3%		1/10%
GLAZIERS	5.48				
IRONWORKERS:					
Structural; Ornamental; Reinforcing	9.40	.55	1.00		.10
All ironworkers on jobs 30 miles or more from Terminal (midway Odessa-Midland)	9.525	.55	1.00		.10
LABORERS	3.94				
LATHERS	9.45				
PAINTERS:					
Brush	8.59				
Spray & sandblasters	9.34				
PLASTERERS	8.20				.01
PLUMBERS & PIPEFITTERS:					
ZONE 1 - shall be 15 miles or less from the Courthouse of either Odessa or Midland	9.41		.44		.02
ZONE 2 - shall be more than 15 miles but less than 30 miles	9.51		.44		.02
ZONE 3 - shall be more than 30 miles but less than 45 miles	9.61		.44		.02
ZONE 4-shall be more than 45 miles	9.91		.44		.02

DECISION NO. TX79-4039

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
ROOFERS	$ 5.65				
SHEET METAL WORKERS	6.32				
TILE SETTERS	5.25				
TRUCK DRIVERS	3.94				
POWER EQUIPMENT OPERATORS:					
Asphalt paving machines	4.25				
Asphalt rakers	4.00				
Backhoes	4.90				
Bulldozers	4.50				
Cranes, derricks & draglines	5.59				
Foundation drills	4.12				
Front end loaders	4.00				
Motor graders	5.25				
Scrapers	4.00				
WELDERS - receive rate prescribed for craft performing operation to which welding is incidental.					

SUPERSEDEAS DECISION

STATE: Texas

COUNTIES: Armstrong, Carson, Castro, Childress, Collingsworth, Dallam, Deaf Smith, Donley, Gray, Hansford, Hartley, Hemphill, Hutchinson, Lipscomb, Moore, Ochiltree, Oldham, Potter, Randall, Roberts, Sherman, Swisher & Wheeler

DECISION NO.: TX79-4048

DATE: Date of Publication

Supersedes Decision No. TX79-4007, dated January 5, 1979, in 44 FR 1679.

DESCRIPTION OF WORK: Building Construction Projects (does not include single family homes & garden type apartments up to & including 4 stories). (Use current heavy & highway general wage determination for Paving & Utilities Incidental to Building Construction).

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
ASBESTOS WORKERS	$10.50	.80	.95		.07
BOILERMAKERS	11.05	.80	1.00		.02
BRICKLAYERS & STONEMASONS	10.70		.40		
CARPENTERS:					
ZONE 1 - Armstrong, Carson, Castro, Collingsworth, Dallam, Deaf Smith, Donley, Gray, Hansford, Hartley, Hemphill, Hutchinson, Lipscomb, Moore, Ochiltree, Oldham, Potter, Randall, Roberts, Sherman, Swisher & Wheeler Counties:					
Carpenters	10.30		.40		.01
Millwrights	10.65		.40		.01
ZONE 2 - Childress County:					
Carpenters	10.36	.48	.50		.07
Millwrights	10.86	.48	.50		.07
CEMENT MASONS	8.30				
ELECTRICIANS:					
ZONE 1 - Armstrong, Carson, Castro, Collingsworth, Dallam, Deaf Smith, Donley, Gray, Hansford, Hartley, Hemphill, Hutchinson, Lipscomb, Moore, Ochiltree, Oldham, Potter, Randall, Roberts, Sherman, Swisher & Wheeler Counties:					
Electricians	11.08	.60	3%+.25		1/2%
Cable splicers	12.19	.60	3%+.25		1/2%
ZONE 2 - Childress County:					
Electricians	10.50	.50	3%		1/10%
Cable splicers	10.75	.50	3%		1/10%
GLAZIERS	7.90			a	
IRONWORKERS:					
ZONE 1 - Armstrong, Carson, Castro, Childress (excluding southeastern 1/4), Collingsworth, Dallam, Deaf Smith, Donley, Gray, Hansford, Hartley, Hemphill, Hutchinson, Lipscomb, Moore, Ochiltree, Oldham, Potter, Randall, Roberts, Sherman, Swisher & Wheeler Cos.	9.95	.55	1.15		.10
ZONE 2 - Childress Co. (Southeastern 1/4):	9.525	.55	1.00		.10
LABORERS:					
GROUP 1 - General or construction laborers	5.67	.53	.32		
GROUP 2 - Air or electric tool ops., jackhammers, vibrator tampers, chipping hammers, pipe wrappers, kettleman, asphalt rakers, sand blasterers, pot-tenders, riprap stone pavers, cutting torch ops. (demolition), mortar mixer (hand or machine), mason tenders, plasterer tenders, hod carriers, loader & placer, chuck tenders, timberman, collapsible form setters, concrete power buggy ops.; carpenter tenders, pipe layers: main, sewer & drainage; make-up man, powderman & blasters; gunite ops. or concrete ops.	5.82	.53	.32		

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
LATHERS	$10.85				.01
LINE CONSTRUCTION:					
ZONE 1 - Childress County:					
Lineman; Operator	10.50	.50	3%		1/2%
Cable splicers	10.75	.50	3%		1/2%
Groundman - 1st 6 months	50%JR	.50	3%		1/2%
Groundman - 2nd 6 months	60%JR	.50	3%		1/2%
Groundman - 1 year & over	70%JR	.50	3%		1/2%
ZONE 2 - Armstrong, Carson, Castro, Collingsworth, Dallam, Deaf Smith, Donley, Gray, Hansford, Hartley, Hemphill, Hutchinson, Lipscomb, Moore, Ochiltree, Oldham, Potter, Randall, Roberts, Sherman, Swisher & Wheeler Counties:					
Lineman	11.08	.60	3%+.25		1/2%
Cable splicers	12.19	.60	3%+.25		1/2%
Groundman:					
More than 1 year experience	7.29	.60	3%+.25		1/2%
Less than 1 year experience	6.39	.60	3%+.25		1/2%
Operator-hole digger, line truck	8.48	.60	3%+.25		1/2%
Flat bed truck driver	6.39	.60	3%+.25		1/2%
MARBLE MASONS (EXTERIOR)	10.70		.40		
PAINTERS:					
GROUP 1 - Brush & roller; paper hangers; perfs-tapers	9.30		.50		
GROUP 2 - Structural steel; swinging stage or chair below 50 ft.	9.42		.50		
GROUP 3 - Spray & sandblasters	10.05		.50		
GROUP 4 - Perfs-tape machine op.	9.55		.50		
PLASTERERS	10.85				.01
PLUMBERS & PIPEFITTERS:					
ZONE 1 - shall extend a distance of 25 road miles from the police station in either Amarillo or Borger	10.37	.45	.65	.60	
ZONE 2 - shall extend a distance of 25 to 50 road miles from either Amarillo or Borger	10.62	.45	.65	.60	
ZONE 3 - shall extend a distance of 50 road miles & over from either Amarillo or Borger	10.87	.45	.65	.60	
ROOFERS	4.50				
SHEET METAL WORKERS	10.89	.50	.55		.11
SPRINKLER FITTERS	11.60	.75	1.05		.08
TRUCK DRIVERS:					
1/2 ton to 3 tons; Ready mix concrete to 3 yds.	2.90				
3 to 5 tons; Ready mix concrete over 3 yds.	3.13				
5 tons and over	3.38				
WELDERS - receive rate prescribed for craft performing operation to which welding is incidental.					

FOOTNOTE FOR GLAZIERS:
a - Paid Holidays A thru F

PAID HOLIDAYS FOR GLAZIERS:
A-New Year's Day; B-Memorial Day; C-Independence Day; D-Labor Day; E-Thanksgiving Day; F-Christmas Day

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
POWER EQUIPMENT OPERATORS					
GROUP 1	$10.25	.40	.50		.10
GROUP 2	9.75	.40	.50		.10
GROUP 3	7.80	.40	.50		.10

POWER EQUIPMENT OPERATORS CLASSIFICATION DEFINITIONS

GROUP 1 - Blade Grader, self-propelled; Clam Shells; Cable Ways; Cranes, power operated (all types); Air Compressors, Pumps, Welding Machines & Light Plants (7 to 12 machines); Derricks, power operated (all types); Draglines; Elevating Graders, self-propelled; Hoist, 2 drum or more; Locomotive; Mixermobiles; Paving Mixers, all types; Pile Drivers; Scrapers; Bulldozers; Side Boom; Cherry Pickers-12½ ton & over; Shovels; Heavy Duty Mechanics; All Welders; All tractors with power attachments; Ditching Machines - crawler type; Farm type Tractor (Loader, 1 yd. & over) with Backhoe; All other equipment of similar nature coming within to Heavy Equipment Classification when power operated

GROUP 2 - Air Compressors, Pumps, Welding Machines, Throttle Valves, Light Plants (3 to 6 machines); Cherry Pickers - under 12½ tons; Ditch Witch - J30 and under; Farm type Tractor (Loader under 1 yd.) with Backhoe; Go-Devil; Mixers, 14 cu. ft. or over; Rollers over 10 tons; Air Compressor and one Tugger; Boilers, 2 or more; Winch Trucks; Front End Scoopmobile, Loader, PayLoader; Blade Grader, towed; Elevators, Building; Fork Lifts; Hoist, single drum or 1 line hoisting (1 tugger); Mixers less than 15 cu. ft.; Rollers; Screening Plants; Crushing Plants; Tractors-Wheel type except when hauling material; All other equipment of similar nature coming within the Light Equipment Classification when power operated

GROUP 3 - Oiler-Fireman-Greaser

SUPERSEDEAS DECISION

STATE: Texas COUNTY: Howard
DECISION NO.: TX79-4049 DATE: Date of Publication
Supersedes Decision No. TX78-4039, dated April 14, 1978, in 43 FR 16130.
DESCRIPTION OF WORK: Building (including Residential) Construction Projects.

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
BRICKLAYERS	$ 7.00				
CARPENTERS	6.10				
CEMENT MASONS	5.00				
ELECTRICIANS	7.40	.30	1%		1/10%
IRONWORKERS, Structural & Ornamental	9.40	.55	1.00		.10
LABORERS:					
Laborers	3.06				
Mason tenders	3.50				
PAINTERS	4.50				
PLUMBERS	4.26				
ROOFERS	4.00				
SHEET METAL WORKERS	5.25				
TILE SETTERS	4.00				
TRUCK DRIVERS	2.90				
WELDERS - receive rate prescribed for craft performing operation to which welding is incidental.					

DECISION NO. TX79-4049 Page 2

INCIDENTAL PAVING & UTILITIES (BUILDING CONSTRUCTION)
INCIDENTAL PAVING & UTILITIES & SITE PREPARATION (RESIDENTIAL CONSTRUCTION)

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Air Tool Man	$ 3.25				
Asphalt Heaterman	4.00				
Asphalt Raker	4.25				
Asphalt Shoveler	3.25				
Batching Plant Scaleman	4.50				
Batterboard Setter	3.65				
Carpenter	4.60				
Carpenter Helper	3.75				
Concrete Finisher (Paving)	4.75				
Concrete Finisher Helper (Paving)	3.25				
Concrete Finisher (Structures)	4.55				
Concrete Finisher Helper (Structures)	4.00				
Electrician	7.50				
Form Builder (Structures)	4.60				
Form Builder Helper (Structures)	3.95				
Form Setter (Paving & Curb)	4.85				
Form Setter Helper (Paving & Curb)	3.50				
Form Setter (Structures)	4.80				
Form Setter Helper (Structures)	3.80				
Laborer, Common	3.25				
Laborer, Utility Man	3.85				
Manhole Builder Brick	3.25				
Mechanic	4.75				
Mechanic Helper	3.75				
Oiler	4.00				
Serviceman	4.05				
Painter (Structures)	6.00				
Painter Helper (Structures)	3.50				
Pipelayer	5.00				
Pipelayer Helper	3.75				
Powderman	4.50				
Powderman Helper	3.25				
Reinforcing Steel Setter (Structures)	4.55				
Reinforcing Steel Setter Helper	3.75				
Sign Erector	4.00				
Sign Erector Helper	3.50				
Spreader Box Man	4.35				
Swamper	4.25				
Power Equipment Operators:					
Asphalt Distributor	4.50				

DECISION NO. TX79-4049

INCIDENTAL PAVING & UTILITIES (BUILDING CONSTRUCTION)
INCIDENTAL PAVING & UTILITIES & SITE PREPARATION (RESIDENTIAL CONSTRUCTION)

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Power Equipment Operators (Cont'd):					
Asphalt Paving Machine	$ 4.50				
Broom or Sweeper Operator	5.00				
Bulldozer, 150 HP and Less	4.20				
Bulldozer, over 150 HP	4.50				
Concrete Paving Finishing Machine	3.50				
Concrete Paving Saw	4.50				
Paving Sub Grader	4.25				
Crane, Clamshell, Backhoe, Derrick, Dragline, Shovel (less than 1½ CY)	4.55				
Crane, Clamshell, Backhoe, Derrick, Dragline, Shovel (1½ CY and Over)	5.00				
Crusher or Screening Plant Op.	4.00				
Elevating Grader	4.10				
Foundation Drill Operator (Crawler Mounted)	4.60				
Foundation Drill Operator (Truck Mounted)	5.50				
Front End Loader (2½ CY & Less)	4.00				
Front End Loader (Over 2½ CY)	4.50				
Hoist (Double Drum and Less)	4.00				
Motor Grader Op., Fine Grade	5.65				
Motor Grader Operator	5.00				
Roller, Steel Wheel (Plant-Mix Pavements)	4.20				
Roller, Steel Wheel (Other-Flat Wheel or Tamping)	3.50				
Roller, Pneumatic (Self-Propelled)	3.65				
Scrapers (17 CY and Less)	4.00				
Scrapers (Over 17 CY)	4.50				
Self-Propelled Hammer	3.50				
Side Boom	3.50				
Tractor (Crawler Type) 150 HP and Less	3.70				
Tractor (Crawler Type) over 150 HP	3.95				
Tractor (Pneumatic) 80 HP & Less	3.50				
Tractor (Pneumatic) over 80 HP	3.80				
Traveling Mixer	4.00				

DECISION NO. TX79-4049

INCIDENTAL PAVING & UTILITIES (BUILDING CONSTRUCTION)
INCIDENTAL PAVING & UTILITIES & SITE PREPARATION (RESIDENTIAL CONSTRUCTION)

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Power Equipment Operators (Cont'd):					
Trenching Machine, Light	$ 4.35				
Trenching Machine, Heavy	5.75				
Wagon Drill, Boring Machine or Post Hole Driller Operator	4.25				
Truck Drivers:					
Single Axle, Light	3.50				
Single Axle, Heavy	3.75				
Tandem Axle or Semitrailer	3.50				
Lowboy-Float	4.65				
Transit-Mix	4.15				
Winch	3.75				
Weighman (Truck Scales)	3.25				
Welder	4.80				

SUPERSEDEAS DECISION

STATE: Texas

COUNTIES: Bell, Bosque, Coryell, Falls, Hill & McLennan

DECISION NO.: TX79-4050

DATE: Date of Publication

Supersedes Decision No. TX79-4006, dated January 5, 1979, in 44 FR 1676.

DESCRIPTION OF WORK: Building Construction Projects (does not include single family homes & garden type apartments up to & including 4 stories).

BUILDING CONSTRUCTION	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vocation	Education and/or Appr. Tr.
ASBESTOS WORKERS:					
ZONE 1 - Bell, Coryell & Falls	$11.05	.60	.60		.08
ZONE 2 - Bosque, Hill & McLennan	10.83	.50	.76		.03
BOILERMAKERS	11.05	.80	1.00		.02
BRICKLAYERS	10.60		.55		.03
CARPENTERS:					
ZONE 1 - Bell & Coryell Cos.					
Carpenters	9.25				
Millwrights	9.50				
ZONE 2 - Bosque, Falls, Hill & McLennan:					
Carpenters	9.58				
Millwrights	10.10				
CEMENT MASONS	9.34	.60	.55		
ELECTRICIANS:					
ZONE 1 - Bell (that part which is nearer to Waco than Austin but excluding that part of Ft. Hood, the boundary which presently is located approx. 2 miles inside the Bell Co. line & the City of Killeen), Bosque, Coryell (except that part of Ft. Hood south of Cowhouse Creek), Falls, Hill & McLennan Cos.	10.00	.60	3%		1/4%
ZONE 2 - Bell (that part which is nearer to Austin than Waco & not to exceed more than 2 miles into Bell Co. from the southeast boundary line of Coryell Co., Gray Field & the City of Killeen) & Coryell (that part south of Cowhouse Creek) Counties	11.50		8%		.8%
ELEVATOR CONSTRUCTORS:					
Mechanics	10.09	.895	.69	4%+a+b	.035
Helpers	70%JR	.895	.69	4%+a+b	.035
Helpers (Probationary)	50%JR				
GLAZIERS	7.30				
IRONWORKERS	10.05	.55	1.00		.12
LABORERS:					
Unskilled	2.97				
Mason tenders & mortar mixers	3.55				
LATHERS	10.10			1.00	.05
LINE CONSTRUCTION:					
Linemen; Linemen operators	12.15		3%		1/2%
Cable splicers	13.37		3%		1/2%
Groundman, 1st 6 months	7.29		3%		1/2%
Groundman, 2nd 6 months	7.90		3%		1/2%
Groundman, 1 year & over	8.51		3%		1/2%
PAINTERS:					
GROUP 1 - Brush	8.15				.04

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DECISION NO. TX79-4050

BUILDING CONSTRUCTION	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vocation	Education and/or Appr. Tr.
PAINTERS (CONT'D):					
GROUP 2 - Boiler pipe & steel, structural steel, window jacks, roofs, stage work, smoke stack, water towers, boatswain chair	$ 8.65				.04
GROUP 3 - Ames tools for dry wall	8.75				.04
GROUP 4 - Spray work & self-feeding rollers	8.90				.04
GROUP 5 - Steam cleaning, sandblasting & hazardous work	9.25				.04
PLASTERERS	9.99	.60	.55		.01
PLUMBERS & PIPEFITTERS:					
ZONE 1 - Area within a 35 mile radius of Waco including Temple, Marlin, Clifton, Hillsboro & Belton	9.50	.30	.33		.03
ZONE 2 - All other areas	9.90	.30	.33		.03
ROOFERS:					
GROUP 1 - Slate, tile, asbestos, roofing & siding	6.95				.03
GROUP 2 - Composition, built-up damp & waterproofing	6.80				.03
GROUP 3 - Kettlemen	5.10				.03
SHEET METAL WORKERS:					
ZONE 1 - Within a radius of 20 miles from the McLennan Co. Court House, Waco	9.19	.45	.44		.07
ZONE 2 - Over 20 miles but less than 45 miles including the towns of Hillsboro, Temple, Marlin, Gatesville & Clifton	9.69	.45	.44		.07
ZONE 3 - Over 45 miles	10.19	.45	.44		.07
SPRINKLER FITTERS	11.60	.75	1.05		.08
TRUCK DRIVERS	2.90				
WELDERS - receive rate prescribed for craft performing operation to which welding is incidental.					

FOOTNOTES FOR ELEVATOR CONSTRUCTORS:

a - 1st 6 mos. - none; 6 mos. to 5 yrs. - 2%; over 5 yrs. - 4% of basic hourly rate.

b - Paid Holidays A thru G

PAID HOLIDAYS FOR ELEVATOR CONSTRUCTORS:

A-New Years' Day; B-Memorial Day; C-Independence Day; D-Labor Day; E-Thanksgiving Day; F-the Friday after Thanksgiving Day; G-Christmas Day

DECISION NO. TX79-4050

BUILDING CONSTRUCTION	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
POWER EQUIPMENT OPERATORS					
GROUP 1	$10.44		.40		
GROUP 2	9.37		.40		
GROUP 3	8.15		.40		
GROUP 4	8.04		.40		

GROUP 1 - Heavy Duty Mechanic; Blade Grader - Self-propelled; Bull Clam; Back Filler; Derricks, power operated (all types); Dragline; Push Cat Operator; Euclid Operator; Bull Dozer and all types of Cat Tractors; Cable-Way; Back Hoe; Crane, Power Operated (all types); Elevating Grader, self-propelled; Hoist, Motor-Driven, two drums or more; Mix Mobile; High-Lifts & loaders, over 1/3 cu. yd. capacity; Winch Truck; Locomotive; Mixer, 14 cu. ft. or over; Paving Mixer (all sizes); Scraper; Trenching Machine (all sizes); Gradall; Foundation Boring Machine; Scoopmobile; Shovel, power operated; Pump Crete Machines; Clam Shell Operator; Rock Crusher Operated on Job; Welding Machine, 6 to 12; Two 125 cu. ft. Compressors; Well points, including installations

GROUP 2 - Blade Grader, Towed; Flex Plane; Form Grader; Mixer, less than 14 cu. ft.; Pulsometer; Truck Crane Driver & Oiler, Combination man; Gasoline or Diesel Driven Welding Machine, 3 to 6; Hoist, Single Drum; Pump, 2½ in. or larger; Pneumatic Roller; High-Lifts & Loaders, 1/3 cu. yd. or less; Forklift, 1500 lbs. capacity or less; Air Compressors, anytime there are two or more attachments operating on a 125 cu. ft. compressor, a light equipment operator shall be employed. One 125 cu. ft. air compressor and one welding machine requires no operator. One 125 cu. ft. compressor and two welding machines or any 2 air compressors equivalent to a 125 cu. ft. air compressor requires a light equipment operator

GROUP 3 - Fireman

GROUP 4 - Oiler

DECISION NO. TX79-4050

INCIDENTAL PAVING & UTILITIES	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Air Tool Man	$ 3.25				
Asphalt Heaterman	4.00				
Asphalt Raker	4.45				
Asphalt Shoveler	4.25				
Batching Plant Scaleman	5.00				
Carpenter	5.00				
Carpenter Helper	3.60				
Concrete Finisher (Paving)	5.00				
Concrete Finisher Helper (Paving)	3.50				
Concrete Finisher (Structures)	4.50				
Concrete Finisher Helper (Structures)	4.25				
Concrete Rubber	4.25				
Electrician	7.00				
Electrician Helper	4.00				
Form Builder (Structures)	4.00				
Form Builder Helper (Structures)	3.75				
Form Setter (Paving and Curb)	5.40				
Form Setter Helper (Paving & Curb)	3.75				
Form Setter (Structures)	5.00				
Form Setter Helper (Structures)	3.75				
Laborer, Common	3.00				
Laborer, Utility Man	3.50				
Mechanic	5.20				
Mechanic Helper	4.10				
Oiler	4.00				
Serviceman	3.50				
Painter (Structures)	3.50				
Piledrivermen	4.00				
Pipelayer: Bosque, Falls, Hill & McLennan	4.00				
Pipelayer (Concrete & Clay): Bell & Coryell Cos.	4.00				
Pipelayer Helper: Bosque, Falls, Hill & McLennan	3.50				
Pipelayer Helper(Concrete & Clay): Bell & Coryell Cos.	3.50				
Plumbers (Bell & Coryell Cos.):					
Zone 1 - 35 miles from Waco including towns of Temple & Belton	9.50	.30	.33		.03
Zone 2 - all area not included in Zone 1	9.90	.30	.33		.03
Powderman	4.45				

NOTICES

DECISION NO. TX79-4050

INCIDENTAL PAVING & UTILITIES	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Reinforcing Steel Setter (Structures)	$ 4.75				
Reinforcing Steel Helper	3.25				
Sign Erector	4.65				
Sign Erector Helper	3.10				
Spreader Box Man	4.35				
Swamper	4.25				
Power Equipment Operators:					
Asphalt Distributor	4.50				
Asphalt Paving Machine	4.70				
Broom or Sweeper Operator	4.30				
Bulldozer, 150 HP and Less	4.50				
Bulldozer, over 150 HP	4.75				
Concrete Paving Curing Machine	5.00				
Concrete Paving Saw	4.75				
Crane, Clamshell, Backhoe, Derrick, Dragline, Shovel (less than 1½ CY)	4.70				
Crane, Clamshell, Backhoe, Derrick, Dragline, Shovel (1½ CY and Over)	6.00				
Crusher or Screening Plant Op.	4.45				
Foundation Drill Operator (Truck Mounted)	4.50				
Foundation Drill Operator Helper	4.25				
Front End Loader (2½ CY & Less)	4.25				
Front End Loader (Over 2½ CY)	5.00				
Motor Grader Op., Fine Grade	5.00				
Motor Grader Operator	4.50				
Roller, Steel Wheel (Plant-Mix Pavements)	3.90				
Roller, Steel Wheel (Other-Flat Wheel or Tamping)	3.85				
Roller, Pneumatic (Self-Propelled)	3.50				
Scrapers (17 CY and Less)	3.75				
Scrapers (Over 17 CY)	4.50				
Tractor (Crawler Type) 150 HP and Less	3.80				
Tractor (Crawler Type) over 150 HP	4.25				
Tractor (Pneumatic) 80 HP & Less	3.55				

DECISION NO. TX79-4050

INCIDENTAL PAVING & UTILITIES	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Power Equipment Operators (Cont'd):					
Tractor (Pneumatic) over 80 HP	$ 4.35				
Traveling Mixer	4.10				
Trenching Machine, Light	4.00				
Trenching Machine, Heavy	4.45				
Wagon Drill, Boring Machine or Post Hole Driller Operator	3.80				
Truck Drivers:					
Single Axle, Light	3.65				
Lowboy-Float	4.00				
Weighman (Truck Scales)	3.20				
Welder	4.00				
Welder Helper	3.60				

STATE: Texas
DECISION NO.: TX79-4053
COUNTIES: Statewide
DATE: Date of Publication
Supersedes Decision No. TX78-4094, dated September 22, 1978, in 43 FR 43233.
DESCRIPTION OF WORK: See "Area Covered by Various Zones"

	ZONE 1	ZONE 2	ZONE 3	ZONE 4	ZONE 5
	Basic Hourly Rates	Basic Hourly Rates	Basic Hourly Rates	Basic Hourly Rates	Basic Hourly Rates
Air Tool Man	$ -	$ 3.40	$ 3.25	$ -	$ 3.00
Asphalt Besterman	4.40	4.50	4.00	3.55	3.75
Asphalt Raker	4.10	4.50	4.25	3.55	3.90
Asphalt Shoveler	-	3.40	3.25	3.00	3.50
Batching Plant Scaleman	5.85	4.85	4.50	4.00	4.25
Batterboard Setter	-	3.40	3.65	3.00	3.85
Carpenter	5.00	5.10	4.60	4.90	4.50
Carpenter Helper	4.25	4.50	3.75	4.00	3.50
Concrete Finisher (Paving)	5.50	5.40	4.75	4.50	4.35
Concrete Finisher Helper (Paving)	4.50	3.40	3.25	3.65	3.65
Concrete Finisher (Structures)	5.50	4.80	4.55	3.90	4.15
Concrete Finisher Helper (Structures)	4.20	4.00	4.00	3.65	3.25
Concrete Rubber	-	-	-	3.35	3.00
Electrician	6.85	6.75	7.50	5.50	6.50
Electrician Helper	-	3.80	-	3.60	4.35
Fireman	-	-	-	-	-
Form Builder (Structures)	5.00	4.70	4.60	3.80	4.00
Form Builder Helper (Structures)	4.20	-	3.95	3.65	3.00
Form Liner (Paving and Curb)	5.50	-	-	3.80	3.10
Form Setter (Paving and Curb)	4.40	4.70	4.85	3.95	4.35
Form Setter Helper (Paving and Curb)	3.60	4.00	3.30	3.35	3.75
Form Setter (Structures)	5.60	5.80	4.80	4.35	4.00
Form Setter Helper (Structures)	4.50	4.55	3.80	3.65	3.55
Laborer, Common	3.60	3.40	3.25	3.00	3.00
Laborer, Utility Man	4.20	3.85	3.85	3.50	3.40
Manhole Builder, Brick	4.25	4.00	3.25	3.25	4.05
Mechanic	5.50	5.75	4.75	4.85	4.80
Mechanic Helper	4.25	4.70	3.75	4.00	3.80
Oiler	4.65	4.55	4.00	3.50	4.15
Serviceman	4.75	4.40	4.05	3.95	3.25
Painter (Structures)	4.60	-	6.00	5.00	4.90
Painter Helper (Structures)	-	-	3.90	4.00	3.00
Piledrivermen	-	-	-	3.40	4.75
Pipelayer	5.30	4.00	5.00	3.75	3.50
Pipelayer Helper	4.35	3.50	3.75	3.25	3.25
Pneumatic Mortarman	-	-	-	-	3.00
Powderman	5.85	5.00	4.50	4.50	4.50
Powderman Helper	-	-	3.25	3.45	4.00
Reinforcing Steel Setter (Paving)	4.50	-	-	-	3.85
Reinforcing Steel Setter (Structures)	5.00	5.20	4.55	4.10	4.15
Reinforcing Steel Setter Helper	3.60	-	3.75	3.40	3.40
Steel Worker (Structural)	-	-	-	3.50	4.10
Steel Worker Helper (Structural)	-	-	-	-	3.75
Sign Erector	$ 4.00	$ -	$ 4.00	$ 3.70	$ 3.75
Sign Erector Helper	3.60	-	3.50	3.25	-
Spreader Box Man	5.10	4.55	4.35	3.90	4.00
Sweeper	4.20	4.50	4.25	4.00	3.75
Power Equipment Operators:					
Asphalt Distributor	5.25	4.00	4.50	3.70	4.15
Asphalt Paving Machine	5.40	4.30	4.50	3.80	4.00
Broom or Sweeper Operator	3.95	4.00	5.00	3.30	3.50
Bulldozer, 150 HP and Less	4.70	4.50	4.20	4.00	4.00
Bulldozer, over 150 HP	5.40	4.75	4.50	5.00	4.60
Concrete Paving Curing Machine	4.75	-	-	4.20	4.00
Concrete Paving Finishing Machine	5.50	4.35	3.50	5.00	-
Concrete Paving Form Grader	5.50	-	-	-	-
Concrete Paving Gang Vibrator	-	-	-	-	4.60
Concrete Paving Grinder	-	-	-	-	5.50
Concrete Paving Joint Machine	-	-	-	-	-
Concrete Paving Joint Sealer	-	-	-	-	-
Concrete Paving Longitudinal Float	-	-	-	-	-
Concrete Paving Mixer	5.00	-	-	-	4.10
Concrete Paving Saw	4.75	4.00	4.50	4.50	3.85
Concrete Paving Spreader	-	-	-	-	4.35
Paving Sub Grader	-	-	4.25	-	-
Crane, Clamshell, Backhoe, Derrick, Dragline, Shovel (less than 1½ CY)	5.00	5.00	4.55	4.35	4.00
Crane, Clamshell, Backhoe, Derrick, Dragline, Shovel (1½ CY and Over)	6.00	6.00	5.00	5.20	5.00
Crusher or Screening Plant Operator	5.15	4.25	4.00	3.80	4.00
Elevating Grader	5.65	4.00	4.10	-	3.50
Form Loader	-	-	-	-	3.25
Foundation Drill Operator (Crawler Mounted)	5.50	5.85	4.60	4.00	7.70
Foundation Drill Operator (Truck Mounted)	5.85	7.00	5.50	-	6.05
Foundation Drill Operator Helper	4.00	4.50	-	-	3.75
Front End Loader (2½ CY and Less)	4.75	4.35	4.00	4.00	3.90
Front End Loader (Over 2½ CY)	5.50	4.90	4.50	4.25	4.65
Hoist (Double Drum and Less)	-	-	4.00	3.10	-
Mixer (Over 16 CF)	4.65	-	-	-	4.50
Mixer (16 CF and Less)	-	-	-	-	-
Motor Grader Operator, Fine Grade	6.00	5.90	5.65	5.25	5.55
Motor Grader Operator	5.30	5.00	5.00	4.60	4.50
Pump Crete	-	-	-	-	-

	ZONE 1	ZONE 2	ZONE 3	ZONE 4	ZONE 5
	Basic Hourly Rates	Basic Hourly Rates	Basic Hourly Rates	Basic Hourly Rates	Basic Hourly Rates
Power Equipment Operators (Cont'd):	$	$	$	$	$
Roller, Steel Wheel (Plant-Mix Pavements)	4.75	4.20	4.20	3.80	3.60
Roller, Steel Wheel (Other-Flat Wheel or Tamping)	4.25	3.95	3.50	3.50	3.45
Roller, Pneumatic (Self-Propelled)	4.15	3.50	3.65	3.45	3.45
Scrapers (17 CY and Less)	4.60	4.00	4.00	4.00	3.75
Scrapers (Over 17 CY)	5.15	4.70	4.50	4.50	4.50
Self-Propelled Hammer	-	-	3.50	-	3.00
Side Boom	4.00	3.40	3.50	-	3.25
Tractor (Crawler Type) 150 HP & Less	3.85	3.75	3.70	3.80	3.25
Tractor (Crawler Type) over 150 HP	4.85	4.60	3.95	4.00	4.75
Tractor (Pneumatic) 80 HP & Less	4.30	3.75	3.50	3.75	3.25
Tractor (Pneumatic) over 80 HP	4.60	4.00	3.80	4.00	4.45
Traveling Mixer	4.75	4.25	4.00	4.15	3.85
Trenching Machine, Light	4.00	4.25	4.35	4.25	3.50
Trenching Machine, Heavy	4.25	-	5.75	4.75	4.50
Wagon Drill, Boring Machine or Post Hole Driller Operator	4.25	4.35	4.25	4.00	4.10
Truck Drivers:					
Single Axle, Light	4.00	3.50	3.50	3.45	3.30
Single Axle, Heavy	4.35	4.20	3.75	-	-
Tandem Axle or Semitrailer	4.05	3.50	3.50	3.70	3.45
Lowboy-Float	5.20	3.60	4.65	4.05	3.70
Transit-Mix	4.25	-	4.15	3.50	-
Winch	4.25	-	3.75	-	3.50
Vibrator Man (Hand Type)	3.60	-	-	3.45	3.00
Weighman (Truck Scales)	3.75	3.50	3.25	3.25	-
Welder	6.00	6.00	4.80	4.80	4.65
Welder Helper	-	3.40	-	3.50	4.00

	ZONE 6	ZONE 7	ZONE 8	ZONE 9	ZONE 10
	Basic Hourly Rates	Basic Hourly Rates	Basic Hourly Rates	Basic Hourly Rates	Basic Hourly Rates
Air Tool Man	$ 3.00	$ 3.00	$ 3.00	$ 3.25	$ 3.40
Asphalt Heaterman	3.90	3.85	3.85	4.00	4.00
Asphalt Raker	3.60	4.75	4.00	4.45	5.00
Asphalt Shoveler	3.60	3.15	-	4.25	3.40
Batching Plant Scaleman	4.50	5.35	4.00	5.00	4.75
Batterboard Setter	-	3.80	-	-	-
Carpenter	4.50	4.85	5.00	5.00	5.00
Carpenter Helper	3.45	3.50	4.00	3.60	4.10
Concrete Finisher (Paving)	3.75	4.50	4.90	5.00	5.50
Concrete Finisher Helper (Paving)	3.55	3.00	4.40	3.50	4.00
Concrete Finisher (Structures)	4.00	4.55	4.65	4.50	5.00
Concrete Finisher Helper (Structures)	3.60	3.85	3.60	4.25	4.25
Concrete Rubber	3.50	3.30	3.00	4.25	3.60
Electrician	7.50	6.55	6.50	7.00	6.75
Electrician Helper	-	3.15	3.00	4.00	4.00
Fireman	-	-	-	-	-
Form Builder (Structures)	4.65	4.85	4.70	4.00	5.30
Form Builder Helper (Structures)	3.60	3.80	4.40	3.75	4.00
Form Liner (Paving and Curb)	3.70	3.50	4.00	-	5.25
Form Setter (Paving and Curb)	3.85	4.10	4.25	5.40	5.00
Form Setter Helper (Paving and Curb)	3.40	3.65	4.05	3.75	4.40
Form Setter (Structures)	3.80	4.65	4.00	5.00	5.00
Form Setter Helper (Structures)	3.40	4.00	3.10	3.75	3.75
Laborer, Common	3.00	3.00	3.00	3.00	3.40
Laborer, Utility Man	3.55	3.60	3.45	3.50	3.90
Manhole Builder, Brick	3.85	3.75	-	-	-
Mechanic	4.10	5.00	5.00	5.20	5.20
Mechanic Helper	3.85	4.25	3.50	4.10	4.00
Oiler	3.80	4.40	4.25	4.00	4.50
Serviceman	4.00	4.50	3.95	3.50	4.00
Painter (Structures)	4.50	5.00	4.90	3.50	-
Painter Helper (Structures)	-	3.50	3.00	-	-
Piledriverman	5.00	5.60	5.25	4.00	4.50
Pipelayer	3.45	4.25	4.25	4.00	4.60
Pipelayer Helper	3.00	3.35	3.50	3.50	4.05
Pneumatic Mortarman	-	-	-	-	4.00
Powderman	5.00	-	4.90	4.45	4.95
Powderman Helper	-	-	3.00	-	-
Reinforcing Steel Setter (Paving)	3.80	-	-	-	4.50
Reinforcing Steel Setter (Structures)	4.30	4.10	4.15	4.75	4.25
Reinforcing Steel Setter Helper	3.05	3.75	3.40	3.25	3.50
Steel Worker (Structural)	-	-	4.50	-	4.25
Steel Worker Helper (Structural)	-	-	3.70	-	4.15

	ZONE 6	ZONE 7	ZONE 8	ZONE 9	ZONE 10
	Basic Hourly Rates	Basic Hourly Rates	Basic Hourly Rates	Basic Hourly Rates	Basic Hourly Rates
Sign Erector	$ 5.00	$ -	$ 4.75	$ 4.65	$ 4.65
Sign Erector Helper	3.50	-	4.00	3.10	3.90
Spreader Box Man	3.75	3.95	4.25	4.35	4.85
Swamper	-	-	4.25	4.25	4.60
Power Equipment Operators:					
Asphalt Distributor	4.15	4.50	4.25	4.50	4.70
Asphalt Paving Machine	4.50	5.05	4.95	4.70	5.25
Broom or Sweeper Operator	3.50	3.60	3.10	4.30	3.60
Bulldozer, 150 HP and Less	3.85	4.20	4.25	4.50	4.75
Bulldozer, over 150 HP	4.45	4.50	5.00	4.75	5.00
Concrete Paving Curing Machine	-	-	4.00	5.00	4.75
Concrete Paving Finishing Machine	4.25	-	-	-	4.75
Concrete Paving Form Grader	-	-	-	-	-
Concrete Paving Gang Vibrator	-	-	-	-	-
Concrete Paving Grinder	-	-	-	-	-
Concrete Paving Joint Machine	-	-	-	-	-
Concrete Paving Joint Sealer	-	-	-	-	-
Concrete Paving Longitudinal Float	-	-	-	-	4.50
Concrete Paving Mixer	-	-	-	-	6.00
Concrete Paving Saw	3.50	-	-	4.75	4.85
Concrete Paving Spreader	-	-	-	-	4.75
Paving Sub Grader	-	-	-	-	4.00
Crane, Clamshell, Backhoe, Derrick, Dragline, Shovel (less than 1½ CY)	4.10	4.50	4.30	4.70	5.15
Crane, Clamshell, Backhoe, Derrick, Dragline, Shovel (1½ CY and Over)	5.00	5.35	6.00	6.00	5.85
Crusher or Screening Plant Operator	3.50	-	4.75	4.45	5.05
Elevating Grader	-	4.00	-	-	-
Form Loader	4.00	-	3.25	-	5.00
Foundation Drill Operator (Crawler Mounted)	-	-	5.75	-	-
Foundation Drill Operator (Truck Mounted)	5.50	-	5.50	4.50	7.00
Foundation Drill Operator Helper	3.75	-	4.25	4.25	4.00
Front End Loader (2½ CY and Less)	3.95	4.50	4.00	4.25	4.55
Front End Loader (Over 2½ CY)	4.60	4.80	4.70	5.00	5.55
Hoist (Double Drum and Less)	-	-	-	-	-
Mixer (Over 16 CF)	-	4.75	-	-	-
Mixer (16 CF and Less)	3.50	-	-	-	-
Motor Grader Operator, Fine Grade	5.15	5.65	5.85	5.00	6.00
Motor Grader Operator	4.75	4.80	4.50	4.50	5.00
Pump Crete	-	-	-	-	-

	ZONE 6	ZONE 7	ZONE 8	ZONE 9	ZONE 10
	Basic Hourly Rates	Basic Hourly Rates	Basic Hourly Rates	Basic Hourly Rates	Basic Hourly Rates
Power Equipment Operators (Cont'd):	$	$	$	$	$
Roller, Steel Wheel (Plant-Mix Pavements)	3.50	4.15	3.75	3.90	4.80
Roller, Steel Wheel (Other-Flat Wheel or Tamping)	3.75	3.50	3.50	3.85	4.00
Roller, Pneumatic (Self-Propelled)	3.50	3.60	3.50	3.50	4.10
Scrapers (17 CY and Less)	3.75	4.00	4.00	3.75	4.50
Scrapers (Over 17 CY)	4.25	4.50	5.00	4.50	5.00
Self-Propelled Hammer	3.15	-	-	-	4.25
Side Boom	-	-	-	-	-
Tractor (Crawler Type) 150 HP & Less	-	3.80	3.50	3.80	4.00
Tractor (Crawler Type) over 150 HP	4.50	4.30	4.00	4.25	5.10
Tractor (Pneumatic) 80 HP & Less	3.75	3.75	3.75	3.55	3.60
Tractor (Pneumatic) over 80 HP	3.80	4.00	4.25	4.35	5.00
Traveling Mixer	3.80	3.80	-	4.10	4.50
Trenching Machine, Light	3.00	3.25	3.50	4.00	-
Trenching Machine, Heavy	-	-	4.85	4.45	5.00
Wagon Drill, Boring Machine or Post Hole Driller Operator	3.75	4.60	3.90	3.80	4.50
Truck Drivers:					
Single Axle, Light	3.40	3.50	3.50	3.65	3.75
Single Axle, Heavy	3.70	3.75	-	-	4.00
Tandem Axle or Semitrailer	3.45	4.10	-	-	4.05
Lowboy-Float	4.00	3.75	-	4.00	4.75
Transit-Mix	-	-	-	-	4.50
Winch	3.50	-	-	-	-
Vibrator Man (Hand Type)	3.00	3.00	3.00	-	-
Weighman (Truck Scales)	-	-	-	3.20	3.75
Welder	4.20	4.25	4.95	4.00	5.00
Welder Helper	3.75	3.75	-	3.60	-

	ZONE 11	ZONE 12	ZONE 13	ZONE 14	ZONE 15
	Basic Hourly Rates	Basic Hourly Rates	Basic Hourly Rates	Basic Hourly Rates	Basic Hourly Rates
Air Tool Man	$ 3.50	$ -	$ 3.05	$ 3.00	$ 4.60
Asphalt Heaterman	4.00	4.00	3.50	-	3.75
Asphalt Raker	5.00	4.25	4.25	3.85	5.15
Asphalt Shoveler	3.25	3.00	4.00	-	4.25
Batching Plant Scaleman	4.60	4.50	3.50	3.25	5.00
Batterboard Setter	3.25	-	-	-	4.15
Carpenter	5.30	5.00	5.45	5.85	6.00
Carpenter Helper	4.00	4.00	4.00	4.30	4.50
Concrete Finisher (Paving)	5.30	6.00	4.75	5.75	6.00
Concrete Finisher Helper (Paving)	4.30	4.00	4.00	4.00	4.80
Concrete Finisher (Structures)	5.10	5.00	5.00	5.75	5.90
Concrete Finisher Helper (Structures)	4.05	4.00	4.50	4.50	4.50
Concrete Rubber	3.25	4.40	-	-	4.25
Electrician	6.75	5.75	5.00	7.00	8.45
Electrician Helper	4.00	-	-	5.50	4.75
Fireman	-	3.50	3.70	3.00	-
Form Builder (Structures)	5.30	5.30	4.75	4.75	5.55
Form Builder Helper (Structures)	4.00	3.25	4.00	4.10	4.00
Form Liner (Paving and Curb)	5.00	5.50	5.75	-	6.00
Form Setter (Paving and Curb)	4.60	5.25	5.00	4.85	5.35
Form Setter Helper (Paving and Curb)	3.80	4.00	4.00	3.50	4.45
Form Setter (Structures)	5.00	5.50	5.60	5.75	5.40
Form Setter Helper (Structures)	3.75	3.55	5.00	4.00	4.00
Laborer, Common	3.00	3.00	3.00	3.00	3.75
Laborer, Utility Man	3.50	3.50	3.85	3.90	4.15
Manhole Builder, Brick	5.50	-	6.50	-	5.50
Mechanic	5.00	5.00	5.50	6.00	6.40
Mechanic Helper	3.75	4.50	4.00	4.30	5.25
Oiler	4.90	3.75	4.65	4.50	5.25
Serviceman	4.50	4.00	4.65	4.00	4.90
Painter (Structures)	5.50	5.25	-	-	6.00
Painter Helper (Structures)	3.75	-	-	-	4.40
Piledriverman	-	5.25	-	5.00	6.00
Pipelayer	4.40	3.80	3.50	3.65	5.20
Pipelayer Helper	3.75	3.50	-	3.00	4.00
Pneumatic Mortarman	-	-	-	-	-
Powderman	5.00	4.25	-	3.75	-
Powderman Helper	-	3.25	-	-	-
Reinforcing Steel Setter (Paving)	4.35	4.25	-	4.00	4.50
Reinforcing Steel Setter (Structures)	4.75	4.00	4.00	4.00	5.15
Reinforcing Steel Setter Helper	4.00	3.85	4.00	-	3.75
Steel Worker (Structural)	4.65	5.00	-	-	6.20
Steel Worker Helper (Structural)	3.50	3.25	-	-	4.90

	ZONE 11	ZONE 12	ZONE 13	ZONE 14	ZONE 15
	Basic Hourly Rates	Basic Hourly Rates	Basic Hourly Rates	Basic Hourly Rates	Basic Hourly Rates
Sign Erector	$ 4.85	$ -	$ -	$ -	$ 3.75
Sign Erector Helper	3.25	-	-	-	-
Spreader Box Man	4.60	4.45	5.00	3.75	4.95
Swamper	4.60	3.50	-	-	-
Power Equipment Operators:					
Asphalt Distributor	4.25	5.00	4.90	4.00	5.00
Asphalt Paving Machine	4.70	4.55	5.00	4.25	6.00
Broom or Sweeper Operator	3.75	3.75	3.80	3.75	4.05
Bulldozer, 150 HP and Less	4.75	4.50	5.00	4.00	5.00
Bulldozer, over 150 HP	5.35	5.00	5.60	5.50	6.00
Concrete Paving Curing Machine	4.75	5.25	-	-	5.75
Concrete Paving Finishing Machine	5.25	5.50	-	-	6.00
Concrete Paving Form Grader	4.00	5.75	-	-	6.00
Concrete Paving Gang Vibrator	-	5.25	-	-	-
Concrete Paving Grinder	-	-	-	-	-
Concrete Paving Joint Machine	-	4.50	-	-	5.50
Concrete Paving Joint Sealer	4.00	4.40	-	-	5.50
Concrete Paving Longitudinal Float	4.50	-	-	-	4.75
Concrete Paving Mixer	5.75	4.50	-	-	-
Concrete Paving Saw	4.10	4.25	-	-	5.50
Concrete Paving Spreader	5.10	4.00	-	-	5.70
Paving Sub Grader	5.25	4.00	-	-	5.75
Crane, Clamshell, Backhoe, Derrick, Dragline, Shovel (less than 1½ CY)	5.05	5.00	5.15	4.65	5.50
Crane, Clamshell, Backhoe, Derrick, Dragline, Shovel (1½ CY and Over)	5.60	5.50	5.60	5.75	6.50
Crusher or Screening Plant Operator	4.50	4.50	-	3.75	5.00
Elevating Grader	-	4.25	-	-	-
Form Loader	3.25	3.75	-	-	3.80
Foundation Drill Operator (Crawler Mounted)	5.50	5.75	-	-	7.70
Foundation Drill Operator (Truck Mounted)	5.50	7.00	5.75	5.00	7.00
Foundation Drill Operator Helper	4.20	4.75	-	4.25	3.75
Front End Loader (2½ CY and Less)	4.75	4.50	4.00	4.00	5.00
Front End Loader (Over 2½ CY)	5.30	5.15	5.25	5.50	6.00
Hoist (Double Drum and Less)	-	-	-	-	-
Mixer (Over 16 CF)	-	4.90	-	-	-
Mixer (16 CF and Less)	3.75	-	-	-	4.50
Motor Grader Operator, Fine Grade	5.65	5.50	6.00	5.80	6.70
Motor Grader Operator	5.00	5.00	5.00	4.60	5.75
Pump Crete	3.75	-	-	-	5.00

	ZONE 11	ZONE 12	ZONE 13	ZONE 14	ZONE 15
	Basic Hourly Rates	Basic Hourly Rates	Basic Hourly Rates	Basic Hourly Rates	Basic Hourly Rates
Power Equipment Operators (Cont'd):	$	$	$	$	$
Roller, Steel Wheel (Plant-Mix Pavements)	4.25	4.40	5.00	3.90	5.05
Roller, Steel Wheel (Other-Flat Wheel or Tamping)	4.30	4.25	4.00	4.25	4.00
Roller, Pneumatic (Self-Propelled)	3.90	4.00	4.55	3.60	4.00
Scrapers (17 CY and Less)	4.75	4.40	4.75	4.50	4.65
Scrapers (Over 17 CY)	5.00	5.00	5.40	5.25	6.00
Self-Propelled Hammer	-	-	-	-	-
Side Boom	-	4.10	5.00	-	5.50
Tractor (Crawler Type) 150 HP & Less	3.50	4.00	4.25	-	4.00
Tractor (Crawler Type) over 150 HP	5.00	4.65	5.40	4.75	5.50
Tractor (Pneumatic) 80 HP & Less	3.75	3.75	3.25	3.50	3.75
Tractor (Pneumatic) over 80 HP	4.75	4.50	4.85	4.70	4.00
Traveling Mixer	4.30	5.15	5.25	4.40	5.25
Trenching Machine, Light	3.75	-	-	-	5.60
Trenching Machine, Heavy	5.10	-	-	-	6.00
Wagon Drill, Boring Machine or Post Hole Driller Operator	4.50	4.35	-	3.75	4.00
Truck Drivers:					
Single Axle, Light	3.90	3.75	4.00	3.75	4.20
Single Axle, Heavy	4.30	4.00	4.00	4.00	4.70
Tandem Axle or Semitrailer	4.00	4.00	4.00	3.75	4.50
Lowboy-Float	4.60	-	5.25	-	5.00
Transit-Mix	4.00	-	-	-	5.00
Winch	4.50	-	-	-	5.00
Vibrator Man (Hand Type)	4.00	3.50	-	-	-
Weighman (Truck Scales)	4.50	4.00	3.00	3.00	3.75
Welder	5.05	4.40	4.50	5.45	6.00
Welder Helper	3.75	3.00	-	-	5.00

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	ZONE 16				
	Basic Hourly Rates	Basic Hourly Rates	Basic Hourly Rates	Basic Hourly Rates	Basic Hourly Rates
Air Tool Man	$ -				
Asphalt Heaterman	4.10				
Asphalt Raker	4.65				
Asphalt Shoveler	-				
Batching Plant Scaleman	4.65				
Batterboard Setter	-				
Carpenter	5.75				
Carpenter Helper	4.00				
Concrete Finisher (Paving)	6.00				
Concrete Finisher Helper (Paving)	4.00				
Concrete Finisher (Structures)	6.10				
Concrete Finisher Helper (Structures)	4.50				
Concrete Rubber	-				
Electrician	8.10				
Electrician Helper	4.60				
Fireman	-				
Form Builder (Structures)	5.45				
Form Builder Helper (Structures)	4.10				
Form Liner (Paving and Curb)	4.50				
Form Setter (Paving and Curb)	5.00				
Form Setter Helper (Paving and Curb)	-				
Form Setter (Structures)	5.85				
Form Setter Helper (Structures)	4.70				
Laborer, Common	4.10				
Laborer, Utility Man	4.50				
Manhole Builder, Brick	-				
Mechanic	6.05				
Mechanic Helper	4.25				
Oiler	5.90				
Serviceman	4.55				
Painter (Structures)	8.00				
Painter Helper (Structures)	5.00				
Piledriverman	5.85				
Pipelayer	6.00				
Pipelayer Helper	4.10				
Pneumatic Mortarman	-				
Powderman	-				
Powderman Helper	-				
Reinforcing Steel Setter (Paving)	4.75				
Reinforcing Steel Setter (Structures)	5.00				
Reinforcing Steel Setter Helper	4.10				
Steel Worker (Structural)	5.50				
Steel Worker Helper (Structural)	-				

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	ZONE 16				
	Basic Hourly Rates	Basic Hourly Rates	Basic Hourly Rates	Basic Hourly Rates	Basic Hourly Rates
Sign Erector	$ 4.50				
Sign Erector Helper	-				
Spreader Box Man	6.00				
Swamper	4.50				
Power Equipment Operators:					
Asphalt Distributor	5.80				
Asphalt Paving Machine	5.25				
Broom or Sweeper Operator	4.10				
Bulldozer, 150 HP and Less	6.00				
Bulldozer, over 150 HP	6.50				
Concrete Paving Curing Machine	4.50				
Concrete Paving Finishing Machine	6.25				
Concrete Paving Form Grader	4.50				
Concrete Paving Gang Vibrator	-				
Concrete Paving Grinder	-				
Concrete Paving Joint Machine	4.50				
Concrete Paving Joint Sealer	-				
Concrete Paving Longitudinal Float	4.50				
Concrete Paving Mixer	-				
Concrete Paving Saw	4.75				
Concrete Paving Spreader	4.75				
Paving Sub Grader	-				
Crane, Clamshell, Backhoe, Derrick, Dragline, Shovel (less than 1½ CY)	5.70				
Crane, Clamshell, Backhoe, Derrick, Dragline, Shovel (1½ CY and Over)	6.50				
Crusher or Screening Plant Operator	-				
Elevating Grader	-				
Form Loader	-				
Foundation Drill Operator (Crawler Mounted)	-				
Foundation Drill Operator (Truck Mounted)	-				
Foundation Drill Operator Helper	-				
Front End Loader (2½ CY and Less)	4.25				
Front End Loader (Over 2½ CY)	6.10				
Hoist (Double Drum and Less)	-				
Mixer (Over 16 CF)	-				
Mixer (16 CF and Less)	-				
Motor Grader Operator, Fine Grade	6.65				
Motor Grader Operator	5.50				
Pump Crete	-				

	ZONE 16				
	Basic Hourly Rates	Basic Hourly Rates	Basic Hourly Rates	Basic Hourly Rates	Basic Hourly Rates
Power Equipment Operators (Cont'd):	$				
Roller, Steel Wheel (Plant-Mix Pavements)	4.10				
Roller, Steel Wheel (Other-Flat Wheel or Tamping)	5.25				
Roller, Pneumatic (Self-Propelled)	4.10				
Scrapers (17 CY and Less)	4.85				
Scrapers (Over 17 CY)	6.00				
Self-Propelled Hammer	-				
Side Boom	-				
Tractor (Crawler Type) 150 HP & Less	4.10				
Tractor (Crawler Type) over 150 HP	5.35				
Tractor (Pneumatic) 80 HP and Less	4.10				
Tractor (Pneumatic) over 80 HP	4.50				
Traveling Mixer	5.85				
Trenching Machine, Light	-				
Trenching Machine, Heavy	-				
Wagon Drill, Boring Machine or Post Hole Driller Operator	4.10				
Truck Drivers:					
Single Axle, Light	4.60				
Single Axle, Heavy	-				
Tandem Axle or Semitrailer	7.10				
Lowboy-Float	7.10				
Transit-Mix	-				
Winch	-				
Vibrator Man (Hand Type)	-				
Weighman (Truck Scales)	-				
Welder	6.30				
Welder Helper	-				

AREA COVERED BY VARIOUS ZONES

ZONE 1 - Archer, Armstrong, Baylor, Briscoe, Carson, Castro, Childress, Clay, Collingsworth, Dallam, Deaf Smith, Donley, Gray, Hall, Hansford, Hardeman, Hartley, Hemphill, Hutchinson, Lipscomb, Montague, Moore, Ochiltree, Oldham, Parmer, Potter, Randall, Roberts, Sherman, Swisher, Wheeler, Wichita & Wilbarger Counties

DESCRIPTION OF WORK: Heavy (excluding tunnels & dams) and Highway Construction (does not include building structures in rest area projects)

ZONE 2 - Bailey, Borden, Cochran, Cottle, Crosby, Dawson, Dickens, Fisher, Floyd, Foard, Gaines, Garza, Hale, Haskell, Hockley, Jones, Kent, King, Knox, Lamb, Lubbock, Lynn, Motley, Scurry, Shackelford, Stephens, Stonewall, Terry, Throckmorton, Yoakum & Young Counties

DESCRIPTION OF WORK: Heavy (excluding tunnels & dams) and Highway Construction (does not include building structures in rest area projects)

ZONE 3 - Andrews, Brown, Callahan, Coke, Coleman, Comanche, Concho, Crane, Crockett, Eastland, Ector, Erath, Glasscock, Howard, Irion, Kimble, Loving, Martin, McCulloch, Menard, Midland, Mills, Mitchell, Nolan, Reagan, Runnels, San Saba, Schleicher, Sterling, Sutton, Taylor, Upton, Ward & Winkler Counties

DESCRIPTION OF WORK: Heavy (excluding tunnels & dams) and Highway Construction (does not include building structures in rest area projects)

ZONE 4 - Brewster, Culberson, El Paso*, Hudspeth, Jeff Davis, Pecos, Presidio, Reeves & Terrell Counties

DESCRIPTION OF WORK: Heavy (excluding tunnels & dams), Water & Sewer Lines and Highway Construction (does not include building structures in rest area projects)

*Not to be used for Heavy Construction in El Paso County

ZONE 5 - Atascosa, Bandera, Bexar, Comal, Dimmit, Edwards, Frio, Guadalupe, Kendall, Kerr, Kinney, LaSalle, Maverick, McMullen, Medina, Real, Uvalde, Val Verde, Wilson & Zavala Counties

DESCRIPTION OF WORK: Heavy (excluding tunnels & dams) and Highway Construction (does not include building structures in rest area projects)

ZONE 6 - Brooks, Cameron, Duval, Hidalgo, Jim Hogg, Kenedy, Starr, Webb, Willacy & Zapata Counties

DESCRIPTION OF WORK: Heavy (excluding tunnels & dams) and Highway Construction (does not include building structures in rest area projects) & Incidental Shore Work.

ZONE 7 - Aransas, Bee, Calhoun, DeWitt, Goliad, Jackson, Jim Wells, Karnes, Kleberg, Lavaca, Live Oak, Nueces, Refugio, San Patricio & Victoria Counties

DESCRIPTION OF WORK: Heavy (excluding tunnels & dams) and Highway Construction (does not include building structures in rest area projects) & Incidental Shore Work

ZONE 8 - Austin, Bastrop, Blanco, Burnet, Caldwell, Colorado, Fayette, Gillespie, Gonzales, Hays, Lee, Llano, Mason, Travis & Williamson Counties

DESCRIPTION OF WORK: Heavy (excluding tunnels & dams) and Highway Construction (does not include building structures in rest area projects)

ZONE 9 - Bell, Bosque, Coryell, Falls, Freestone, Hamilton, Hill, Lampasas, Limestone, McLennan & Navarro Counties

DESCRIPTION OF WORK: Heavy (excluding tunnels & dams) and Highway Construction (does not include building structures in rest area projects)

ZONE 10 - Cooke, Denton, Hood, Jack, Johnson, Palo Pinto, Parker, Sommervell, Tarrant* & Wise Counties

DESCRIPTION OF WORK: Heavy (excluding tunnels & dams), Water & Sewer Lines and Highway Construction (does not include building Structures in rest area projects)

*Not to be used for Heavy Construction in Tarrant County

ZONE 11 - Collin, Dallas, Ellis, Grayson & Rockwall Counties

DESCRIPTION OF WORK: Heavy (excluding tunnels, dams & work performed on the site of water or sewage treatment facilities) and Highway Construction (does not include building structures in rest area projects)

ZONE 12 - Bowie, Camp, Cass, Delta, Fannin, Franklin, Gregg, Harrison, Hopkins, Hunt, Kaufman, Lamar, Marion, Morris, Rains, Red River, Rusk, Smith, Titus, Upshur, Van Zandt & Wood Counties

DESCRIPTION OF WORK: Heavy (excluding tunnels & dams) and Highway Construction (does not include building structures in rest area projects)

ZONE 13 - Anderson, Angelina, Cherokee, Henderson, Houston, Jasper, Nacogdoches, Newton, Panola, Polk, Sabine, San Augustine, San Jacinto, Shelby, Trinity & Tyler Cos.

DESCRIPTION OF WORK: Heavy (excluding tunnels & dams) and Highway Construction (does not include building structures in rest area projects) & Incidental Shore Work

DECISION NO. TX79-4053

ZONE 14 - Brazos, Burleson, Grimes, Leon, Madison, Milam, Robertson, Walker & Washington Cos.

DESCRIPTION OF WORK: Heavy (excluding tunnels & dams) and Highway Construction (does not include building structures in rest area projects)

ZONE 15 - Brazoria, Fort Bend, Galveston, Harris, Matagorda, Montgomery, Waller & Wharton Counties

DESCRIPTION OF WORK: Highway Construction (does not include building structures in rest area projects)

ZONE 16 - Chambers, Hardin, Jefferson*, Liberty & Orange* Counties

DESCRIPTION OF WORK: Heavy Construction (excluding tunnels & dams) and Highway Construction (does not include building structures in rest area projects) & Incidental Shore Work

*Not to be used for Heavy Construction & Incidental Shore Work in Jefferson & Orange Cos.

SUPERSEDEAS DECISION

STATE: Wyoming COUNTY: Statewide
DECISION NUMBER: WY79-5108 DATE: Date of Publication
Supersedes Decision No. WY78-5014 dated March 10, 1978, in 43 FR 10276
DESCRIPTION OF WORK: Highway Projects (does not include bridges over navigable waters; tunnels; rest areas which include building structures; and railroad construction)

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
CARPENTERS	$ 8.74	.40	.60		.15
CEMENT MASONS	8.50	.50			
IRONWORKERS:					
Structural	8.00				
Reinforcing	7.27	.40			
PAINTERS:					
Brush and Spray	7.06	.35			
LINE CONSTRUCTION:					
All work over 34.5 KV all work on steel towers and/or multiple wood structures, all cross country underground communications work, and all motor traffic controlling, streets and highway lighting:					
Cable Splicer	11.00	.45	3%+.25		4/10%
Linemen	10.00	.45	3%+.25		4/10%
Equipment Operators	9.01	.45	3%+.25		4/10%
Groundmen	7.37	.45	3%+.25		4/10%
All work 34.5 KV and under:					
Lineman	10.00	.45	3%+.25		4/10%
Line Equipment Operator	8.62	.45	3%+.25		4/10%
Groundman	7.37	.45	3%+.25		4/10%

LABORERS	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Group 1: Axeman and hand faller; Bin Wall Installer Helpers; Concrete Worker (wet or dry); Concrete Workers (curing and drying); Dumpman; Erector and Installer (including the installation and erection of fences, snow fences, guard rails, median rails, median posts, signs and right-of-way marker); Form Stripper; Form Setter Helper (paving); General Labor; Gunite Helper; Heater Tender; Landscaper Helper; Material Handler (lumber, rods, cement, concrete); Nozzleman, air and water; Pipe Setters' Helpers (non-metallic); Pipe Setters' Helpers (corrugated); Pre-watering, pre-wetting and pre-irrigation (all work); Rip Rap Man; Sandblaster Pot Tender; Signal Men; Grade Concrete, etc. Scissor Man or Hopper Man; Stake Jumper for equipment; Tar and Asphalt Pot Tender; Wrecking and demolition crews	$ 5.78				

LABORERS (Cont'd)	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Group 2: Asphalt Raker and Tamper; Bin Wall Installer; Bituminous Curb Builder; Cement Mason or Finisher; Helper and Tender; Chuck Tender; Form Setter (paving); Hand Operated Vibratory Roller; Landscaper; Mortar Man on stone riprap; Operator of pneumatic, electric, gas tamper and similar mechanical tools; Pipe Setter (corrugated culvert pipe sectional, multiplate and similar type); Pipe Setter; Pipelayer (non-metallic); Pipewrapper; Powderman Helper; Power type concrete buggy (push or ride); Power Saw Operator (clearing); Vibrator - concrete	$ 5.88				
Group 3: Concrete Saw; Gunite Nozzleman; High Scaler (using air tools form bos'n chair, swing stage, lift belt, or block and tackle shall receive $.20 per hour more than the classified rate); Jackhammer and pavement breaker; Sandblaster Nozzleman; Sewer Pipe Installer (non-metallic), clay, concrete, etc. (Caulker, Collarman, Jointer, Mortarman, Rigger, Jacker)	6.03				
Group 4: Powderman and Blaster; Wagon Drill, Air-trac, Diamond and other drills for blasting powder or grouting	6.30				

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
LABORERS (Cont'd)					
Group 5: Tunnel and Underground Work: Brakeman; Swamper; Vibrator Man	$ 6.26				
Bull Gang; Dumpman; Mucker; Trackman	6.10				
Miners (drillers) Machine Men; Timbermen; Steelmen; Drill Doctor; Form Setter and Mover; Spader; Tuggers spilling and/or Caisson Workers; Powderman; Jackhammermen; Finishers	6.53				
Nipper; chucktender; Topman; Toplander	6.37				
POWER EQUIPMENT OPERATORS					
Group 1	7.75	.40	.35		
Group 2	7.80	.40	.35		
Group 3	7.85	.40	.35		
Group 4	7.89	.40	.35		
Group 5	7.92	.40	.35		
Group 6	7.97	.40	.35		
Group 7	8.01	.40	.35		
Group 8	8.03	.40	.35		
Group 9	8.14	.40	.35		
Group 10	8.20	.40	.35		
Group 11	8.22	.40	.35		
Group 12	8.40	.40	.35		
Group 13	8.44	.40	.35		
Group 14	8.51	.40	.35		
Group 15	8.57	.40	.35		
Group 16	8.74	.40	.35		
Group 17	9.08	.40	.35		

POWER EQUIPMENT OPERATORS

Group 1: Auger Machine Operator (post holes, etc.); Batch Bin Weighman, Scissorman or Hopperman; Beginner Operator; Brakeman and Helper; Crusher Oiler; Oiler Utility; Screed Operator; Tractor Operators (farm, crawler or wheel type, 60 HSP (drawbar) or less with or without use of power attachments, except for use of back hoe or bucket)

Group 2: Broom Operators, self-propelled; Cableway Signalman (bellboy); Concrete Saw (self-propelled); Fireman; Power Loader, belt and bucket type

Group 3: Air Compressor over 315 cu. ft. capacity; Chip Spreader Operator; Form Grader Operator; Joint Machine Operator; Longitudinal Float Operator; Mixer Operator Concrete (under one yard); Helper (welder or heavy duty); Roller Operators, self-propelled (pneumatic, rubber tired, sheep foot, vibratory or combination type); Tire Repairman

Group 4: Pump Operator (all others)

Group 5: Conveyor Belt Operator; Fork Lift and Lumber Staker; Screening Plant Operator

Group 6: A-Frame Truck; Tractor Operators (farm, crawler or wheel type, over 60 HSP (drawbar) without use of power attachments

Group 7: Oiler, Lead Utility

Group 8: Gunnite and Grout Machine Operator; Mulching Machine Operator; Oil Distributor

Group 9: Front End Loader (up to and including 1½ cu. yds.); Pavement Breakers, Hydro-tamper and similar type machines; Pumps, well points

Group 10: Hoist Operator (one drum)

POWER EQUIPMENT OPERATORS

Group 11: Haulage Motorman and Industrial type Motormen; Motor Patrol Operator (all others); Pump Operator (in tunnels, shafts, raises); Hydro type Cranes (up to 15 tons)

Group 12: Air Compressor, two or more machines or tunnels, shafts, raises of plant Operator; Asphalt Plant Operator; Bituminous Lay-down Machine Operator; CMI Machine and similar; Concrete Batch Plant; Concrete Finish Machine Operator; Concrete Multi Blade Span Saw (Hunt process or similar); Concrete Spreader and Paver Operator; Crusher Operator; Drilling Machine, integrated (Core, Rotary, Caisson, Diamond); Elevating Grader; Front End Loader (over 1½ cu. yds.); Jumbo Form Operator; Mixer Operator, base course pug mill type; Mixer Bituminous Operator (travel plant); Mixer Operator Concrete (over one yard); Motor Patrol Operator (finish); Mucking Machine Operator (all types); Pneumatic Guns; Pumporete Operator; Roller Operator, (tandem steel wheel, three axle or three wheel); Scraper Equipment (all types); Shovels, Draglines, Cranes, Piledrivers, all truck mounted cranes, (manufacturers' rating) up to 3½ yards, all attachments; Hydro type Cranes, (15 ton and over); Shuttle Car Operator; Subgrade Machine Operator (power); Tractor Operator, all with use of power attachments and including Pushcat, Dozer, Tournadozer, etc. (The use of power attachment shall not include disking, pulling or rollers, and similar unskilled actions); Trenching Machine Operator; Wash Plant Operator

Group 13: Welder, Machine Doctor

Group 14: Hoist Operator (two or more drums of shafts or raises); Repairman; Mechanics; Machine Doctors, Welders and Helper; Heavy Duty Mechanic, Machine Doctor

Group 15: Cableway Operators; Mixer Dual Drum; Cranes, (Whirley, Gantry, Stiffleg, Overhead traveling)

Group 16: Shovels, Draglines, Cranes, Piledrivers, all truck mounted Cranes (manufacturer's rating) 3½ yards to 7 cu. yds., all attachments; Wheel Excavator Operator

Group 17: Shovels, Draglines, Cranes, Piledrivers, all truck mounted Cranes, (manufacturer's rating) 7 cu. yds. and over, all attachments

TRUCK DRIVERS	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Pick-up Truck Drivers (when used for hauling)	$ 6.22	.40			
Dump Truck Drivers (water level capacity box):					
7 cu. yds. and less	6.27	.40			
Over 7 cu. yds. to and including 10 cu. yds.	6.42	.40			
Over 10 cu. yds. to and including 13 cu. yds.	6.52	.40			
Over 13 cu. yds. to and including 20 cu. yds.	7.02	.40			
Over 20 cu. yds. to and including 25 cu. yds.	7.02	.40			
Over 25 cu. yds. to and including 30 cu. yds.	7.12	.40			
Over 30 cu. yds. to and including 35 cu. yds.	7.17	.40			
Over 35 cu. yds. to and including 40 cu. yds.	7.22	.40			
Over 40 cu. yds. to and including 45 cu. yds.	7.27	.40			
Over 45 cu. yds. (to be negotiated prior to use)					
Snow Plow Truck Drivers (the cu. yd. rate of the truck driver classification):					
Pilot Car Drivers	6.22	.40			
Gravel Spreader	6.27	.40			
Flat Rack Material Truck Drivers:					
Less than 2 tons	6.27	.40			
2 tons to 5 tons	6.42	.40			
Over 5 tons	6.52	.40			
Low Boy and Tandem Axle Float Drivers	7.02	.40			
Gang Truck Drivers	6.27	.40			

TRUCK DRIVERS (Cont'd)	Basic Hourly Rates	Fringe Benefits Payments: H & W	Pensions	Vacation	Education and/or Appr. Tr.
Stringing Truck Drivers:					
Single axle type truck	$ 6.27	.40			
Multiple axle type truck, semi	7.02	.40			
Winch Trailer Truck Drivers (cable and hoist)	6.52	.40			
Utility Winch Truck Drivers	6.52	.40			
"A" Frame Truck Drivers	6.52	.40			
Warehousemen, Partsmen and Helpers	6.27	.40			
Material Checkers	6.42	.40			
Transit Mix or wet mix Truck Drivers:					
Less than 5 cu. yds.; Single axle	6.52	.40			
Over 5 cu. yds. to and including 10 cu. yds.:					
Tandem axle	6.62	.40			
Over 10 cu. yds.	6.72	.40			
Power Broom Drivers and/or Operator	6.42	.40			
Water Truck Drivers:					
2500 gal. or less (straight truck)	6.27	.40			
2500 gal. or less (semi truck)	6.42	.40			
Over 2500 gal. to and including 3600 gal.	6.52	.40			
Over 3600 gal. (straight truck)	6.62	.40			
Over 3600 gal. (semi truck)	6.72	.40			

TRUCK DRIVERS (Cont'd)	Basic Hourly Rates	Fringe Benefits Payments: H & W	Pensions	Vacation	Education and/or Appr. Tr.
Heavy Duty (Euclids, electric or similar type)	$ 7.02	.40			
Fuel Service Truck Drivers	6.27	.40			
Greasemen, Tiremen, Service Men and Helpers	6.27	.40			
Truck Mechanics and Helpers (shop and field):					
Field Mechanics	7.22	.40			
Helpers - field (welders, mechanics, etc.)	6.78	.40			

SUPERSEDEAS DECISION

STATE: Wyoming

COUNTIES: Converse, Goshen, Laramie, Natrona, Niobrara and Platte

DECISION NUMBER: WY79-5109

DATE: Date of Publication

Supersedes Decision No. WY78-5015 dated March 10, 1978, in 43 FR 10281

DESCRIPTION OF WORK: Building Projects (does not include single family homes and garden type apartments up to and including 4 stories) and heavy construction

BUILDING CONSTRUCTION	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
ASBESTOS WORKERS	$12.14	.55	$ 1.35		
BOILERMAKERS	12.30	.85	1.00		.02
BRICKLAYERS; Stonemasons:					
Goshen, Laramie and Platte Cos.	11.02		.30		
Converse, Natrona and Niobrara Counties	11.10	.45	.30		.05
CARPENTERS:					
Carpenters	9.73	.65	.65	.75	.15
Piledrivermen	10.13	.65	.65	.75	.15
CEMENT MASONS:					
Cement Masons	10.30	.50			.05
Working on swinging stage or temporary platform over 20 ft. high	10.80	.50			.05
Composition material, epoxy	10.55	.50			.05
ELECTRICIANS:					
Goshen, Laramie, Niobrara and Platte Counties					
Electricians	11.15	.72	3%+.50		3/4of1%
Cable Splicers	11.40	.72	3%+.50		3/4of1%
Converse and Natrona Counties					
Contracts $150,000 and under:					
Electricians	10.30	.72	3%+.50		3/4of1%
Contracts over $150,000:					
Electricians	10.90	.72	3%+.50		3/4of1%
ELEVATOR CONSTRUCTORS	11.71	.895	.56	a	.025
ELEVATOR CONSTRUCTORS' HELPERS	70%JR	.895	.56	a	.025
ELEVATOR CONSTRUCTORS' HELPERS (PROB.)	50%JR				
IRONWORKERS:					
Structural; Ornamental; Reinforcing	11.05	.70	1.25		.25
MARBLE, TILE & TERRAZZO WORKERS:					
Converse, Natrona and Niobrara Counties	11.10	.45	.30		
MILLWRIGHTS	10.86	.80	.85	8%	.13

PAINTERS:	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Converse, Natrona and Niobrara Counties					
Painters, Brush and roll; Hardwood finishers; Sandblast; Pot tenders	$10.39	.70	.75		
Painters; Spray; Swing stage and Chair	11.19	.70	.75		
Paperhanging; Drywall Finishers (hand)	10.64	.70	.75		
Sandblast (interior); Steeplejack	11.83	.70	.75		
Sandblast (exterior)	11.39	.70	.75		
Hazardous Work	11.14	.70	.75		
PLUMBERS; Steamfitters:					
Goshen, Laramie and Platte Cos.					
Zone 1 (15 miles radius from Cheyenne Post Office)	9.57	.75	.60	1.50	.18
Zone 2 (10 miles radius beyond Zone 1)	10.42	.75	.60	1.50	.18
Zone 3 (15 miles radius beyond Zone 2)	11.34	.75	.60	1.50	.18
Zone 4 (Jurisdiction beyond Zone 3)	12.56	.75	.60	1.50	.18
Zone 5 (Footnote "b")					
General contracts $2,500,000.00 or less	10.22	.75	.60	1.50	.18
General contracts over $2,500,000.00	9.57	.75	.60	1.50	.18
Converse, Natrona and Niobrara Counties					
Zone 1 (10 miles radius from Post Office in Casper)	12.00	.80	1.10	2.00	.25
Zone 2 (10 miles radius beyond Zone 1)	12.72	.80	1.10	2.00	.25
Zone 3 (20 miles radius beyond Zone 2)	13.43	.80	1.10	2.00	.25
Zone 4 (40 miles beyond Zone 3)	14.52	.80	1.10	2.00	.25
Zone 5 (Jurisdiction beyond Zone 4)	15.34	.80	1.10	2.00	.25

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
ROOFERS	$ 9.65				
SHEET METAL WORKERS:					
Converse, Natrona and Niobrara Counties	10.92	.41	1.10		.02
Goshen, Laramie and Platte Cos.	11.63	.53	.41		.08
SPRINKLER FITTERS	11.50	.75	1.05		.08
WELDER: RIGGER: Receive rate prescribed for craft performing operation to which welding or rigging is incidental.					

FOOTNOTES:

a. Employer contributes 8% basic hourly rate for over 5 years' service and 6% basic hourly rate for 6 months to 5 years' service as Vacation Pay Credit. 7 Paid Holidays: A through F., and the Friday after Thanksgiving Day.

b. Use only in the Cities of Laramie, Torrington, Wheatland, Evanston, Green River and Rock Spring within a 5 mile radius from the Post Office.

PAID HOLIDAYS:

A-New Year's Day; B-Memorial Day; C-Independence Day; D-Labor Day; E-Thanksgiving Day; F-Christmas Day.

LABORERS (Building Construction)					
Group 1	$ 6.97	.33	.40	$ 1.00	.05
Group 2	7.22	.33	.40	1.00	.05
Group 3	7.47	.33	.40	1.00	.05
Group 4	7.47	.33	.40	1.00	.05
Group 5	7.52	.33	.40	1.00	.05
Group 6	7.37	.33	.40	1.00	.05
Group 7	7.27	.33	.40	1.00	.05
Group 8	7.12	.33	.40	1.00	.05
Group 9	7.87	.33	.40	1.00	.05
HEAVY CONSTRUCTION					
Carpenters	8.74	.40	.35		
Cement Masons	8.50	.50			
Ironworkers, Structural	8.00	.35			
Ironworkers, Reinforcing	7.27	.40			
Painters, brush and spray	7.06	.35			

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LABORERS
(Building Construction)

Group 1: Axeman and hand faller; Concrete worker (wet or dry) (curing and drying); Car and truck loader; Dumpman; Erector and installer (includes the installation and erection of all fences, right-of-way, median fences, snow fence, etc., guard rails, section rails, reference posts, guide posts, signs and right-of-way markers); Form stripper; Form setter helper (paving); General laborer; Gunite helper; Landscaper helper; Material handler (lumber, rods, cement, concrete); Nozzleman (air and water); Pipe setter helpers, non-metallic; Pipe setters' helpers, corrugated; All work pertaining to pre-watering, pre-irrigation and pre-wetting; Rodman; Riprap Man; Sandblaster Pot tender; Signalman, grade, concrete, etc.; Scissorman or hopper man; Stake jumper for equipment; Tar and asphalt pot tender; Wrecking and demolition crews; Unloading and packing of steel rods and mesh (reinforcing); Heater tender and pilot car operator

Group 2: Asphalt raker and tamper; Bin wall installer; Bituminous curb builder; Carpenter tender; Cement mason tender; Chuck tender; Form setter (paving); Hand operated vibrator roller; Landscaper; Mechanical form cleaner; Mortar man on stone riprap; Operator of pneumatic, electric, gas tamper and similar mechanical tools; Powderman helper; Pipe setter, corrugated; Culvert pipe, multi-plate, sectional plate and similar type; Pipe wrapper; Power-type concrete buggy (push); Power saw operator (clearing); Vibrator (concrete); Creosote material handler (corrosive enamel or its equal); Burner (cutting torch)

Group 3: Concrete saw; Gunite nozzleman; High scaler (using air tools from bos'n chair, swing stage lift belt, or block and tackle, shall receive $.20 per hour more than the classified rate); Jackhammer and pavement breaker; Sandblaster nozzleman; Sewer pipe installer, non-metallic; Caulker; Collarman; Jointer; Mortarman; Rigger; Jacker; Power-type concrete buggy (ride); Shoring and lagging of open ditch

Group 4: Powderman and blaster; Wagon drill, air track, diamond and other drills for blasting powder or grouting

Group 5: Hod carriers; Mason tender; Plasterers tenders; Terrazzo tenders; Tile setter tenders, and scaffold builders

Group 6: Tunnel and underground work: Miners (drills) Machine man; Timberman; Steelman; Drill Doctor; Form setter and movers; Spaders; Tuggers; Spilling and/or caisson workers; Jackhammer men; Finishers; Re-bar man; Powderman

Group 7: Nipper; Chuck tender; Top man or toplander

Group 8: Brakeman and vibrator man

Group 9: Mucker and bull gang laborer

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LABORERS Heavy Construction	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Group 1:					
Axeman and hand faller; Bin Wall installer helpers; Concrete worker (wet or dry); Concrete workers (curing and drying); Dumpman; Erector and installer (including the installation and erection of fences, snow fences, guard rails, median rails, median posts, signs and right-of-way marker); Form stripper; Form setter helper (paving); General labor; Gunite helper; Heater tender; Landscaper helper; Material handler (lumber, rods, cement, concrete); Nozzleman, air and water; Pipe setters' helpers (non-metallic); Pipe setters' helpers (corrugated); Pre-watering, pre-wetting and pre-irrigation (all work); Rip rap man; Sandblaster pot tender; Signalmen; Grade concrete, etc.; Scissorman or hopperman; Stake jumper for equipment; Tar and asphalt pot tender; Wrecking and demolition crews	$ 5.78				

LABORERS (Cont'd) Heavy Construction	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Group 2:					
Asphalt raker and tamper; Bin wall installer; Bituminous curb builder; Cement mason or finisher; Helper and tender; Chuck tender; Form setter (paving); Hand operated vibratory roller; Landscaper; Mortar man on stone; Riprap; Operator of penumatic, electric, gas tamper and similar mechanical tools; Pipe setter (corrugated culvert pipe sectional, multiplate and similar type); Pipe setter; Pipelayer (non-metallic); Pipe-wrapper; Powderman helper; Power type concrete buggy (push or ride); Power saw operator (clearing); Vibrator, concrete	$ 5.88				
Group 3:					
Concrete saw; Gunite nozzleman; High scaler (using air tools from bos'n chair, swing stage, lift belt or block and tackle shall receive $.20 per hour more than the classified rate); Jackhammer and pavement breaker; Sandblaster nozzleman; Sewer pipe installer (non-metallic), clay, concrete, etc.; (Caulker, Collarman, Jointer, Mortarman, Rigger, Jacker)	6.02				
Group 4:					
Powderman and blaster; Wagon drill, Air-trac, Diamond and other drills for blasting powder or grouting	6.30				

LABORERS (Cont'd) Heavy Construction	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Group 5: Tunnel and Underground Work:					
Brakeman; Swamper; Vibratorman	$ 6.26				
Bull gang; Dumpman; Mucker; Trackman	6.10				
Miners (drillers); Machine men; Timbermen; Steelmen; Drill doctor; Form setter and mover; Spader; Tuggers, spilling and/or caisson workers; Powdermen; Jackhammermen; Finishers	6.53				
Nipper; Chucktender; Topman; Toplander	6.37				
POWER EQUIPMENT OPERATORS Heavy Construction					
Group 1	7.75	.40	.35		
Group 2	7.80	.40	.35		
Group 3	7.85	.40	.35		
Group 4	7.89	.40	.35		
Group 5	7.92	.40	.35		
Group 6	7.97	.40	.35		
Group 7	8.01	.40	.35		
Group 8	8.03	.40	.35		
Group 9	8.14	.40	.35		
Group 10	8.20	.40	.35		
Group 11	8.22	.40	.35		
Group 12	8.40	.40	.35		
Group 13	8.44	.40	.35		
Group 14	8.51	.40	.35		
Group 15	8.57	.40	.35		
Group 16	8.74	.40	.35		
Group 17	9.08	.40	.35		

POWER EQUIPMENT OPERATORS
Heavy Construction

Group 1: Auger Machine Operator (post holes, etc.); Batch Bin Weighman, Scissorman or Hopperman; Beginner Operator; Brakeman and Helper; Crusher Oiler; Oiler Utility; Screed Operator; Tractor Operators (farm, crawler or wheel type, 60 HSP (drawbar) or less with or without use of power attachments, except for use of back hoe or bucket)

Group 2: Broom Operators, self-propelled; Cableway Signalman (bellboy); Concrete Saw (self-propelled); Fireman; Power Loader, belt and bucket type

Group 3: Air Compressor over 315 cu. ft. capacity; Chip Spreader Operator; Form Grader Operator; Joint Machine Operator; Longitudinal Float Operator; Mixer Operator Concrete (under one yard); Helper (welder or heavy duty); Roller Operators, self-propelled (pneumatic, rubber tired, sheep foot, vibratory or combination type); Tire Repairman

Group 4: Pump Operator (all others)

Group 5: Conveyor Belt Operator; Fork Lift and Lumber Staker; Screening Plant Operator

Group 6: A-Frame Truck; Tractor Operators (farm, crawler or wheel type, over 60 HSP (drawbar) without use of power attachments

Group 7: Oiler, Lead Utility

Group 8: Gunnite and Grout Machine Operator; Mulching Machine Operator; Oil Distributor

Group 9: Front End Loader (up to and including 1½ cu. yds.); Pavement Breakers, Hydro-tamper and similar type machines; Pumps, well points

Group 10: Hoist Operator (one drum)

POWER EQUIPMENT OPERATORS (Cont'd)
Heavy Construction

Group 11: Haulage Motorman and Industrial type Motormen; Motor Patrol Operator (all others); Pump Operator (in tunnels, shafts, raises); Hydro type Cranes (up to 15 tons)

Group 12: Air Compressor, two or more machines or tunnels, shafts, raises of plant Operator; Asphalt Plant Operator; Bituminous Lay-down Machine Operator; CMI Machine and similar; Concrete Batch Plant; Concrete Finish Machine Operator; Concrete Multi Blade Span Saw (Hunt process or similar); Concrete Spreader and Paver Operator; Crusher Operator; Drilling Machine, integrated (Core, Rotary, Caisson, Diamond); Elevating Grader; Front End Loader (over 1½ cu. yds.); Jumbo Form Operator; Mixer Operator, base course pug mill type; Mixer Bituminous Operator (travel plant); Mixer Operator Concrete (over one yard); Motor Patrol Operator (finish); Mucking Machine Operator (all types); Pneumatic Guns; Pumpcrete Operator; Roller Operator, (tandem steel wheel, three axle or three wheel); Scraper Equipment (all types); Shovels, Draglines, Cranes, Piledrivers, all truck mounted cranes, (manufacturers' rating) up to 3½ yards, all attachments; Hydro type Cranes, (15 ton and over); Shuttle Car Operator; Subgrade Machine Operator (power); Tractor Operator, all with use of power attachments and including Pushcat, Dozer, Tournadozer, etc. (The use power attachment shall not include disking, pulling or rollers, and similar unskilled actions); Trenching Machine Operator; Wash Plant Operator

Group 13: Welder, Machine Doctor

Group 14: Hoist Operator (two or more drums of shafts or raises); Repairman; Mechanics; Machine Doctors, Welders and Helper; Heavy Duty Mechanic, Machine Doctor

Group 15: Cableway Operators; Mixer Dual Drum; Cranes, (Whirley, Gantry, Stiffleg, Overhead traveling)

Group 16: Shovels, Draglines, Cranes, Piledrivers, all truck mounted Cranes (manufacturer's rating) 3½ yards to 7 cu. yds., all attachments; Wheel Excavator Operator

Group 17: Shovels, Draglines, Cranes, Piledrivers, all truck mounted Cranes, (manufacturer's rating) 7 cu. yds. and over, all attachments

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
TRUCK DRIVERS Heavy Construction					
Pick-up Truck Drivers (when used for hauling)	$ 6.22	.40			
Dump Truck Drivers (water level capacity box):					
7 cu. yds. and less	6.27	.40			
Over 7 cu. yds. to and including 10 cu. yds.	6.42	.40			
Over 10 cu. yds. to and including 13 cu. yds.	6.52	.40			
Over 13 cu. yds. to and including 20 cu. yds.	7.02	.40			
Over 20 cu. yds. to and including 25 cu. yds.	7.02	.40			
Over 25 cu. yds. to and including 30 cu. yds.	7.12	.40			
Over 30 cu. yds. to and including 35 cu. yds.	7.17	.40			
Over 35 cu. yds. to and including 40 cu. yds.	7.22	.40			
Over 40 cu. yds. to and including 45 cu. yds.	7.27	.40			
Over 45 cu. yds. (to be negotiated prior to use)					
Snow Plow Truck Drivers (the cu. yd. rate of the truck driver classification):					
Pilot Car Drivers	6.22	.40			
Gravel Spreader	6.27	.40			
Flat Rack Material Truck Drivers:					
Less than 2 tons	6.27	.40			
2 tons to 5 tons	6.42	.40			
Over 5 tons	6.52	.40			
Low Boy and Tandem Axle Float Drivers	7.02	.40			
Gang Truck Drivers	6.27	.40			

TRUCK DRIVERS (Cont'd) Heavy Construction	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Stringing Truck Drivers:					
Single axle type truck	$ 6.27	.40			
Multiple axle type truck, semi	7.02	.40			
Winch Trailer Truck Drivers (cable and hoist)	6.52	.40			
Utility Winch Truck Drivers	6.52	.40			
"A" Frame Truck Drivers	6.52	.40			
Warehousemen, Partsmen and Helpers	6.27	.40			
Material Checkers	6.42	.40			
Transit Mix or wet mix Truck Drivers:					
Less than 5 cu. yds.; Single axle	6.52	.40			
Over 5 cu. yds. to and including 10 cu. yds.: Tandem axle	6.62	.40			
Over 10 cu. yds.	6.72	.40			
Power Broom Drivers and/or Operator	6.42	.40			
Water Truck Drivers:					
2500 gal. or less (straight truck)	6.27	.40			
2500 gal. or less (semi truck)	6.42	.40			
Over 2500 gal. to and including 3600 gal.	6.52	.40			
Over 3600 gal. (straight truck)	6.62	.40			
Over 3600 gal. (semi truck)	6.72	.40			

TRUCK DRIVERS (Cont'd) Heavy Construction	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Heavy Duty (Euclids, electric or similar type)	$ 7.02	.40			
Fuel Service Truck Drivers	6.27	.40			
Greasemen, Tiremen, Service Men and Helpers	6.27	.40			
Truck Mechanics and Helpers (shop and field):					
Field Mechanics	7.22	.40			
Helpers - field (welders, mechanics, etc.)	6.78	.40			

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